

March 31, 2009

# Health Information Security and Privacy Collaboration

## Intrastate and Interstate Consent Policy Options Collaborative—Final Report

Prepared for

**RTI International**

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Chicago, IL 60606

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Prepared by

Intrastate and Interstate Consent Policy Options Collaborative

California, Illinois, North Carolina, Ohio

Health Information Security & Privacy  
**COLLABORATION**



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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 21<sup>st</sup> 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.

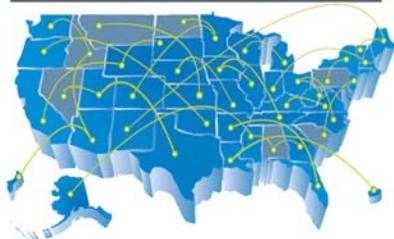
The analyses conducted by the Intrastate and Interstate Consent Policy Options Collaborative can serve as a foundation for consent actions at the state and federal levels and facilitate adoption and enforcement of consent standards, which in turn will increase nationwide participation in HIE.

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## Appendix A: Central Bibliography of Consent Documents

Health Information Security & Privacy

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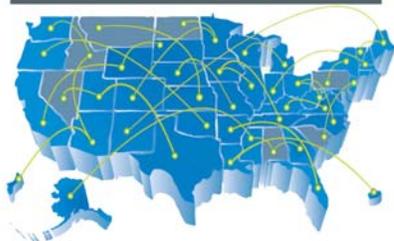
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX B: COMPARATIVE SUMMARY ANALYSIS EMERGENCY DEPARTMENT**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## Committee

**Privacy**—Consent for Sharing Emergency Department Information

## Issue

Patient consent to exchange laboratory information through a health information exchange (HIE) for treatment. This issue analysis will examine how the consent options will affect clinician and laboratory business processes, public perception, and legal liabilities of all parties involved.

## Background

Currently, consent is not required for sharing some prescription and laboratory information among health care providers/payers under HIPAA and California law.

## Assumptions

- Treating physician and various providers (labs, pharmacies, other physicians) can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing clinical information will be used for treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those patients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus potentially providing a better quality of care. However, this option may result in (1) less data being available because patients choose not to seek care, or (2) less accurate information being available because patients provide incorrect information.
  - *Opt In with Restrictions*—this choice will result in the least information being available to the physician.
  - *Opt Out*— this choice will result in *more* information being available because all patient information will be in the system except for those patients who choose to opt out.
  - *Opt In*—this choice will result in less information being available since patients will need to take an action to be included in the system.

- *Opt Out with Exceptions*—this choice will result in *some* information being available because patient information will be in the system—except for those patients who choose to opt out and the information patients choose to exclude.

## Notes

- **Consent**—A patient’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.
- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

**Table B-1A. Patient—Quality of Care**

**Specific Issue:** Patient wants effective treatment balanced with protection of their information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care. Patient receives effective, appropriate treatment, avoids unnecessary risk. Expediting referrals increases quality of care. Scarce resources are available when needed.	+ More quality of care (portion IN the HIE)	– Least quality of care (portion not IN the HIE); patient receives unnecessary treatment that over-utilizes scarce resources. Unsafe situation if cath lab is unavailable to someone who really needs that treatment.	• Some quality of care (portion not IN the HIE) + More patient choice specificity	– Less quality of care (portion not IN the HIE) – Less patient choice (IN or OUT)
+ Has the most patient participation  NA  NA	• Has the potential for more patient participation • For patients who do not opt out  NA	– Has the potential for the least patient participation. • For patients who do not opt in • For patients who choose to restrict significant information	• Has the potential for some patient participation • For patients who do not opt out • For patients who choose to restrict significant information	• Has the potential for lesser patient participation • For patients who do not opt in  NA
– No patient choice	• Some patient choice (OUT or IN)	+ Most patient choice and specificity in choice	NA	NA

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table B-1B. Provider—Quality of Care**

**Specific Issue:** Provider wants to deliver effective treatment in the most efficient and cost-effective way.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care	+ More quality of care (portion IN)	– Least quality of care (portion not IN)	• Some quality of care (portion IN)	– Less quality of care (portion not IN)
+ Most cost-effective	• Somewhat cost-effective	– Least cost-effective	– Least cost-effective	– Less cost-effective
– Most safeguards required to protect patient information due to volume information	• Some safeguards required to protect patient information due to volume	+ Least safeguards required to protect patient information due to volume	+ Fewest safeguards required to protect patient information due to volume	• Less safeguards required to protect patient information due to lesser volume
+ Fewest safeguards required to protect patient information due to lack of complexity	• Some safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	• Some safeguards required to protect patient information due to lack of complexity

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table B-2A. Patient—Level of Trust: HIE**

**Specific Issue:** Patient wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.<sup>1</sup> (Trust the HIE and health care providers regarding protection of their information.)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least need for education due to complexity	+ Lesser need for education due to complexity	– Most need for education due to complexity	– Most need for education due to complexity	• More need for education due to complexity and availability
– No patient choice, low trust	• Some degree of patient choice/trust	+ Most patient choice/trust	+ Most patient choice/trust	+ More patient choice/trust
+ Least potential errors due to volume of information	• Some potential errors due to volume of information	– Most potential errors due to least volume of information and complexity	– Most potential errors due to less volume of information and complexity	– More potential errors due to volume of information
– Most need to protect patient information due to volume	• Less need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Some need to protect patient information due to volume	• Some need to protect patient information due to volume
+ Least need to protect patient information due to complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	• Lesser need to protect patient information due to complexity

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and by whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information. [Errors amplified as carried forward through HIE. Increased professional responsibility.] This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug, and alcohol, minors, sexually transmitted diseases, and family planning.

<sup>1</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

**Table B-2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.<sup>1</sup> (Trust between providers)

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Least potential errors due to volume	+ Less potential errors somewhat due to volume	– Most potential errors due to volume and complexity	– Most potential errors due to complexity and somewhat due to volume	– More potential errors due to volume
– Most need to protect patient information due to volume	– More need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Medium need to protect patient information due to volume	+ Less need to protect patient information due to volume
+ Least need to protect patient information due to complexity	+ Less need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	+ Less need to protect patient information due to complexity
+ Least need for staff and patient education due to complexity	• Some need for staff and patient education	– Most need for staff and patient education	– Most need for staff and patient education	– More need for staff and patient education

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information<sup>2</sup> [Errors amplified as carried forward through HIE. Increased professional responsibility.]

<sup>1</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

<sup>2</sup> This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.

**Table B-3A. Savings and Cost Avoidance**

**Specific Issue:** Savings and cost avoidance—provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests, increased accuracy and effectiveness, long-term savings, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.

Risk analysis—could affect a small number of cases, but if the adverse outcome is death, etc., it could have a costly outcome.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most savings from business processes impacts due to volume and complexity. Costs are appropriate and minimal.	+ More savings from business processes impact due to volume and complexity	– Over-utilizes scarce and expensive resources of helicopter and cardiac cath lab	– Least savings from business processes impact due to volume and complexity	• Less savings from business processes impact due to volume and complexity
+ Most savings from access to complete information, payments, increased accuracy and quality of care	+ More savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Less savings from access to complete information, payments, increased accuracy and quality of care
– Most cost to educate due to volume	– More cost to educate due to volume	+ Least cost to educate due to volume	+ Least cost to educate due to volume	• Some cost to educate due to volume
+ Least cost to educate due to complexity	• Some cost to educate due to complexity	– Most cost to educate due to complexity	– Most cost to educate due to complexity	– More cost to educate due to complexity and outreach
NA	NA	– Least savings from business processes impact due to volume and complexity	NA	NA

**Table B-3B. Investment**

**Specific Issue:** Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient consent choices (ongoing): (1) cost of enforcement effort (design and implementation); (2) second process for those patients not participating in exchange or for sensitive information; (3) sustainability and success of HIE system affected by the percentage of participating patients and providers.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least cost of process improvement	• Lesser cost of process improvement	– Most cost of process improvement	– Most cost of process improvement	• More cost of process improvement
– Most cost to address sensitive information—requires secondary process	– Most cost to address sensitive information—requires secondary process	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	– Most cost to address sensitive information—requires secondary process
+ Most sustainable	+ More sustainable	– Least sustainable	– Less sustainable	• Somewhat sustainable

**Table B-4. Technology**

**Specific Issue:** Technology—compatibility, integration and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least complex	• Somewhat complex	– Most complex	– Most complex	– More complex
+ Least challenge to small practice providers	• Some challenge to small practice providers	– Most challenge to small practice providers	– Most challenge to small practice providers	• More challenge to small practice providers

**Table B-5. National Efforts**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

**Table B-6. Liability and Laws**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
Some legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.

**Table B-7. CalPSAB Principles**

**Specific Issue:** Consistency or inconsistency with the CalPSAB principles: (1) openness, (2) health information quality, (3) individual participation, (4) collection limitation, (5) use limitation, (6) purpose limitation, (7) security safeguards—NA, and (8) accountability—NA.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Consistent with health information quality	+ Consistent with health information quality	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>
- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with health information quality	- Inconsistent with health information quality	- Inconsistent with health information quality

**Table B-8. Summary**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care	- Least quality of care	• Some quality of care	- Less quality of care
+ Least costly/most sustainable	+ Less costly/most sustainable	- Most costly/most sustainable	- Most costly/most sustainable	• More costly/most sustainable
• Some legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk
- Inconsistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles
- Least patient choice	• Some patient choice	+ Most patient choice	+ Most patient choice	+ More patient choice

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX C: COMPARATIVE SUMMARY ANALYSIS E-PRESCRIBING**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## Committee

**Privacy Committee**—Patient Consent for Sharing Health Information for e-Prescribing

### Issue

Patient consent to exchange medication information through a health information exchange (HIE) for treatment. This issue analysis will examine how the consent options will affect clinician and pharmacist business processes, public perception, and legal liabilities of all parties involved.

### Background

Currently, consent is not required for sharing some medication history among health care providers/payers under HIPAA and California law. Current e-prescribing in California under the Pharmacy Board regulations only allows transmission of a prescription and any other information required by law to a pharmacist of the patient's choice.

### Assumptions

- Treating physician and a pharmacy can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing medication information will be limited to treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those patients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- For purposes of this analysis, the following definitions are provided:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus potentially providing a better quality of care. However, this option may result in (1) less data being available because patients choose not to seek care, or (2) less accurate information being available because patients provide incorrect information.
  - *Opt Out*—this choice will result in *more* information being available because all patient information will be in the system except for those patients who choose to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.

- *Opt Out with Exceptions*—this choice will result in *some* information being available because patient information will be in the system—except for those patients who choose to opt out and the information patients choose to exclude.
- *Opt In*—this choice will result in *less* information being available because patients will need to take an action to be included in the system.

## Notes

- **E-Prescribing**—The transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.
- **Consent**—A patient’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.
- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

**Table C-1A. Patient—Quality of Care**

**Specific Issue:** Patient wants effective treatment balanced with protection of their information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
– Lack of choice may result in less patient participation	+ More patient participation	• Some patient participation	– Has the potential for the some patient participation	– Has the potential for the least patient participation for patients who do not opt in.
– No patient choice over use or exchange of records	• Some patient choice	+ Most patient choice	+ More patient choice specificity	– Less patient choice—in or out
– Patients may choose to not seek care	NA	+ Most specificity in choice	NA	NA
– Patients may choose to withhold information	NA	NA	NA	NA
– Patients may choose to provide erroneous information	NA	NA	NA	NA
– Potential for less quality of care for those who choose to not participate	• Has the potential for more quality of care for patients who do not opt out.	– Least quality of care • Has potential for least patient participation for patients who do not opt in • For patients who choose to restrict significant information	• Some quality of care • For patients who do not opt out. • For patients who choose to restrict significant information	– Less quality of care
– Potential for poor information integrity	NA	+ Better information integrity	NA	NA
+ Decreased risk of harm due to errors in prescriptions.	NA	NA	NA	NA
+ Decreased risk of drug and allergy interactions due to better coordination of patient alerts.	NA	NA	NA	NA

Note: Quality of care based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table C-1B. Provider—Quality of Care**

**Specific Issue:** Provider wants to deliver effective treatment in the most efficient and cost effective way.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care	<ul style="list-style-type: none"> <li>Has the potential for more quality of care for patients who do not opt out.</li> </ul>	<ul style="list-style-type: none"> <li>Least quality of care (portion not IN)                             <ul style="list-style-type: none"> <li>For patients who do not opt in.</li> <li>For patients who choose to restrict significant information</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Some quality of care                             <ul style="list-style-type: none"> <li>For patients who do not opt out.</li> <li>For patients who choose to restrict significant information</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Less quality of care</li> </ul>
+ Most patient participation	+ More patient participation	<ul style="list-style-type: none"> <li>Has the potential for the least patient participation</li> </ul>	<ul style="list-style-type: none"> <li>Has the potential for the some patient participation.</li> </ul>	<ul style="list-style-type: none"> <li>Has the potential for the less patient participation for patients who do not opt in.</li> </ul>
+ Most cost effective	<ul style="list-style-type: none"> <li>Somewhat cost effective</li> </ul>	<ul style="list-style-type: none"> <li>Least cost effective</li> </ul>	<ul style="list-style-type: none"> <li>Least cost effective</li> </ul>	<ul style="list-style-type: none"> <li>Less cost effective</li> </ul>
<ul style="list-style-type: none"> <li>Most safeguards required to protect patient information due to most volume of information</li> </ul>	<ul style="list-style-type: none"> <li>Some safeguards required to protect patient information due to volume</li> </ul>	<ul style="list-style-type: none"> <li>Fewest safeguards required to protect patient information due to least volume</li> </ul>	<ul style="list-style-type: none"> <li>Least safeguards required to protect patient information due to least volume</li> </ul>	<ul style="list-style-type: none"> <li>Less safeguards required to protect patient information due to less volume</li> </ul>
<ul style="list-style-type: none"> <li>Fewest safeguards required to protect patient information due to lack of complexity</li> </ul>	<ul style="list-style-type: none"> <li>Less safeguards required to protect patient information due to less complexity</li> </ul>	<ul style="list-style-type: none"> <li>Most safeguards required to protect patient information due to most complexity</li> </ul>	<ul style="list-style-type: none"> <li>Most safeguards required to protect patient information due to most complexity</li> </ul>	<ul style="list-style-type: none"> <li>Less safeguards required to protect patient information due to less complexity</li> </ul>
+ Facilitates communications between physicians and pharmacists	+ Facilitates more communications between physicians and pharmacists	NA	NA	NA
+ Most availability to information in relocation or disaster situations	+ Most availability to information in relocation or disaster situations	NA	NA	NA

Note: Quality of care based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table C-2A. Patient—Level of Trust: HIE**

**Specific Issue:** Patient wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least potential drug errors due to most volume of information	– Less potential drug errors due to more volume of information	– Most potential drug errors due to least volume of information and complexity	• Some potential drug errors due to less volume of information and complexity	– More potential drug errors due to less volume of information
– No patient choice, least trust	• Less patient choice and trust—no control over sensitive information	+ Most patient choice and trust	+ Most patient choice and trust	+ More patient choice and trust
– Most need to protect patient information due to most volume	– Less need to protect patient information due to less volume	+ Least need to protect patient information due to least volume	• Some need to protect patient information due to volume	• Some need to protect patient information due to volume
+ Least need to protect patient information due to least complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to most complexity	NA	+ Less need to protect patient information due to less complexity
+ Least need for education due to complexity	+ Less need for education due to less complexity	– Most need for education due to complexity	NA	• More need for education due to more complexity
– May not be available for non-HIE pharmacies	– May not be available for non-HIE pharmacies	– May not be available for non-HIE pharmacies	– May not be available for non-HIE pharmacies	– May not be available for non-HIE pharmacies
– Concern about system failures and no prescription fills.	– Concern about system failures and no prescription fills	– Concern about system failures and no prescription fills	– Concern about system failures and no prescription fills	– Concern about system failures and no prescription fills
– Decreased patient/provider trust relationship due to no choice	+ Increased patient/provider trust relationship due to choice	NA	NA	NA

Note: Level of trust in HIE—influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

**Table C-2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least potential drug errors due to most volume	+ Less potential drug errors due to more volume	– Most potential drug errors due to least volume	– Most potential drug errors due to least volume	– More potential drug errors due to less volume
– Most need to protect patient information due to most volume	– More need to protect patient information due to more volume	+ Least need to protect patient information due to least volume	+ Less need to protect patient information due to less volume	+ Less need to protect patient information due to less volume
+ Least need to protect patient information due to least complexity	+ Less need to protect patient information due to less complexity	– Most need to protect patient information due to most complexity	– More need to protect patient information due to More complexity	+ Less need to protect patient information due to less complexity
+ Least need for staff and patient education due to least complexity	+ Less need for staff and patient education due to less complexity	– Most need for staff and patient education due to most complexity	– Most need for staff and patient education due to most complexity	+ Less need for staff and patient education due to less complexity
NA	+ Increased patient/provider trust relationship	NA	NA	NA

Note: Level of trust in HIE—influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

**Table C-3A. Savings and Cost Avoidance**

**Specific Issue:** Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, long- term savings, better quality of care, quicker reimbursements, accessing payer info for claims and eligibility.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most savings from business processes impacts due to most volume and least complexity	+ More savings from business processes impact due to more volume and less complexity	– Least savings from business processes Impact due to least volume and most complexity	– Least savings from business processes impact due to least volume and most complexity	• Less savings from business processes impact due to less volume and less complexity
+ Most savings from access to complete information, payments, increased accuracy and quality of care	+ More savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Less savings from access to complete information, payments, increased accuracy and quality of care
– Most cost to educate due to most volume	– More cost to educate due to more volume	+ Least cost to educate due to least volume	+ Least cost to educate due to least volume	• Some cost to educate due to volume
+ Least cost to educate due to least complexity	• Some cost to educate due to some complexity	– Most cost to educate due to most complexity	– Most cost to educate due to most complexity	– More cost to educate due to some complexity and outreach

**Table C-3B. Investment**

**Specific Issue:** Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient choice (ongoing). (1) Cost of enforcement effort (design and implementation). (2) Secondary process for those patients not participating in exchange or for sensitive info. (3) Sustainability and success of HIE system affected by the percentage of participating patients and providers.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least cost of process improvement	• Less cost of process improvement	– Most cost of process improvement	– Most cost of process improvement	• More cost of process improvement
– Most cost to address sensitive information—requires secondary process	– Most cost to address sensitive information—requires secondary process	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	– Most cost to address sensitive information—requires secondary process
+ Most sustainable	+ More sustainable	– Least sustainable	– Less sustainable	• Somewhat sustainable
+ Most ease of workflow integration	NA	NA	NA	NA
+ Least liability due to reduced errors and clinical decision support	NA	NA	NA	NA
+ Least paperwork, phone calls for office staff	NA	NA	NA	NA
+ Most likely to reduce drug abuse from fraudulent prescriptions	NA	NA	NA	NA

**Table C-4. Technology**

**Specific Issue:** Technology—compatibility, integration and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least complex	• Somewhat complex	– Most complex	– Most complex	– More complex
+ Least challenge to small practice providers	• Some challenge to small practice providers	– Most challenge to small practice providers	– Most challenge to small practice providers	• More challenge to small practice providers
+ Least difficult to implement for technical support and maintenance	NA	NA	NA	NA
– Increased potential for breaches if not safeguarded	NA	NA	NA	NA
– May have problems integrating with current systems	NA	NA	NA	NA

**Table C-5. National Efforts**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

Note: Markle—Connecting for Health and the NCVHS—National Commission on Vital & Health Statistics address patient consent to access their information, not patient consent to control the input of their information into an HIE or for exchange.

**Table C-6. Liability and Laws**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Some legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.

**Table C-7. CalPSAB Principles**

**Specific Issue:** Consistency or inconsistency with the CalPSAB Principles. (1) openness, (2) health information quality, (3) individual participation, (4) collection limitation, (5) use limitation, (6) purpose limitation, (7) security safeguards, (8) accountability

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most consistent with: <ul style="list-style-type: none"> <li>• health information quality</li> </ul>	+ More consistent with: <ul style="list-style-type: none"> <li>• health information quality</li> </ul>	+ Most consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Most consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ More consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>
– Least consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	– Less consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	– Least consistent with: <ul style="list-style-type: none"> <li>• health information quality</li> </ul>	– Least consistent with: <ul style="list-style-type: none"> <li>• health information quality</li> </ul>	– Least consistent with: <ul style="list-style-type: none"> <li>• health information quality</li> </ul>

**Table C-8. Summary**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care	- Diminished quality of care	• Some quality of care	- Less quality of care
+ Least costly/most sustainable	+ Less costly/more sustainable	- Most costly/least sustainable	- More costly/less sustainable	- Somewhat costly/less sustainable
• Some legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk
- Inconsistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles
- Least patient choice	• Some patient choice	+ Most patient choice	+ More patient choice	• Some patient choice
+ Most likely to reduce adverse drug reactions	+ More likely to reduce adverse drug reactions	- Least likely to reduce adverse drug reactions	- Less likely to reduce adverse drug reactions	- Least likely to reduce adverse drug reactions
+ Most likely to detect drug shopping	+ More likely to detect drug shopping	- Least likely to detect drug shopping	- Less likely to detect drug shopping	- Least likely to detect drug shopping

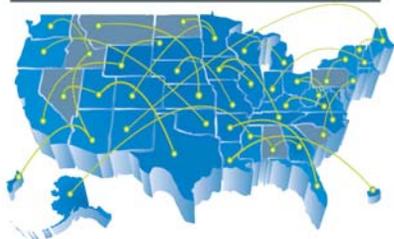
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX D: COMPARATIVE SUMMARY ANALYSIS MENTAL HEALTH**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Committee**

**PRIVACY**—Client consent to exchange mental health information through a health information exchange (HIE) in a clinic setting

## **Issue**

Client consent to exchange mental health information through an HIE for treatment, specifically for e-prescribing and laboratory exchanges. This issue analysis will examine how the consent/permission options will affect client, clinician, business processes, public perception, and legal liabilities of all parties involved.

## **Background**

Client consent currently is not required for sharing some information among health care providers to effectuate treatment and referrals for treatment under California law. However, client consent must be obtained for any other disclosures to providers who are not employed at a facility and who do not have medical or psychological responsibility for the client's care.

## **Assumptions**

- This analysis is specific to health information protected by mental health laws which includes provisions limiting access to such information. This analysis does not address other similar protected health information such as HIV, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.
- This analysis applies to Lanterman-Petris-Short (LPS) covered entities.
- In addition to other laws, Welfare and Institutions Code (WIC) section 5328 et. seq. governs authorizations for release of mental health information in certain settings.
- Treating physician and a pharmacy can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing laboratory and medication information is limited to treatment.
- Technology is able to carry out policy and requirements.
- Consent alternative was chosen by client at a previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those clients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to clients choosing not to seek care or less accurate information being available due to clients providing incorrect information.

- *Opt Out*—this choice will result in *more* information being available, as all client information will be in the system except for those clients choosing to opt out.
- *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
- *Opt Out with Exceptions*—this choice will result in *some* information being available in the system for those clients that have opted out, but selected to “except” certain medical information, which will remain in the HIE.
- *Opt In*—this choice will result in *less* information being available since clients will need to take an action to be included in the system.

## Notes

- **Preferred Terms**—Clients/consumers rather than patient.
- **Client Philosophy**—Client prefers to manage and control his/her mental health information and may not wish to have the information shared.
- **E-Prescribing**—The transmission, using electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.
- **Consent**—A client’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.
- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

**Table D-1. Client-Public Acceptance/Social Drivers**

Specific Issue	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Client-public acceptance/ social drivers	<ul style="list-style-type: none"> <li>- <b>Least acceptance</b></li> <li>1. Most client discomfort due to the sensitivity of client information</li> <li>2. No client control over information</li> <li>3. Historically, perception of mental health information being protected</li> <li>4. Long history of stigma and apprehension of being treated differently</li> <li>5. Clients may not understand implications</li> <li>6. May result in clients not seeking needed treatments</li> <li>7. May result in clients withholding important medical information</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Less acceptance</b></li> <li>1. Some client discomfort due to the sensitivity of client information</li> <li>2. Some client control over information</li> <li>3. More favorable if client opts out because information is protected</li> <li>4. Impact on emergency room if don't have the client information</li> </ul>	<ul style="list-style-type: none"> <li>+ <b>Most acceptance</b></li> <li>1. Least client discomfort due to the sensitivity of client information</li> <li>2. Most client control over information</li> <li>3. Potential discrimination consequences from providers if system reflects restrictions based on mental health</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Somewhat likely to have public acceptance</b></li> <li>1. Least client discomfort due to the sensitivity of client information</li> <li>2. More client control over information</li> <li>3. Potential discrimination consequences from providers if system reflects restrictions based on mental health</li> </ul>	<ul style="list-style-type: none"> <li>+ <b>More acceptance</b></li> <li>1. Some client discomfort due to the sensitivity of client information</li> <li>2. Some client control over information</li> <li>3. Not likely to be accepted by clients; too black and white</li> <li>4. Client fear that once information is in, cannot remove it</li> </ul>

**Table D-2. CalPSAB Principles**

Specific Issues	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Consistency or inconsistency with the CalPSAB principles:	<b>+ Most consistent with:</b>	<b>+ More consistent with:</b>	<b>+ Most consistent with:</b>	<b>+ Most consistent with:</b>	<b>+ More consistent with:</b>
1. Openness	<ul style="list-style-type: none"> <li>health information quality</li> </ul>	<ul style="list-style-type: none"> <li>health information quality</li> </ul>	<ul style="list-style-type: none"> <li>openness</li> </ul>	<ul style="list-style-type: none"> <li>openness</li> </ul>	<ul style="list-style-type: none"> <li>openness</li> </ul>
2. Health information quality	<b>- Least consistent with:</b>	<b>- Less consistent with:</b>	<ul style="list-style-type: none"> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<ul style="list-style-type: none"> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<ul style="list-style-type: none"> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>
3. Individual participation	<ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> </ul>	<ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> </ul>	<b>- Least consistent with:</b>	<b>- Least consistent with:</b>	<b>- Least consistent with:</b>
4. Collection limitation	<ul style="list-style-type: none"> <li>use limitation</li> <li>purpose limitation</li> </ul>	<ul style="list-style-type: none"> <li>use limitation</li> <li>purpose limitation</li> </ul>	<ul style="list-style-type: none"> <li>health information quality</li> </ul>	<ul style="list-style-type: none"> <li>health information quality</li> </ul>	<ul style="list-style-type: none"> <li>health information quality</li> </ul>
5. Use limitation					
6. Purpose limitation					
7. Security safeguards					
8. Accountability					

**Table D-3. Quality of Care**

<b>Specific Issue</b>	<b>No Consent</b>	<b>Opt Out (Client Auto IN)</b>	<b>Opt In w/Restrictions (Client Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Client Auto IN Plus Choice)</b>	<b>Opt In (Client Auto OUT)</b>
Provider wants to deliver effective treatment in the most efficient way.	<p><b>+ Most quality of care</b></p> <ol style="list-style-type: none"> <li>1. Most information available for treatment</li> <li>2. Most participation</li> <li>3. Least negative drug interactions</li> <li>4. Least opportunity for drug shopping</li> <li>5. Least duplicate laboratory testing</li> <li>6. Least conducive to information being available during relocations or disasters</li> </ol> <p>– Most safeguards required to protect client information due to most volume of information</p> <p>– Most mental health providers (psychiatrist and psychologists) prefer options that meet client approval</p> <p>+ Least complex safeguards required to protect client information due to lack of complexity</p>	<p><b>+ More quality of care</b></p> <ol style="list-style-type: none"> <li>1. More information available for treatment</li> <li>2. Less participation</li> <li>3. Less negative drug interactions</li> <li>4. Less opportunity for drug shopping</li> <li>5. Less duplicate laboratory testing</li> <li>6. More conducive to information being available during relocation and disaster</li> </ol> <p>– More safeguards required to protect client information due to more volume of information</p> <p>– Mental health providers (psychiatrist and psychologists) prefer options that meet client approval</p> <p>+ Less complex safeguards required to protect client information due to less complexity</p>	<p><b>– Least quality of care</b></p> <ol style="list-style-type: none"> <li>1. Least information available for treatment</li> <li>2. Least participation</li> <li>3. Most negative drug interactions</li> <li>4. Most opportunity for drug shopping</li> <li>5. Most duplicate laboratory testing</li> <li>6. Least conducive to information being available during relocation and disaster</li> </ol> <p>+ Fewest safeguards required to protect client information due to least volume of information</p> <p>– Mental health providers (psychiatrist and psychologists) prefer options that meet client approval</p> <p>– Most complex safeguards required to protect client information due to most complexity</p>	<p><b>• Some quality of care</b></p> <ol style="list-style-type: none"> <li>1. Some information available for treatment</li> <li>2. Some participation</li> <li>3. More negative drug interactions</li> <li>4. More opportunity for drug shopping</li> <li>5. Some duplicate laboratory testing</li> <li>6. Somewhat conducive to information being available during relocation and disaster</li> </ol> <p>• Some safeguards required to protect client information due to volume of information</p> <p>– Mental health providers (psychiatrist and psychologists) prefer options that meet client approval</p> <p>– Most complex safeguards required to protect client information due to most complexity</p>	<p><b>– Less quality of care</b></p> <ol style="list-style-type: none"> <li>1. Some information available for treatment</li> <li>2. Less participation</li> <li>3. Some negative drug interactions</li> <li>4. More opportunity for drug shopping</li> <li>5. More duplicate laboratory testing</li> <li>6. Less conducive to information being available during relocation and disaster</li> </ol> <p>+ Less safeguards required to protect client information due to less volume of information</p> <p>– Mental health providers (psychiatrist and psychologists) prefer options that meet client approval</p> <p>+ Less complex safeguards required to protect client information due to less complexity</p>

(continued)

**Table D-3. Quality of Care (continued)**

Specific Issues	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Provider wants to deliver effective treatment in the most efficient way. (continued)	<ul style="list-style-type: none"> <li>- Least likely to enhance client/physician relationship due to client choice as sensitive information is automatically in the system</li> <li>- Most potential liability from HIE errors due to no client choice</li> </ul>	<ul style="list-style-type: none"> <li>- Less likely to enhance client/physician relationship due to client choice as sensitive information is automatically in the system</li> <li>• Some potential liability from HIE errors due to complexity of client choices</li> </ul>	<ul style="list-style-type: none"> <li>+ More likely to enhance client/physician relationship due to client choice as sensitive information can be excluded from the system</li> <li>- More potential liability from HIE errors due to complexity of client choices</li> </ul>	<ul style="list-style-type: none"> <li>+ More likely to enhance client/physician relationship due to client choice as sensitive information can be excluded from the system</li> <li>- More potential liability from HIE errors due to complexity of client choices</li> </ul>	<ul style="list-style-type: none"> <li>• Somewhat likely to enhance client/physician relationship due to client choice as all information may be excluded from the system</li> <li>• Some potential liability from HIE errors due to complexity of client choices</li> </ul>
Client wants effective treatment balanced with protection of their information.	<ul style="list-style-type: none"> <li>- <b>Least quality of care</b></li> <li>1. Quality of care could be compromised if mental health information is in the system</li> <li>2. Access to mental health information can work against client</li> <li>3. Diagnostic discrimination based on psychiatric history</li> <li>- Least client choice—none</li> <li>- Least protective of clients' sensitive information</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Less quality of care</b></li> <li>1. Quality of care could be compromised if mental health information is in the system</li> <li>2. Access to mental health information can work against client</li> <li>3. Diagnostic discrimination based on psychiatric history</li> <li>- Less client choice</li> <li>- Less protection of clients' sensitive information but client has to opt out, which requires client action</li> </ul>	<ul style="list-style-type: none"> <li>+ <b>Most quality of care</b></li> <li>1. Quality of care could be compromised if mental health information is in the system</li> <li>2. Access to mental health information can work against client</li> <li>3. Diagnostic discrimination based on psychiatric history</li> <li>+ Most client choice</li> <li>+ Most protection of clients' sensitive information but client has to opt out, which requires client action</li> <li>+ Clients may seek treatment if given a choice</li> </ul>	<ul style="list-style-type: none"> <li>+ <b>More quality of care</b></li> <li>1. Quality of care could be compromised if mental health information is in the system</li> <li>2. Access to mental health information can work against client</li> <li>3. Diagnostic discrimination based on psychiatric history</li> <li>+ More client choice</li> <li>+ More protection of clients' sensitive information but client has to opt out, which requires client action</li> <li>+ Clients may seek treatment if given a choice</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Some quality of care</b></li> <li>1. Client choice</li> <li>2. Quality of care becomes duty of provider/client to dialogue—as well as client to provide factual health information</li> <li>3. Diagnostic discrimination based on psychiatric history</li> <li>• Some client choice</li> <li>• Some protection of clients' sensitive information but client has to opt out, which requires client action.</li> <li>- Either/Or—not really choice</li> </ul>

(continued)

**Table D-3. Quality of Care (continued)**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Client Auto IN)</b>	<b>Opt In w/Restrictions (Client Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Client Auto IN Plus Choice)</b>	<b>Opt In (Client Auto OUT)</b>
Client wants effective treatment balanced with protection of their information. (continued)	NA	NA	+ Facilitate participation for those who do not want mental health information in exchange but would otherwise choose to opt out	+ Facilitate participation for those who do not want mental health information in exchange but would otherwise choose to opt out	NA

Note: Based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table D-4. Level of Trust in HIE**

Specific Issues	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Client wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.	<p>– <b>Least client trust/choice</b></p> <ol style="list-style-type: none"> <li>1. Need for education from client decision-making perspective</li> <li>2. Least confusing to the client</li> <li>3. Least client choice likely to erode trust</li> </ol>	<p>– <b>Less client trust/choice</b></p> <ol style="list-style-type: none"> <li>1. Need for education due to choices and consequences of choices</li> <li>2. May be confusing to client</li> <li>3. Some client choice which is most likely to enhance trust</li> <li>4. More available information may enhance provider trust in quality of information</li> <li>5. Requires action to “protect” information</li> </ol>	<p>+ <b>Most client trust/choice</b></p> <ol style="list-style-type: none"> <li>1. Most need for education due to complex choices and consequences of choices—may be confusing to client</li> <li>2. Most client choice which is most likely to enhance trust</li> <li>3. Least available information may erode provider trust in quality of information</li> </ol>	<p>+ <b>More client trust/choice</b></p> <ol style="list-style-type: none"> <li>1. Most need for education due to complex choices and consequences of choices—may be confusing to client</li> <li>2. Most client choice which is most likely to enhance trust</li> <li>3. Least available information may erode provider trust in quality of information</li> </ol>	<p>• <b>Some client trust/choice</b></p> <ol style="list-style-type: none"> <li>1. Need for education due to choices and consequences of choices—may be confusing to client</li> <li>2. More client choice which is most likely to enhance trust</li> <li>3. Less available information may erode provider trust in quality of information</li> </ol>

(continued)

**Table D-4. Level of Trust in HIE (continued)**

Specific Issues	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Provider wants other providers in HIE to safeguard information and provide accurate and complete information.	+ Least potential errors due to most volume of information	+ Less potential errors due to more volume of information	- Most potential errors due to less volume of information	• Some potential errors due to volume of information	- More potential errors due to less volume of information
	+ Most information available to improve treatment decisions	+ More information available to improve treatment decisions	- Least information available to improve treatment decisions	- Less information available to improve treatment decisions	• Some information available to improve treatment decisions
	- Most need to protect client information due to most volume	- More need to protect client information due to more volume	+ Least need to protect client information due to least volume	• Some need to protect client information due to less volume	• Some need to protect client information due to volume
	+ Least complex security necessary to protect client information due to least complexity	+ Less complex security needed to protect client information due to less complexity	- Most complex security needed to protect client information due to most complexity	- Most complex security needed to protect client information due to most complexity	+ Less complex security needed to protect client information due to less complexity
	+ Most available information may enhance provider trust in quality of information	+ More available information may enhance provider trust in quality of information	- Least available information may diminish provider trust in quality of information	- Less available information may diminish provider trust in quality of information	• Some available information may diminish provider trust in quality of information
	+ No need for education on client choices	+ Less need for education due to less complexity on client choices	- Most need for education due to most complexity of client choices	- Most need for education due to most complexity of client choices	+ Less need for education due to less complexity on client choices
	+ Least potential drug errors due to volume of client information	+ Less potential drug errors due to more volume of client information	- Most potential drug errors due to least volume of client information	- More potential drug errors due to less volume of client information	• Some potential drug errors due to volume of client information
	- Most provider liability due to volume of information available for decision making	- More provider liability due to more volume of information available for decision making	+ Least provider liability due to least volume of information available for decision making	+ Less provider liability due to less volume of information available for decision making	• Some provider liability due to volume of information available for decision making
	+ Least education needed for staff due to least complexity	+ Less education needed for staff due to less complexity	- Most education needed for staff due to most complexity	- Most education needed for staff due to most complexity	+ Less education needed for staff due to less complexity

Note: Influenced by client choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard client information, and ability to provide extra protections of sensitive information (errors amplified as carried forward through HIE, increased professional responsibility).

**Table D-5a. Savings and Cost Avoidance**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Client Auto IN)</b>	<b>Opt In w/Restrictions (Client Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Client Auto IN Plus Choice)</b>	<b>Opt In (Client Auto OUT)</b>
Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, savings in long term, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.	+ Most savings from business processes impacts due to volume of data and least complexity + Most savings from access to complete information to increase accuracy and improved quality of care - Most cost to educate due to most volume of participants + Least cost to educate due to least complexity. + Most savings due to less harmful drug interactions, drug shopping, duplicate lab tests, and client harm + Most information available to obtain reimbursements	+ More savings from business processes impact due to volume and complexity + More savings from access to complete information, payments, increased accuracy, and quality of care - More cost to educate due to more volume of participants + Less cost to educate due to less complexity + More savings due to less harmful drug interactions, drug shopping, duplicate lab tests, and client harm + More information available to obtain reimbursements	- Least savings from business processes impact due to workload impact and complexity - Least savings from access to complete information to increase accuracy and improved quality of care + Less costly to educate due to less volume of participants - Most cost to educate due to most complexity - Least savings due to more potential harmful drug interactions, drug shopping, duplicate lab tests, and client harm - Least information available to obtain reimbursements	- Least savings from business processes impact due to volume and complexity - Least savings from access to complete information, payments, increased accuracy, and quality of care + Least cost to educate due to least volume of participants - Most cost to educate due to most complexity - Least savings due to less harmful drug interactions, drug shopping, duplicate lab tests, and client harm - Least information available to obtain reimbursements	- Less savings from business processes impact due to volume and complexity - Less savings from access to complete information, payments, increased accuracy, and quality of care • Some cost to educate due to volume of participants + Less cost to educate due to less complexity - Less savings due to less harmful drug interactions, drug shopping, duplicate lab tests, and client harm - Less information available to obtain reimbursements

**Table D-5b. Investment**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Client Auto IN)</b>	<b>Opt In w/Restrictions (Client Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Client Auto IN Plus Choice)</b>	<b>Opt In (Client Auto OUT)</b>
Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing client choice (ongoing).	+ Least cost for process improvement + Most sustainable + Least potential maintenance activities as no client choices to be implemented - Most cost to address sensitive information—requires secondary process	+ Less cost for process improvement + More sustainable + Less potential maintenance activities to implement client choices and changes - Most cost to address sensitive information—requires secondary process.	- Most cost for process improvement - Least sustainable - Most potential maintenance activities to implement client choices and changes + Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	- Most Cost for process improvement - Less sustainable - Most potential maintenance activities to implement client choices and changes + Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	<ul style="list-style-type: none"> <li>• Some cost for process improvement</li> <li>• Some sustainable</li> <li>• Some potential maintenance activities to implement client choices and changes</li> <li>- Most cost to address sensitive information—requires secondary process</li> </ul>
<ul style="list-style-type: none"> <li>• Cost of enforcement effort (design and implementation)</li> <li>• Secondary process for those clients not participating in exchange or for sensitive information</li> <li>• Sustainability and success of HIE system affected by the percentage of participating clients and providers</li> </ul>					

**Table D-6. Technology**

Specific Issues	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Compatibility, integration, and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.	<ul style="list-style-type: none"> <li>+ <b>Least complex</b></li> <li>+ Least challenge to small practice providers</li> <li>+ Least likely to require system changes</li> </ul>	<ul style="list-style-type: none"> <li>+ <b>Less complex</b></li> <li>+ Less challenge to small practice providers</li> <li>+ Less likely to require system changes</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Most complex</b></li> <li>- Most challenge to small practice providers</li> <li>- Most likely to require system changes</li> <li>- Most challenge to implement, restricted information withheld</li> <li>- Most challenges if need to go back and retroactively delete data</li> </ul>	<ul style="list-style-type: none"> <li>- <b>Most complex</b></li> <li>- Most challenge to small practice providers</li> <li>- Most likely to require system changes</li> <li>- Most challenge to implement, restricted information withheld</li> <li>- Most challenges if need to go back and retroactively delete data</li> </ul>	<ul style="list-style-type: none"> <li>- <b>More complex</b></li> <li>- More challenge to small practice providers</li> <li>- More likely to require system changes</li> </ul>

**Table D-7. National Efforts**

Specific Issue	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
NA	NA	NA	NA	NA	NA

Note: Markle—Connecting for Health and the NCVHS—National Commission on Vital & Health Statistics address client consent to access their information, not client consent to control the input of their information into an HIE or for exchange.

**Table D-8. Political Viability**

Specific Issue	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
Political Viability	- Most likely to be negatively received by consumer advocates	- More likely to be negatively received by consumer advocates	+ Least likely to be negatively received by consumer advocates	+ Least likely to be negatively received by consumer advocates	+ Less likely to be negatively received by consumer advocates

Note: Markle—Connecting for Health and the NCVHS—National Commission on Vital & Health Statistics address client consent to access their information, not client consent to control the input of their information into an HIE or for exchange.

**Table D-9. Liability and Laws (based on limited review of CA laws only)**

Specific Issue	No Consent	Opt Out (Client Auto IN)	Opt In w/Restrictions (Client Auto OUT Plus Choice)	Opt Out w/Exceptions (Client Auto IN Plus Choice)	Opt In (Client Auto OUT)
NA	NA	NA	NA	NA	NA

Note: No identifiable legal risk; mental health information may be shared between providers for treatment purposes.

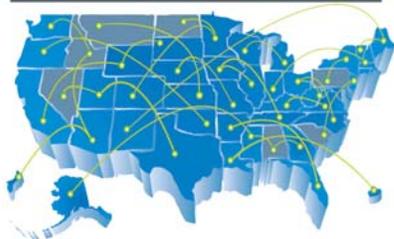
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX E: COMPARATIVE SUMMARY ANALYSIS LABORATORIES**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## Committee

**Privacy**—Consent for Sharing Laboratory Information

## Issue

Patient consent to exchange laboratory information through a health information exchange, for treatment. This issue analysis will examine how the consent options will affect clinician and laboratory business processes, public perception, and legal liabilities of all parties involved.

## Background

Currently, consent is not required for sharing some laboratory information among health care providers/payers under HIPAA and California law.

## Assumptions

- Treating physician and a pharmacy can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing laboratory information will be limited to treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those patients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- Lab information goes to multiple entities. The lab collects and tests, then transmits to the requestor and into the sharable EHR.
- For purposes of this analysis, the following definitions are provided:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus potentially providing a better quality of care. However, this option may result in (1) less data being available because patients choose not to seek care, or (2) less accurate information being available because patients provide incorrect information.
  - *Opt Out*—this choice will result in *more* information being available because all patient information will be in the system except for those patients who choose to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.

- *Opt Out with Exceptions*—this choice will result in *some* information being available because patient information will be in the system—except for those patients who choose to opt out and the information patients choose to exclude.
- *Opt In*—this choice will result in *less* information being available because patients will need to take an action to be included in the system.

## Notes

- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

**Table E-1A. Patient—Quality of Care**

**Specific Issue:** Patients want effective treatment balanced with protection of their information

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care (portion IN the HIE)	– Least quality of care (portion not IN the HIE)	• Some quality of care (portion not IN the HIE)	– Less quality of care (portion not IN the HIE)
+ Most potential increase in efficacy of care	+ More potential increase in efficacy of care	– Least potential increase in efficacy of care	• Some potential increase in efficacy of care	– Less potential increase in efficacy of care
+ Most patient participation	+ More patient participation for patients who do not opt out.	– Least patient participation for: 1. patients who do not opt in, 2. patients who choose to restrict significant information	• Some patient participation for: 1. patients who do not opt out, 2. patients who choose to restrict significant information	– Less patient participation for patients who do not opt in.
– No patient choice	• Some patient choice (OUT or IN)	+ Most patient choice and specificity in choice	+ More patient choice and specificity in choice	• Some patient choice (IN or OUT)

Note: Quality of care is based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table E-1B. Provider—Quality of Care**

**Specific Issue:** Provider wants to deliver effective treatment in the most efficient and cost-effective way.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care—all patients IN	+ More quality of care for portion IN	– Least quality of care for portion not IN	• Some quality of care for portion IN	– Less quality of care for portion not IN
+ Most cost effective	• Somewhat cost effective	– Least cost-effective	– Least cost-effective	– Less cost-effective
– Most safeguards required to protect patient information due to high volume of information	– More safeguards required to protect patient information due to lower volume of information	+ Fewest safeguards required to protect patient information due to low volume of information	• Some safeguards required to protect patient information due to low volume of information	+ Fewer safeguards required to protect patient information due to less volume of information
+ Fewest safeguards required to protect patient information due to low complexity	• Some safeguards required to protect patient information due to low complexity	– Most safeguards required to protect patient information due to high complexity	– Most safeguards required to protect patient information due to high complexity	• Some safeguards required to protect patient information due to low complexity

Note: Quality of care is based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Table E-2A. Patient—Level of Trust: HIE**

**Specific Issue:** Patient wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Least need for education due to low complexity	+ Less need for education due to less complexity	– Most need for education due to most complexity	– Most need for education due to most complexity	• More need for education due to more complexity
+ Least potential errors due to high volume of information	• Some potential errors due to volume of information	– Most potential errors due to least volume of information and most complexity	– Most potential errors due to most volume of information and most complexity	– More potential errors due to less volume of information
– No patient choice, low trust	• Some patient choice/trust	+ Most patient choice/trust	+ Most patient choice/trust	+ More patient choice/trust
– Most need to protect patient information due to high volume	– Less need to protect patient information due to more volume	+ Least need to protect patient information due to least volume	• Some need to protect patient information due to volume	• Some need to protect patient information due to volume
+ Least need to protect patient information due to low complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to most complexity	– Most need to protect patient information due to most complexity	+ Less need to protect patient information due to less complexity

Note: Level of trust in HIE—influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

**Table E-2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Least potential errors due to most volume	+ Less potential errors somewhat due to more volume	– Most potential errors due to low volume and most complexity	– Most potential errors due to most complexity and somewhat due to less volume	– More potential errors due to low volume
– Most need to protect patient information due to high volume	– More need to protect patient information due to volume	+ Least need to protect patient information due to low volume	• Some need to protect patient information due to volume	+ Less need to protect patient information due to low volume
+ Least need to protect patient information due to least complexity	+ Less need to protect patient information due to less complexity	– Most need to protect patient information due to most complexity	– Most need to protect patient information due to most complexity	+ Less need to protect patient information due to less complexity
+ Least need for staff and patient education	• Some need for staff and patient education	– Most need for staff and patient education	– Most need for staff and patient education	– More need for staff and patient education

Note: Level of trust in HIE—influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

**Table E-3. Savings and Cost Avoidance**

**Specific Issue:** Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests, increased accuracy and effectiveness, long-term savings, better quality of care, quicker reimbursements, accessing payer info for claims and eligibility. (Degree of cost avoidance will apply to all ancillary services in health care.)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most savings from business process impacts due to most volume, least complexity and non-duplicative lab tests	+ More savings from business process impact due to most volume, less complexity and non-duplicative lab tests	– Least savings from business process impact due to least volume, most complexity and most potential for duplicate lab tests	– Least savings from business process impact due to less volume, most complexity, with some potential for duplicative lab tests	– Less savings from business process impact due to less volume, less complexity with some non-duplicative lab tests
+ Most savings from access to complete information, payments, increased accuracy and quality of care	+ More savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Less savings from access to complete information, payments, increased accuracy and quality of care
– Most cost to educate due to most volume	– More cost to educate due to more volume	+ Least cost to educate due to least volume	+ Least cost to educate due to less volume	• Some cost to educate due to volume
+ Least cost to educate due to least complexity	• Some cost to educate due to complexity	– Most cost to educate due to most complexity	– Most cost to educate due to most complexity	– More cost to educate due to less complexity but need for outreach

**Table E-4. Technology**

**Specific Issue:** Technology—compatibility, integration and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least complex	• Somewhat complex	– Most complex	– Most complex	– More complex
+ Least challenge to small practice providers	• Some challenge to small practice providers	– Most challenge to small practice providers	– Most challenge to small practice providers	• More challenge to small practice providers

**Table E-5. National Efforts**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

Note: Markle—Connecting for Health and the NCVHS—National Commission on Vital & Health Statistics address patient consent to access their information, not patient consent to control the input of their information into an HIE or for exchange.

**Table E-6. Liability and Laws**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Some legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution

**Table E-7. CalPSAB Principles**

**Specific Issue:** Consistency or inconsistency with the CalPSAB Principles. (1) openness, (2) health information quality, (3) individual participation, (4) collection limitation, (5) use limitation, (6) purpose limitation, (7) security safeguards—NA, (8) accountability—NA

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>
<b>– Inconsistent with:</b> <ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<b>– Inconsistent with:</b> <ul style="list-style-type: none"> <li>openness</li> <li>individual participation</li> <li>collection limitation</li> <li>use limitation</li> <li>purpose limitation</li> </ul>	<b>– Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>– Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>– Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>

**Table E-8. Summary**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Promotes quality of care	+ Promotes quality of care	– Diminishes quality of care	+ Promotes quality of care	– Diminishes quality of care
+ Least costly/most sustainable	+ Less costly/most sustainable	– Most costly/least sustainable	– Most costly/least sustainable	– More costly/less sustainable
• Some legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk
– Inconsistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles
– Least patient choice	• Some patient choice	+ Most patient choice	+ Most patient choice	+ More patient choice
+ Most likely to reduce duplicate tests	+ More likely to reduce duplicate tests	– Least likely to reduce duplicate tests	– Less likely to reduce duplicate tests	– Less likely to reduce duplicate tests

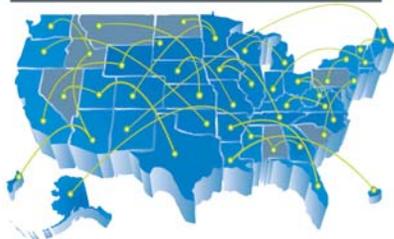
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX F: COMPARATIVE ANALYSIS LABORATORY**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Committee**

HISPC Consent Policy Options Workgroup and NCHICA HIE Council's Policy Development Committee

## **Scenario One**

Client consent to exchange mental health information through an HIE for treatment, specifically for e-prescribing and laboratory exchanges. This issue analysis will examine how the consent/permission options will affect client, clinician, business processes, public perception, and legal liabilities of all parties involved.

## **Assumptions**

- The scenario involves exchange of health information contained in electronic health records (EHRs) that conform to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- The scenario involves health care providers who are recognized as separate health care organizations.
- All of the requesting and responding providers in the scenario exchange health information with each other but are not necessarily participants in an HIO.
- If given a choice, the consumer is consenting to having some or all of her health information be collected and stored in an EHR that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- In the case of Opt In with Restrictions and Opt Out with Exceptions, health information that is protected by specific laws limiting access to the information, such as HIV-positive status or test results, mental health or substance abuse information, either will be excepted from (carved out of) the EHR or restricted by the consumer.
- The providers will comply with mandatory reporting laws.
- The purpose of the exchange of health information is for treatment.
- Technology is able to carry out the requirements of the consent options.

## **Instructions**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Table F-1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission and regardless of consumer preferences. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed; and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Table F-2. Quality of Care**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Consumer wants effective treatment balanced with protection of his or her health information.</p> <p>Physician wants access to accurate and complete records to make informed decisions and provide cost-effective treatment.</p> <p>Laboratory wants to efficiently perform tests and provide accurate results in the most cost-effective way.</p> <p>Quality of care in this scenario is measured by the availability of the consumer’s medical history relevant to the lab test requested and that the ordering physician is able to compare the results of the test with the results of previous tests.</p>	<p>+ High quality of care due to maximum participation and access to needed information</p> <p>- No choice over collection and use of health information may deter consumers from accessing health care providers; failure to seek preventive care or coordinated care</p>	<p>+ More potential for quality of care due to expected volume</p> <p>+ Offers consumers who would otherwise not seek treatment due to privacy concerns an option to opt out of HIE</p> <p>- Less quality of care than no choice due to smaller volume of records available to the provider</p>	<p>+ This option provides consumers with maximum control over disclosure and use of their health information.</p> <p>- Because this option provides consumers with the most control over whether their health information is available for HIE, this option is likely to result in low volume.</p> <p>- Most potential for duplication and errors due to complexity and potential for low volume</p>	<p>+ Because this consent option provides consumers with the ability to restrict access to some, but not all of their health information, consumers will be less likely to opt out, resulting in increases participation and relatively higher volume of records available for exchange—thus meeting the consumer’s need for choice while reducing risk of duplication and adverse events.</p> <p>- Consumers may choose to restrict access to needed health information, increasing the risk of errors and need for duplication of tests, etc.</p>	<p>- Less potential for quality of care benefits when compared with no choice and opt out consent alternatives because the default is that the health information is not placed in an EHR and is not available for HIE, resulting in less volume of records and need to duplicated tests, etc.</p>

Note: + = pro; - = con.

**Table F-3. Business Practice Impact**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Providers want HIE to improve business processes by reducing redundancy, paperwork, and reimbursement turnaround time.</p> <p>Providers will avoid adopting consent options that require secondary processes to accommodate consumer choice.</p>	<ul style="list-style-type: none"> <li>+ Least complex</li> <li>+ Most efficient</li> <li>+ Least need for consumer education</li> <li>- Maximum participation and volume of records; thus, the impact on business process with respect to managing and safeguarding the information is significant</li> <li>- Need for business process to protect information that requires consent under state and federal law.</li> </ul>	<ul style="list-style-type: none"> <li>+ Least complex of the choice options</li> <li>- More complex than no consent</li> <li>- Requires a consent management system</li> </ul>	<ul style="list-style-type: none"> <li>- Most potential for business impact due to complexity</li> <li>- Most need for consumer and stakeholder education</li> </ul>	<ul style="list-style-type: none"> <li>- Complex to implement and to monitor for compliance</li> <li>- Consumer education need</li> </ul>	<ul style="list-style-type: none"> <li>+ Less business impact than no choice and opt out due to lower volume of records available for HIE due to default that the records are not placed in an EHR</li> <li>- Greater emphasis must be placed on education of the consumer with respect to the benefits of HIE and the consequences of not choosing to opt in</li> </ul>

Note: + = pro; - = con.

**Table F-4. Public Confidence—Trust in HIE**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Consumers want transparency. They want to be informed about HIE policies and practices and be assured that their health care providers and or the eHIO will abide by principles that limit the use and disclosure of their health information, and will comply with laws, regulations, standards and policies that protect the consumer’s health information.</p> <p>Providers want providers who have access to their client’s EHRs to safeguard the information they collect, store or use and only ensure that their clients EHRs contain health information that is accurate, up to date, complete and relevant to the purpose for which it is to be used.</p> <p>Public trust in HIE is dependent on the establishment and maintenance of trust relationships with consumers and among participating providers.</p>	<p>+ Providers: Maximum trust due to maximum participation and volume of records; no choice option offers the least risk of duplication and errors than the other alternatives</p> <p>- Consumer: Least trust due to no choice</p>	<p>+ Consumer may opt out of HIE, thus more potential for consumer confidence and trust in HIE</p> <p>- Provider: Less volume of records available than no choice so less trust in HIE due to less potential for access to complete and accurate records</p>	<p>+ Most trust due to most consumer choice</p> <p>- Least trust among providers due to least access to complete records; most duplication; and most complexity</p>	<p>+ This consent option allows consumers a better alternative to opt out only because if a consumer wants to deny HIE access to some, but not all of their health information, this option will accommodate them.</p> <p>- Because this option allows more consumer choice and control over the electronic disclosure of their health information, the provider may not have access to the consumer’s complete record—thus decreasing the provider’s confidence in HIE.</p>	<p>+ Assuming that consumers are sufficiently informed about HIE, they are more likely to trust HIE if they are given the choice as to whether they wish to participate.</p> <p>- Because of the high potential for low participation and low volume of records, provider confidence in HIE is likely to be low.</p>

Note: + = pro; - = con.

**Table F-5. Health Care Cost Avoidance**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Providers and consumers want long-term savings and lower costs due to less paper work, improved communication, reduced duplicative tests and improved consumer safety.</p> <p>Providers want value from their investments in technology and cost-effective mechanisms to manage consent, safeguard information and educated consumers.</p>	<p>+ Least risk of duplication and errors</p> <p>+ Most savings from access to complete information and payment and eligibility information</p> <p>+ Least complex, so least cost per consumer to educate</p> <p>- Most total cost to educate due to volume</p> <p>- Most cost to implement a system to identify and protect confidential information to comply with state and federal laws requiring consent</p>	<p>+ Opt out is the least complex of the choice alternatives</p> <p>+ Default is that records are available, so most volume compared to other choice alternatives</p> <p>- Less cost savings potential than no choice due to less participation and volume of records available to providers</p> <p>- More complex so more cost to educate consumers and providers</p>	<p>- Least cost savings due to potential for least volume and most complexity</p>	<p>- More costly due to complexity and low volume of records available for exchange</p>	<p>- Less cost-effectiveness due to less volume and increased complexity (less access to complete records, more duplication, more time lags regarding reimbursement and eligibility determinations)</p> <p>- Need for secondary system to protect confidential health information of consumers who opt in</p> <p>- More cost to educate consumers</p>

Note: + = pro; - = con.

**Table F-6. Liability and Laws**

Specific Issue	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Liability and laws	<ul style="list-style-type: none"> <li>- Most risk of liability due to potential for noncompliance with state and federal consent laws</li> </ul>	-	<ul style="list-style-type: none"> <li>+ Because consumers must permit the electronic disclosure of their health information, the risk of legal liability for violation of state and federal consent laws is low.</li> </ul>	<ul style="list-style-type: none"> <li>+ Less risk of liability for failure to comply with state and federal laws that require written consent for disclosure because system will allow the consumer to specifically consent to the placement of the protected health information in an EHR and available for HIE.</li> <li>- The complexity of the consent option increases risk of error.</li> </ul>	<ul style="list-style-type: none"> <li>+ Since consumer permission is required to participate in HIE, the risk of liability for failure to comply with mandatory consent laws is much less.</li> </ul>

Note: + = pro; - = con.

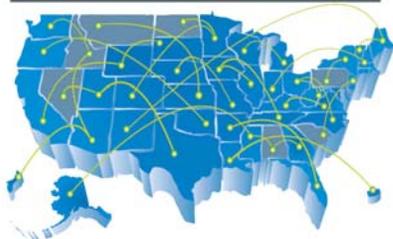
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX G: COMPARATIVE ANALYSIS OUTPATIENT CARE COORDINATION**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Committee**

HISPC Consent Policy Options Workgroup and NCHICA HIE Council's Policy Development Committee

## **Scenario Five**

For this case, the consumer is 90 years old with a history of dementia and would be providing permission to allow her health information to be placed into an interoperable electronic health record that is accessible across more than one health care organization. At least the following four health care organizations would be able to access, store, manage and exchange her health information: (1) the inpatient hospital where she received hip replacement surgery; (2) her primary care physician; (3) the hospital's outpatient care coordinator; and (4) a home health care provider hired by the outpatient care coordinator. The health information shared includes records pertaining to the consumer's mental health history.

## **Assumptions**

- The scenario involves exchange of health information contained in electronic health records (EHRs) that conform to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- The scenario involves health care providers who are recognized as separate health care organizations.
- All of the requesting and responding providers in the scenario exchange health information with each other but are not necessarily participants in an HIO.
- If given a choice, the consumer is consenting to having some or all of her health information to be collected and stored in an EHR that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- In the case of Opt In with Restrictions and Opt Out with Exceptions, health information that is protected by specific laws limiting access to the information, such as HIV positive status or test results, mental health or substance abuse information, either will be excepted from (carved out of) the EHR or restricted by the consumer.
- The providers will comply with mandatory reporting laws.
- The purpose of the exchange of health information is for treatment.
- Technology is able to carry out the requirements of the consent options.

## **Instructions**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business

processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Table G-1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission and regardless of consumer preferences. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice</b> Consumer's health information is <b>not</b> automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR, (ii) for what purposes the EHR may or may not be accessed, and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR, (ii) for what purposes their EHR may or may not be accessed, and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice</b> Consumer's health information is <b>not</b> automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Table G-2. Quality of Care**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Consumer wants effective treatment balanced with protection against unauthorized access to her health information.</p> <p>Provider wants to deliver effective treatment in the most timely and efficient way.</p> <p>Quality of care in this scenario is measured by the availability of information concerning the consumer’s ability to effectively stay in her home while recovering from inpatient surgery. The consumer has dementia and is unable to care for herself without the assistance of home health providers.</p>	<p>+ Maximum access to needed information should improve quality of care and decrease risk of harm due to errors</p> <p>- No choice over who may use and exchange records may deter consumers from accessing health care providers</p> <p>- Concern that minimum necessary exchange of information may not be observed for purposes other than treatment (even though this scenario assumes release of information is only for treatment) might increase risk that consumer would not seek follow-up (home health) care</p> <p>- Concern about release of mental health information or psychotherapy notes might increase this risk as well</p>	<p>+ Expected high volume of participation because consumers are offered some choice regarding release of their information—so those consumers who would not otherwise seek care for fear that their health information would be electronically exchanged are more likely to seek care if they understand that they are allowed to opt out</p> <p>- Lesser quality of care: the quality of the care coordination is directly dependent on the completeness and accuracy of the health information shared by all of the providers involved in consumer’s care, including information concerning the consumer’s inpatient care. If the consumer opts out of either the exchange of information from her primary care physician or from the home health care agency, then the outpatient care coordinator will not have a complete record with which to develop an outpatient care plan. If the home care providers are unaware of the consumer’s mental health history because the consumer opted out of the exchange of the physician’s records, the lack of information may decrease the effectiveness of the care that is provided to the consumer in her home.</p>	<p>- Possibility of the least amount of information being shared of all alternatives, which may result in the lowest quality of care</p>	<p>+ Could enable greater consumer participation in the HIO than opt out</p> <p>+ Allows increased specificity of permission: In this scenario, the consumer may choose to opt out only with respect to the sharing of her mental health information or to allow the sharing only to certain providers for the purposes of care coordination; thus, more information is likely to be available for exchange than with opt out</p> <p>- More complex than opt out, and it is possible that different providers will have fragmented, incomplete information about the consumer’s health care history and status, thereby leading to higher risk of treatment errors</p>	<p>+ Likely that even greater participation than opt out with exceptions</p> <p>- Same as opt out except: potential lesser quality of care due to likely decreased participation, since the default is that the consumer’s health information is unavailable</p> <p>- In this scenario, since consumer is elderly and suffers from dementia, she may not know of or be able to exercise her choice to opt in, in the absence of a consumer representative</p> <p>- Providers will need to seek the consumer’s consent or treat her as a new consumer and therefore gather information about her history at the time of encounter, thereby increasing the risk of error and treatment delays</p> <p>- Needed information for emergency care may not be available without consent or presence of consumer representative</p>

**Table G-2. Quality of Care (continued)**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Quality of care	NA	<ul style="list-style-type: none"> <li>- Each provider needs to know whether the consumer's record is complete and, if not, what information is missing</li> <li>- There is an increased potential for misdiagnosis or error in an emergency if the consumer is unable for some reason to keep track of where she has opted out and inform a provider about the potentially incomplete record</li> </ul>	NA	NA	NA

Note: + = pro; - = con.

**Table G-3. Business Practice Impact**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Providers want HIE system that minimizes changes in work flow, minimizes investments in technology, and decreases paperwork and administrative burdens.	<p><b>Inpatient hospital:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of sharing health information that supports continuity of care</li> </ul> <p><b>Physician:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of responding to requests to share consumer health information with outpatient care coordinator</li> </ul> <p><b>Outpatient care coordinator:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease of making referral to home health care provider</li> </ul> <p><b>Home health care provider:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease of obtaining needed health information to ensure appropriate level of care</li> </ul> <p><b>Inpatient hospital:</b></p> <ul style="list-style-type: none"> <li>- Maximizes burden to educate and assure consumers that their health information is protected from unauthorized use</li> <li>- Burden to keep any psychotherapy notes separate in records absent consumer's authorization to share them</li> </ul>	<ul style="list-style-type: none"> <li>- Will require one registration and care coordination process for those consumers who do not opt out and a second process for those who opt out</li> <li>- Can all providers afford to assist/educate consumers in making the decision whether to opt out?</li> <li>- When are these decisions made?</li> <li>- A decision made at the ER will likely be different than a decision in a non-emergency setting</li> <li>- From an operational perspective, the provider must develop mechanisms used to ensure that the consumer's choice is implemented and a tracking mechanism to distinguish between consumers who have opted out and those who have not exercised that choice.</li> <li>- Providers must also develop educational materials that inform consumers of their rights to opt out and the implications of opting out.</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out with exceptions</li> <li>- Maximum business impact for the least amount of participation</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out—except has greater potential to cause confusion and increased need for education and tracking mechanisms</li> <li>- Increased costs due to the above</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out</li> </ul>

(continued)

**Table G-3. Business Practice Impact (continued)**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Business practice impact	<p><b>Physician:</b></p> <ul style="list-style-type: none"> <li>- Maximizes burden to educate and assure consumers that their health information is protected from unauthorized use</li> <li>- May be in violation of North Carolina privacy laws regarding release of mental health records</li> </ul> <p><b>Outpatient care coordinator:</b></p> <ul style="list-style-type: none"> <li>- Same as physician and inpatient hospital</li> </ul> <p><b>Home health care provider:</b></p> <ul style="list-style-type: none"> <li>- Same as inpatient hospital</li> </ul>	<ul style="list-style-type: none"> <li>- The provider’s opt out policy should be clear regarding expiration dates, liability issues, and procedures for how the consumer may opt back in</li> </ul>	NA	NA	NA

Note: + = pro; - = con.

**Table G-4. Public Confidence—Trust in HIE**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Consumers want to be informed about the policies and practices of the HIE and to trust that the HIE will abide by principles that limit the use and disclosure of their health information, and will comply with laws, regulations, standards, and policies that protect consumers' health information.</p> <p>Provider wants other providers participating in the HIE to safeguard information and share information that is accurate, complete, and relevant to the purpose for which it is to be used.</p>	<ul style="list-style-type: none"> <li>+ Perception of public trust is dependent on the establishment and maintenance of trust relationships with consumers and among participating providers</li> <li>- Maximum perceived threat to consumer's right to privacy may lead to low trust levels</li> </ul>	<ul style="list-style-type: none"> <li>+ Consumer: More trust because choice to opt out is provided, so less perceived threat to privacy</li> <li>- Provider: may have less trust because more risk of incomplete records</li> <li>- Is it realistic to assume that consumers can make these decisions, and that the decisions will be meaningful when made?</li> <li>- Consumer: may have less trust because more education needed to understand the consent model and its implications</li> </ul>	<ul style="list-style-type: none"> <li>+ Consumer: Maximum trust because maximum choice</li> <li>- Provider: Least trust due to consumer's amount of control over what information is released to whom</li> </ul>	<ul style="list-style-type: none"> <li>+ Consumer: More trust because offers consumer variety of choices</li> <li>- Provider: less trust because providers are unable to access health information that is complete and accurate and may never know if they don't have complete information</li> <li>- Is it realistic to assume that consumers can make these decisions?</li> <li>- Consumer: variety of choices may confuse consumers, resulting in distrust of the system</li> </ul>	<ul style="list-style-type: none"> <li>+ Consumer: Given more choice, so likely more trust</li> <li>- Less trust due to potential lower participation in the HIO and increased likelihood that the consumer's available health information is incomplete and inaccurate</li> </ul>

Note: + = pro; - = con.

**Table G-5. Health Care Cost Avoidance**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Providers and consumers want less paperwork, improved communication, reduced duplicative tests, and increased accuracy and effectiveness.	<ul style="list-style-type: none"> <li>+ Maximizes ability to provide continuity of care and coordination of outpatient care of elderly consumer with dementia</li> <li>- If consumer avoids seeking home health care or refuses outpatient care coordination due to limited rights to privacy concerns, the consumer's health status may deteriorate, leading to higher costs.</li> </ul>	<ul style="list-style-type: none"> <li>+ More savings compared to the other choice due to more volume than the other choice alternatives</li> <li>- Less savings and less cost-effective compared to no choice</li> <li>- Some providers may not be able to afford added costs incurred in assisting/educating consumers about this choice and in implementing the tracking mechanism.</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out with exceptions</li> <li>- Least cost-effective due to likely low participation in the HIO and maximum complexity</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out, except:</li> <li>- Less cost-effective than opt out, due to consumer's variety of consent options</li> <li>- Greater need for consumer and provider education</li> <li>- Greater need for system safeguards</li> </ul>	<ul style="list-style-type: none"> <li>- Less participation in the HIO; more complexity to train and advise about the options</li> <li>- Less cost-effective than other alternatives</li> </ul>

Note: + = pro; - = con.

**Table G-6. Liability and Laws**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Liability and laws	<ul style="list-style-type: none"> <li>- Is consumer competent to consent to treatment? If not, is there an appropriate legal representative to give consent? (See N.C.G.S. § 90-21.13(c))</li> <li>- Does the record contain health information acquired by a mental health facility, thus making the information confidential? (See G.S. 122C-52)</li> <li>- Do the requesting and consulting providers fall within the definition of "facility"? (See G.S. 122C-3) Are providers thus allowed to share the consumer's confidential information without the consumer's consent for purposes described in this scenario?</li> <li>- Does the consumer's record contain any psychotherapy notes? If so, HIPAA does not allow their use by or disclosure to anyone other than the creator of the notes absent the consumer's authorization, except in very limited circumstances (45 C.F.R. § 508(a)(2)).</li> </ul>	<ul style="list-style-type: none"> <li>+ If consumer opts out, no apparent violation of NC mental health laws requiring consumer consent to release mental health information except for emergency treatment</li> <li>- If consumer doesn't opt out of exchange by providers who would otherwise exchange consumer mental health information, provider may be in violation of North Carolina law (N.C.G.S. § 122C-52)</li> <li>- Will HIPAA require providers to notify other providers of the consumer's decision to opt out?</li> <li>- Will the request to opt out be deemed a request for a restriction under HIPAA?</li> <li>- Does the consumer's record contain any psychotherapy notes? If so, HIPAA does not allow their use by or disclosure to anyone other than the creator of the notes absent the consumer's authorization, except in very limited circumstances (45 C.F.R. § 508(a)(2)).</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out with exceptions</li> </ul>	<ul style="list-style-type: none"> <li>+ If consumer opts out with respect to mental health information, no violation of North Carolina mental health laws regarding release of this information without consumer's consent</li> <li>+ Question: Can consumers opt out (either total or regarding sharing of psychotherapy notes) alone, without the consumer's specific execution of a HIPAA-compliant authorization, permit health care providers to share psychotherapy notes?</li> <li>- More potential liability due to increased potential for failure to comply with patient's consent directives</li> <li>+ Less likely to violate North Carolina mental health privacy laws, because provider's permission of consumer choice with respect to mental health information complies with these laws</li> </ul>	<ul style="list-style-type: none"> <li>- Same as opt out</li> </ul>

Note: + = pro; - = con.

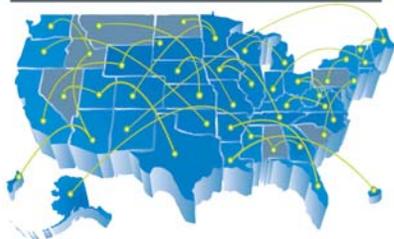
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX H: COMPARATIVE ANALYSIS LABORATORY**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Committee**

HISPC Consent Policy Options Workgroup and NCHICA HIE Council's Policy Development Committee.

## **Scenario Five**

Consumer, a 50-year-old male claiming depression due to marital separation, visits psychiatrist in private practice. Psychiatrist prescribes antidepressant for consumer and refers consumer to outpatient substance abuse counselor, asking that counselor confirm consumer's appearance for treatment and provide psychiatrist with periodic updates of consumer's progress in treatment. The health information shared includes records pertaining to the consumer's mental health and substance abuse history.

## **Assumptions**

- The scenario involves exchange of health information contained in electronic health records (EHRs) that conform to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- The scenario involves health care providers who are recognized as separate health care organizations.
- All of the requesting and responding providers in the scenario exchange health information with each other but are not necessarily participants in an HIO.
- If given a choice, the consumer is consenting to having some or all of her health information to be collected and stored in an EHR that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- In the case of Opt In with Restrictions and Opt Out with Exceptions, health information that is protected by specific laws limiting access to the information, such as HIV positive status or test results, mental health or substance abuse information, either will be excepted from (carved out of) the EHR or restricted by the consumer.
- The providers will comply with mandatory reporting laws.
- The purpose of the exchange of health information is for treatment.
- Technology is able to carry out the requirements of the consent options.

## **Instructions**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Table H-1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission and regardless of consumer preferences. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice.</b> Consumer’s health information is <b>not</b> automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed; and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice.</b> Consumer’s health information is <b>not</b> automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Table H-2. Quality of Care**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Consumer wants effective treatment balanced with protection of his or her health information.</p> <p>Physician wants access to accurate and complete records to make informed decisions and provide cost-effective treatment.</p> <p>Laboratory wants to efficiently perform tests and provide accurate results in the most cost-effective way.</p> <p>Quality of care in this scenario is measured by the availability of the consumer’s medical history relevant to the lab test requested and that the ordering physician is able to compare the results of the test with the results of previous tests.</p>	<p>+ Maximum access to needed information should:</p> <ul style="list-style-type: none"> <li>• improve quality of care</li> <li>• decrease risk of harm due to errors</li> <li>• decrease liability</li> </ul> <p>– No choice over who may use and exchange records may deter consumers from seeking treatment, especially where sensitive information is concerned.</p>	<p>+ More potential for improved quality of care due to higher expected volume than opt in option because default is to allow HIE</p> <p>+ Offers consumers who would otherwise not seek treatment due to privacy concerns control over whether their health information will be available for HIE</p> <p>– More potential for poor quality of care if the requesting provider does not have electronic access to the consumer’s health information because the consumer opted out of HIE</p>	<p>+ This option provides consumer with maximum control over disclosure and use of their health information.</p> <p>– Because this option provides consumers with the most choice, this option is likely to result in lower volume of records available to requesting providers, resulting in greater potential for duplication and errors.</p>	<p>+ Because this consent option provides consumers with the ability to restrict access to some, but not all of their health information, consumers will be less likely to opt out, resulting in increases participation and relatively more volume of records available for exchange—thus meeting the consumer’s need for choice while reducing risk of duplication and adverse events.</p> <p>– Consumers may choose to restrict access to needed health information, increasing the risk of errors and need for duplication of tests, etc.</p>	<p>– Less potential for quality of care benefits when compared to no choice and opt out consent alternatives because the default is that the health information is not placed in an EHR and is not available for HIE, resulting in less volume of records and need to duplicated tests, etc.</p>

Note: + = pro; – = con.

**Table H-3. Business Practice Impact**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Providers want HIE to improve business processes by reducing redundancy, paperwork, and reimbursement turnaround time.</p> <p>Providers will avoid adopting consent options that require secondary processes to accommodate consumer choice.</p>	<p><b>Psychiatrist:</b></p> <ul style="list-style-type: none"> <li>- Maximizes ease and efficiency of making referrals, sharing health information that supports continuity of care</li> <li>+ Less paperwork/fewer calls</li> <li>- Maximizes burden to assure patients that their health information is protected from unauthorized use</li> <li>- Requires consumer's authorization if will share psychotherapy notes</li> <li>- Requires more staff training/policies</li> <li>- Requires more consumer education</li> </ul>	<ul style="list-style-type: none"> <li>+ Compared with other consent options, "opt out" is the least complex</li> <li>- Would require consumer education program</li> <li>- This consent option is more complex than no choice.</li> <li>- Requires provider to implement a consent management system</li> <li>- Provider not likely to benefit from HIE to the extent consumers</li> </ul>	<ul style="list-style-type: none"> <li>- Most potential for business impact due to complexity</li> <li>- Most need for consumer and stakeholder education</li> </ul>	<ul style="list-style-type: none"> <li>- Complex</li> <li>- Consumer education need</li> </ul>	<ul style="list-style-type: none"> <li>+ Less business impact than no choice and opt out due to less volume of records available for HIE due to default is that the records are not placed in an EHR</li> <li>- Greater emphasis must be placed on education of the consumer with respect to the benefits of HIE and the consequences of not choosing to opt in.</li> </ul>

(continued)

**Table H-3. Business Practice Impact (continued)**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
NA	<p><b>Outpatient substance abuse counselor:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of responding to requests to share consumer health information with psychiatrist.</li> <li>- Will be in violation of federal substance abuse laws unless specific written consumer consent for most releases is obtained</li> <li>- Must include notice about redisclosure each time substance abuse information is released</li> </ul>	NA	NA	NA	NA

Note: + = pro; - = con.

**Table H-4. Public Confidence—Trust in HIE**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Consumers want transparency. They want to be informed about HIE policies and practices and be assured that their health care providers and/or the eHIO will abide by principles that limit the use and disclosure of their health information, and will comply with laws, regulations, standards, and policies that protect the consumer’s health information.</p> <p>Providers want providers who have access to their client’s EHRs to safeguard the information they collect, store, or use and only ensure that their clients’ EHRs contain health information that is accurate, up to date, complete, and relevant to the purpose for which it is to be used.</p> <p>Public trust in HIE is dependent on the establishment and maintenance of trust relationships with consumers and among participating providers.</p>	<p>+ Perception of public trust is dependent on the establishment and maintenance of trust relationships with consumers and among participating providers.</p> <p>- Consumers’ perception of lack of right to privacy can lead to low trust levels and possible refusal to seek treatment or participate in HIO.</p>	<p>+ Offering the consumer the choice to opt out is likely to encourage more consumers to participate and build confidence and trust in HIE.</p> <p>- Because there is likely to be less participation and thus a lower volume of records available for HIE, the completeness and accuracy of records available for exchange will be less than no choice, resulting in less confidence and trust in HIE among providers and consumers.</p>	<p>+ Highest level of trust in HIE due to maximum consumer choice regarding participation</p> <p>- Least trust among providers due to least access to complete records, most duplication, and most complexity</p>	<p>+ This consent option allows consumers a better alternative to opt out only because if a consumer wants to deny HIE access to some, but not all of their health information, this option will accommodate that.</p> <p>+ Because this option allows consumers more choice and control over the electronic disclosure of their health information, they will be more likely to participate.</p> <p>- Because this option allows more consumer choice and control over the electronic disclosure of their health information, the provider may not have access to the consumer’s complete record—thus decreasing the provider’s confidence in HIE.</p>	<p>+ Assuming that consumers are sufficiently informed about HIE, they are more likely to trust HIE if they are given the choice as to whether they wish to participate.</p> <p>- Because of the high potential for low participation and low volume of records, provider confidence in HIE is likely to be low.</p>

Note: + = pro; - = con.

**Table H-5. Health Care Cost Avoidance**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p>Providers and consumers want long-term savings and lower costs due to less paperwork, improved communication, reduced duplicative tests, and improved consumer safety.</p> <p>Providers want value from their investments in technology and cost-effective mechanisms to manage consent, safeguard information and educated consumers.</p>	<p>+ Allows for appropriate referral to outpatient substance abuse counselor</p> <p>- If consumer avoids seeking treatment for depression or substance abuse due to concerns about limited rights to privacy, the consumer's health status may deteriorate, leading to higher costs, or the consumer may become suicidal.</p>	<p>+ Because the opt out consent option is the least complex of the consent options, it is likely to be the least expensive to implement.</p> <p>- Opt out consent option will likely result in less participation and thus less volume of records available for HIE, resulting in less potential in cost savings when compared to no choice.</p> <p>- Providers will need to invest in consumer education programs to inform consumers about the benefits of HIE and the consequences of their choice.</p> <p>+ Because the default is that health records are available for HIE, this option is likely to result the highest level of volume than other consent options—resulting in higher cost savings due to reductions in paper work and redundancy.</p>	<p>- Least cost savings due to potential for least volume and maximum complexity and maximum need for consumer education</p>	<p>- More costly due to complexity and low volume of records available for exchange</p>	NA

Note: + = pro; - = con.

**Table H-6. Liability and Laws**

Specific Issues	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Liability and laws	<ul style="list-style-type: none"> <li>+ Mental health information may be provided to substance abuse counselor and back to psychiatrist (NCGS § 122C-55).</li> <li>- Likely violates federal substance abuse laws unless client’s written permission to release information back to treating psychiatrist is obtained (42 CFR §§ 2.1, 2.2).</li> <li>- Prohibition on re-disclosure of substance abuse information (42 CFR § 2.32)</li> <li>- Psychotherapy notes may not be released without patient authorization or court order (45 CFR § 164.508(a)(2)).</li> </ul>	NA	<ul style="list-style-type: none"> <li>+ Because consumers must permit the electronic disclosure of their health information, the risk of legal liability for violation of state and federal consent laws is low.</li> </ul>	<ul style="list-style-type: none"> <li>+ Less risk of liability for failure to comply with state and federal laws that require written consent for disclosure because system will allow the consumer to specifically consent to the placement of the protected health information in an EHR and available for HIE.</li> <li>- The complexity of the consent option increases risk of error.</li> </ul>	<ul style="list-style-type: none"> <li>+ Since consumer permission is required to participate in HIE, the risk of liability for failure to comply with mandatory consent laws is much less.</li> </ul>

Note: + = pro; - = con.

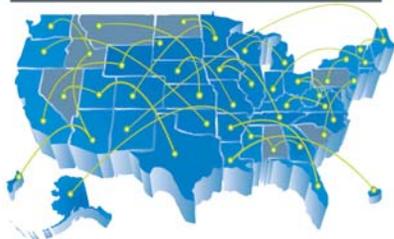
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX I: COMPARATIVE ANALYSIS MINOR SEEKING STD TESTING**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Committee**

HISPC Consent Policy Options Workgroup and NCHICA HIE Council's Policy Development Committee

### **Scenario One**

Patient is a 17-year-old female who visits her school health clinic and informs the nurse that she fears she may have a sexually transmitted disease. School nurse refers student to private practice physician for testing and provides student with samples of birth control pills and condoms. Physician examines student, orders tests, and determines that student has urinary tract and yeast infections. Physician prescribes medication to treat conditions. The student would be providing permission to allow her health information to be entered into an interoperable electronic health record that will be accessible to authorized providers and their staff within a single health care organization as well as across multiple health care organizations.

### **Assumptions**

- The scenario involves exchange of health information contained in electronic health records (EHRs) that conform to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- The scenario involves health care providers who are recognized as separate health care organizations.
- All of the requesting and responding providers in the scenario exchange health information with each other but are not necessarily participants in an HIO.
- If given a choice, the consumer is consenting to having some or all of her health information to be collected and stored in an EHR that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- In the case of Opt In with Restrictions and Opt Out with Exceptions, health information that is protected by specific laws limiting access to the information, such as HIV positive status or test results, mental health or substance abuse information, either will be excepted from (carved out of) the EHR or restricted by the consumer.
- The providers will comply with mandatory reporting laws.
- The purpose of the exchange of health information is for treatment.
- Technology is able to carry out the requirements of the consent options.

### **Instructions**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business

processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Table I-1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission and regardless of consumer preferences. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice.</b> Consumer’s health information is <b>not</b> automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed; and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice.</b> Consumer’s health information is <b>not</b> automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Table I-2. Quality of Care**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Minor wants effective treatment and accurate records balanced with protection against unauthorized access to her health information (in particular, she doesn't want parents to know she is sexually active).</p> <p>Providers want to deliver effective treatment in the most timely and efficient way and to encourage consumer to seek treatment.</p>	<p>+ Maximum access to needed information should:</p> <ul style="list-style-type: none"> <li>• Improve quality of care</li> <li>• Decrease risk of harm due to errors</li> <li>• Decrease liability</li> <li>• Maximize ability to provide continuity of care and coordination of care for appropriate treatment of infections and preventive care for minor</li> </ul> <p>- No choice over who may use and exchange records may deter minors in this situation from seeking treatment, especially where sensitive information is concerned</p> <p>- Alternatively, minors may not be truthful with providers if they know their information can be released without their consent.</p>	<p>+ Greater potential to improve quality of care due to higher expected volume of records than opt in option, because most people probably won't opt out</p> <p>+ Likely to have relatively complete and accurate information</p> <p>+ Due to amount and accuracy of information, fewer duplicative tests and medication errors</p> <p>- Somewhat lower volume of records available to providers because some consumers will choose to opt out</p> <p>- Some consumers may avoid seeking treatment</p> <p>- These may result in some increase in duplicate tests and medication errors.</p>	<p>+ Because this option provides consumers with the ability to restrict access to some but not all of their health information, consumers may be less likely to opt out, resulting in increased participation and relatively greater volume of records available for exchange.</p> <p>+ Relatively complete and accurate information</p> <p>+ Fewer duplicate tests and medication errors than with non-granular options</p> <p>- Likely somewhat lower volume of records available to providers through HIE because some consumers still will choose to opt out for certain records</p> <p>- Lower quality of care for those consumers who do restrict access to some or all of their information</p> <p>- Potential for higher number of duplicate tests/medication errors for those restricting information</p>	<p>+ Because this option provides consumers with the ability to restrict access to some but not all of their health information, consumers will be less likely to opt out, resulting in increased participation and relatively greater volume of records available for exchange.</p> <p>+ Relatively complete and accurate information</p> <p>+ Fewer duplicate tests and medication errors than with non-granular options</p> <p>- Likely somewhat lower volume of records available to providers through HIE because some consumers still will choose to opt out for certain records</p> <p>- If consumers choose to restrict access to needed health information, risk of increased errors and duplication of tests, etc.</p>	<p>+ Relatively high participation likely due to choice, leading to somewhat more information available to providers and higher quality of care than for more granular consent options</p> <p>- Less potential for increased quality of care when compared to no choice and opt out</p> <p>- Likely lower volume of records, greater duplicate tests and medication errors</p>

Note: + = pro; - = con.

**Table I-3. Business Practice Impact**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Providers want HIE system that minimizes changes in workflow, minimizes investments in technology, decreases paperwork and administrative burdens, and results in quicker reimbursement.</p> <p>Payers want HIE system that provides them with comprehensive information regarding care for which they are paying; decreased costs of care.</p>	<p><b>School health clinic:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of making referrals and sharing health information with private practice physician (which supports continuity of care)</li> <li>+ Less paperwork/fewer calls</li> <li>+ No change in process of obtaining consent, so less money needed for education</li> </ul> <p><b>Physician:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of responding to requests to share consumer health information with school health clinic in follow-up, if necessary, and prescribing to pharmacy electronically</li> <li>+ Less paperwork/fewer calls</li> <li>+ No change in process of obtaining consent, so less money needed for education</li> </ul> <p><b>Pharmacy:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease of filing claim for insurance and getting paid for prescription</li> </ul>	<ul style="list-style-type: none"> <li>+ The least complex of the options that permit consent, so fairly easy to administer</li> <li>- More burdensome to administer than no choice</li> <li>- Would need to maintain separate records for consumers who opt out</li> <li>- Would require consumer and staff education program about the consent option, which would increase costs to providers</li> </ul>	<ul style="list-style-type: none"> <li>+ Because more sophisticated technology is required, security of information may be greater.</li> <li>- Complex technology increases cost of technology.</li> <li>- Complex consent options require greater staff and consumer education, as does fact that information cannot be exchanged unless consumer opts in.</li> </ul>	<ul style="list-style-type: none"> <li>+ Because more sophisticated technology is required, security of information may be greater.</li> <li>- Complex technology increases cost of technology.</li> <li>- Complex consent options require greater staff and consumer education.</li> </ul>	<ul style="list-style-type: none"> <li>+ Still fairly easy and inexpensive to administer due to low complexity of consent option</li> <li>- Greater need to educate both staff and consumers regarding the benefits of HIE and the consequences of not choosing to opt in</li> <li>- Such education will be more time consuming and costly.</li> </ul>

(continued)

**Table I-3. Business Practice Impact (continued)**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
NA	<ul style="list-style-type: none"> <li>+ If e-prescribing used, improves likelihood of accurate filling and limits likelihood of prescription being a forgery</li> </ul> <p><b>Insurer:</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease of obtaining needed health information to ensure appropriate level of care provided</li> <li>+ If consumer refuses care due to perceived lack of privacy, insurer saves money.</li> </ul> <p><b>School health clinic:</b></p> <ul style="list-style-type: none"> <li>- Maximizes burden to assure consumers that their health information is protected from unauthorized use here. Is clinic required to know and advise consumer that referral to physician may result in consumer's information being shared with parents if parents ask physician?</li> </ul> <p><b>Physician:</b></p> <ul style="list-style-type: none"> <li>- Does physician have obligation to advise consumer that if consumer pays for visit with parents' insurance card, parents may be provided information if they ask?</li> </ul>	NA	NA	NA	NA

(continued)

**Table I-3. Business Practice Impact (continued)**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
NA	<ul style="list-style-type: none"> <li>- Physician office may need policy on how it will address this issue.</li> </ul> <p><b>Pharmacy:</b></p> <ul style="list-style-type: none"> <li>- Same as physician and school health clinic?</li> </ul>	NA	NA	NA	NA

Note: + = pro; - = con.

**Table I-4. Public Confidence—Trust in HIE**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Consumers want to be informed about the policies and practices of the HIO and to trust that the HIO will abide by principles that limit the use and disclosure of their health information; will take extra precautions for sensitive information; and will comply with laws, regulations, standards, and policies that protect consumers' health information.</p> <p>Providers want other providers participating in the HIO to safeguard information and share information that is accurate, complete, and relevant to the purpose for which it is to be used.</p>	<p>+ Providers and payers are more likely to trust in HIE if they obtain what they consider all necessary information in order to provide or pay for care.</p> <p>- Consumer's perception of lack of right to privacy is likely to lead to low trust levels and possible refusal to seek treatment, give providers accurate and complete information, or participate in HIO.</p>	<p>+ Offering the consumer the choice to opt out likely will encourage more consumers to participate and build confidence and trust in HIE.</p> <p>- Because there is likely to be less consumer participation and thus less volume of records than with no choice option, records are likely to be somewhat less complete and accurate than if no choice, resulting in less confidence and trust in HIE among providers.</p>	<p>+ This option provides consumers with maximum control over uses and disclosures of their health information and, accordingly, is likely to result in highest consumer level of trust in HIE.</p> <p>- Due to possibility of least access to complete records, this option may result in least trust among providers.</p>	<p>+ Because this option allows more consumer choice and control over the electronic disclosure of their health information, there is a greater likelihood of consumer confidence and participation in HIE.</p> <p>- Because this option allows more consumer choice and control over the electronic disclosure of their health information, the provider may not have access to the consumer's complete record, so provider's confidence in HIE likely will decrease.</p>	<p>+ More likely to increase consumer confidence since no information is exchanged unless consumers opt in.</p> <p>- Because of potential for lower consumer participation and lower volume of records, provider confidence in HIE is likely to be somewhat lower than for no choice or opt out.</p>

Note: + = pro; - = con.

**Table I-5. Savings/Health Care Cost Avoidance**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Providers, payers, and consumers want less paperwork, improved communication, fewer duplicate tests, increased accuracy and effectiveness of diagnosis and treatment, and long-term savings.	<ul style="list-style-type: none"> <li>+ Exchange of information allows for appropriate referral to ob/gyn, avoids duplication of tests, and increases likelihood that consumer receives effective care.</li> <li>- If consumer avoids seeking medical care from school clinic or physician or filling prescription due to concern about limited right to privacy, the consumer's health status may deteriorate and she may fail to use birth control, leading to higher costs.</li> </ul>	<ul style="list-style-type: none"> <li>+ Because the opt out consent option is the least complex of the consent options, it is likely to be the least expensive to implement.</li> <li>- Opt out consent option will likely result in less participation and thus lower volume of records available for HIE, resulting in less potential in cost savings when compared to no choice.</li> <li>- Providers will need to invest in consumer education programs to inform consumers about the benefits of HIE and the consequences of their choice.</li> <li>+ Because the default is that health records are available for HIE, this option is likely to result in a higher level of volume than other consent options, resulting in higher cost savings due to reductions in paperwork and redundancy.</li> </ul>	<ul style="list-style-type: none"> <li>- Least cost savings may be available due to potential for least volume of records available, maximum complexity of consent option, and maximum need for staff and consumer education.</li> </ul>	<ul style="list-style-type: none"> <li>- More costly due to complexity and low volume of records available for exchange.</li> </ul>	NA

Note: + = pro; - = con.

**Table I-6. Liability and Laws**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Liability and laws	<ul style="list-style-type: none"> <li>+ NCGS 90-21.4(a), 90-21.5 (Minors may consent to prevention, diagnosis, and treatment for venereal disease, and physicians can't be held liable for providing such services without obtaining the minor's parents' consent.)</li> <li>- No choice results in a maximum perceived threat to consumer's right to privacy.</li> <li>- NCGS 90-21.4(b) ("If a parent . . . contacts the physician concerning the treatment or medical services being provided to the minor, the physician may give information.") So how does physician office or pharmacy respond to call from parents, if parents indicate they will not pay for treatment unless physician informs them of reason for minor's visit?</li> </ul>	<ul style="list-style-type: none"> <li>+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information.</li> <li>+ Somewhat lower volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice option, because providers can only be held accountable to know information in their possession.</li> <li>+ Less complex consent option may decrease the risk of inappropriate release of information.</li> </ul>	<ul style="list-style-type: none"> <li>+ Because consumers must permit the electronic disclosure of any of their health information, the risk of legal liability for violation of state and federal release of information laws is perhaps the lowest of all the consent options.</li> <li>+ Possibly the smallest volume of information in the EHR may lead to the least risk of malpractice liability, because providers can only be held accountable to know information in their possession.</li> <li>- The complexity of this consent option may increase the risk of inappropriate release of information.</li> </ul>	<ul style="list-style-type: none"> <li>+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information</li> <li>+ Somewhat lower volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice option, because providers can only be held accountable to know information in their possession.</li> <li>- The complexity of this consent option may increase the risk of inappropriate release of information.</li> </ul>	<ul style="list-style-type: none"> <li>+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information</li> <li>+ Somewhat lower volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice or opt out options, because providers can only be held accountable to know information in their possession.</li> <li>+ Less complex consent option may decrease the risk of inappropriate release of information.</li> </ul>

Note: + = pro; - = con.

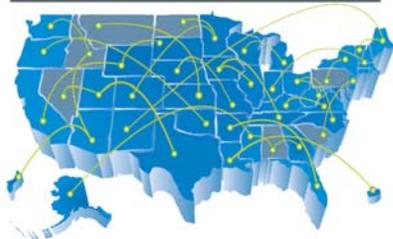
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX J: COMPARATIVE ANALYSIS REPORTABLE DISEASE**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## Committee

HISPC Consent Policy Options Workgroup and NCHICA HIE Council's Policy Development Committee

## Scenario Five

**Reportable Disease.** In this scenario, 25-year-old male visits primary care physician for routine physical. Physician orders lab tests from clinical lab, which performs test and sends results to physician. Physician determines that consumer has HIV—a reportable disease—prescribes medication for consumer, and sends report of diagnosis to County Health Department, as required by law. County Health Department requests, and physician provides, information regarding consumer's past medical history and treatment. The health information includes records pertaining to the consumer's HIV infection.

## Assumptions

- The scenario involves exchange of health information contained in electronic health records (EHRs) that conform to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- The scenario involves health care providers who are recognized as separate health care organizations.
- All of the requesting and responding providers in the scenario exchange health information with each other but are not necessarily participants in an HIO.
- If given a choice, the consumer is consenting to having some or all of his health information to be collected and stored in an EHR that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized providers and staff both within health care organizations and across more than one health care organization.
- In the case of Opt In with Restrictions and Opt Out with Exceptions, health information that is protected by specific laws limiting access to the information, such as HIV positive status or test results, mental health or substance abuse information, either will be excepted from (carved out of) the EHR or restricted by the consumer.
- The providers will comply with mandatory reporting laws.
- The purpose of the exchange of health information is for treatment.
- Technology is able to carry out the requirements of the consent options.

## Instructions

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Table J-1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission and regardless of consumer preferences. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice.</b> Consumer's health information is <b>not</b> automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify: (i) who may access their EHR, (ii) for what purposes the EHR may or may not be accessed, and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice.</b> Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR, (ii) for what purposes their EHR may or may not be accessed, and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice.</b> Consumer's health information is <b>not</b> automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Table J-2. Quality of Care**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Consumer wants effective treatment balanced with protection against unauthorized access to his/her health information.</p> <p>Provider wants to deliver effective treatment in the most timely and efficient way.</p>	<ul style="list-style-type: none"> <li>+ Maximum access to needed information should:</li> <li>+ improve quality of care</li> <li>+ decrease risk of harm due to errors</li> <li>+ maximize ability to provide continuity of care and coordination of care for appropriate treatment of consumer</li> <li>- No choice over who may use and exchange records may deter consumers from accessing health care providers, especially where sensitive information is concerned</li> <li>- Alternatively, consumers may not be truthful with providers if they know their information can be released without their consent.</li> </ul>	<ul style="list-style-type: none"> <li>+ Higher participation because few consumers opt out, so potentially greater quality of care</li> <li>+ Due to amount and accuracy of information, fewer duplicative tests and medication errors</li> <li>- Somewhat less volume of records available to providers because some consumers will choose to opt out</li> <li>- Some consumers may avoid seeking treatment.</li> <li>- With sensitive information, if consumer's only choices are to opt out or have all information included, consumers who opt out may see reduced quality of care, more duplicative tests and exams.</li> <li>- Some potential for errors due to smaller volume of information</li> </ul>	<ul style="list-style-type: none"> <li>+ Because this option provides consumers with the ability to restrict access to some but not all of their health information, consumers may be less likely to opt out, resulting in increased participation and relatively greater volume of records available for exchange.</li> <li>+ Relatively complete and accurate information</li> <li>+ Fewer duplicative tests and medication errors than with non-granular options</li> <li>- Likely somewhat less volume of records available to providers through HIE because some consumers still will choose to opt out for certain records</li> <li>- Lower quality of care for those consumers who do restrict access to some or all of their information</li> <li>- Potential for higher number of duplicative tests/medication errors for those restricting information</li> </ul>	<ul style="list-style-type: none"> <li>+ Because this option provides consumers with the ability to restrict access to some but not all of their health information, consumers will be less likely to opt out, resulting in increased participation and relatively greater volume of records available for exchange.</li> <li>+ Relatively complete and accurate information</li> <li>+ Fewer duplicative tests and medication errors than with non-granular options</li> <li>- Likely somewhat less volume of records available to providers through HIE because some consumers still will choose to opt out for certain records</li> <li>- If consumers choose to restrict access to needed health information, risk of increased errors and duplication of tests, etc.</li> </ul>	<ul style="list-style-type: none"> <li>+ Relatively high participation likely due to choice, leading to somewhat more information available to providers and higher quality of care than for more granular consent options</li> <li>- Less potential for increased quality of care when compared to no choice and opt out</li> <li>- Likely less volume of records, greater duplicate tests and medication errors</li> </ul>

Note: + = pro; - = con.

**Table J-3. Business Practice Impact**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Providers want HIE system that minimizes changes in work flow, minimizes investments in technology, decreases paperwork and administrative burdens, and results in quicker reimbursement.	<p><b>Physician</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of sharing health information that supports referral to clinical lab</li> <li>+ Most cost-effective because simple concept, so few dollars required for education</li> <li>+ No change in process of obtaining consent, so easy to administer</li> </ul> <p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>+ Maximizes ease and efficiency of responding to request for lab test and sharing of results</li> </ul> <p><b>Public Health Department:</b></p> <p><b>Physician</b></p> <ul style="list-style-type: none"> <li>- Maximizes burden to assure consumers that their health information is protected from unauthorized use, especially where sensitive information is concerned</li> </ul> <p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>- Maximizes burden to assure consumers that their health information is protected from unauthorized use</li> </ul> <p><b>Public Health Department</b></p> <ul style="list-style-type: none"> <li>- Most safeguards required to protect sensitive information from inappropriate release</li> </ul>	<ul style="list-style-type: none"> <li>+ The least complex of the options that permit consent, so fairly easy to administer</li> <li>- More burdensome to administer than no choice</li> <li>- Would need to maintain separate records for consumers who opt out</li> <li>- Would require consumer and staff education program about the consent option, which will increase costs to providers</li> </ul>	<ul style="list-style-type: none"> <li>+ Because more sophisticated technology is required, security of information may be greater.</li> <li>- Complex technology increases cost of technology</li> <li>- Complex consent options require greater staff and consumer education, as does the fact that information cannot be exchanged unless consumer opts in.</li> </ul>	<ul style="list-style-type: none"> <li>+ Because more sophisticated technology is required, security of information may be greater.</li> <li>- Complex technology increases cost of technology.</li> <li>- Complex consent options require greater staff and consumer education.</li> </ul>	<ul style="list-style-type: none"> <li>+ Still fairly easy and inexpensive to administer due to low complexity of consent option</li> <li>- Greater need to educate both staff and consumers regarding the benefits of HIE and the consequences of not choosing to opt in</li> <li>- Such education will be more time consuming and costly.</li> </ul>

Note: + = pro; - = con.

**Table J-4. Public Confidence—Trust in HIE**

Specific Issues	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
<p>Consumers want to be informed about the policies and practices of the HIE and to trust that the HIE will abide by principles that limit the use and disclosure of their health information, and will comply with laws, regulations, standards, and policies that protect consumers' health information.</p> <p>Providers want other providers participating in the HIO to safeguard information and share information that is accurate, complete, and relevant to the purpose for which it is to be used.</p>	<p>+ Perception of public trust is dependent on the establishment and maintenance of trust relationships with consumers and among participating providers.</p> <p>- Consumers' perception of lack of right to privacy is likely to lead to low trust levels and possible refusal to seek treatment, give providers accurate and complete information, or participate in HIO.</p>	<p>+ Offering the consumer the choice to opt out likely will encourage more consumers to participate and build confidence and trust in HIE.</p> <p>- Because there is likely to be less consumer participation and thus less volume of records than with no choice option, records are likely to be somewhat less complete and accurate than if no choice, resulting in less confidence and trust in HIE among providers.</p>	<p>+ This option provides consumers with maximum control over use and disclosure of their health information and, accordingly, is likely to result in highest consumer level of trust in HIE.</p> <p>- Due to possibility of least access to complete records, this option may result in least trust among providers.</p>	<p>+ Because this option allows more consumer choice and control over the electronic disclosure of their health information, there is a greater likelihood of consumer confidence and participation in HIE.</p> <p>- Because this option allows more consumer choice and control over the electronic disclosure of their health information, the provider may not have access to the consumer's complete record, so provider's confidence in HIE likely will decrease.</p>	<p>+ More likely to increase consumer confidence because no information is exchanged unless consumers opt in.</p> <p>- Because of potential for lower consumer participation and lower volume of records, provider confidence in HIE is likely to be somewhat lower than for no choice or opt out.</p>

Note: + = pro; - = con.

**Table J-5. Savings/Health Care Cost Avoidance**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Providers and consumers want less paperwork, improved communication, reduced duplicative tests, increased accuracy and effectiveness of treatment, and long-term savings.	<ul style="list-style-type: none"> <li>+ Minimizes duplicative tests</li> <li>+ Most savings due to simplicity of administering and likely high volume of records</li> <li>- If consumer avoids seeking health care due to limited rights to privacy concerns, the consumer's health status may deteriorate, leading to higher costs.</li> <li>- Likely costly to educate consumers, especially where sensitive information involved</li> </ul>	<ul style="list-style-type: none"> <li>+ Because the opt out consent option is the least complex of the consent options, it is likely to be the least expensive to implement.</li> <li>- Opt out consent option will likely result in less participation and, thus, less volume of records available for HIE, resulting in less potential in cost savings when compared to no choice.</li> <li>- Providers will need to invest in consumer education programs to inform consumers about the benefits of HIE and the consequences of their choice.</li> <li>- Because the default is that health records are available for HIE, this option is likely to result in the highest level of volume than other consent options, resulting in higher cost savings due to reductions in paper work and redundancy.</li> </ul>	<ul style="list-style-type: none"> <li>- Least cost savings may be available due to potential for least volume of records available, maximum complexity of consent option, and maximum need for staff and consumer education.</li> </ul>	<ul style="list-style-type: none"> <li>- More costly due to complexity and low volume of records available for exchange.</li> </ul>	NA

Note: + = pro; - = con.

**Table J-6. Risks/Threats to Right to Consumer Privacy**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Risks/threats to right to consumer privacy	+ None - No choice results in a maximum perceived threat to consumers' right to privacy.	NA	NA	NA	NA

Note: + = pro; - = con.

**Table J-7. Liability and Laws**

Specific Issue	No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Liability and laws	+ 10A NCAC 41A.0101 and NCGS §§ 130A-135 and -139 require physicians to report consumer's name and address to local health director, and there is safe harbor for doing so. - NCGS § 130A-143 provides that all information and records that identify a person with AIDS is "strictly confidential" and may not be released except with written consent, for purposes of public health, pursuant to subpoena or court order, or for statistical purposes if de-identified. - Accordingly, it would appear that consumer should consent for release of information to lab.	+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information. + Somewhat less volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice option, because providers can only be held accountable to know information in their possession. + Less complex consent option may decrease the risk of inappropriate release of information.	+ Because consumers must permit the electronic disclosure of any of their health information, the risk of legal liability for violation of state and federal release of information laws is perhaps the lowest of all the consent options. + Possibly the smallest volume of information in the EHR may lead to the least risk of malpractice liability, because providers can only be held accountable to know information in their possession. - The complexity of this consent option may increase the risk of inappropriate release of information.	+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information. + Somewhat less volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice option, because providers can only be held accountable to know information in their possession. - The complexity of this consent option may increase the risk of inappropriate release of information.	+ Less risk of liability for failure to comply with state and federal release of information laws because consumers can consent to or withhold consent for release of sensitive information. + Somewhat less volume of information in the EHR may lead to slightly less risk of malpractice liability than no choice or opt out options, because providers can only be held accountable to know information in their possession. + Less complex consent option may decrease the risk of inappropriate release of information.

Note: + = pro; - = con.

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX K: GUIDE TO THE DEVELOPMENT AND USE OF INTRASTATE CONSENT POLICY ALTERNATIVES ANALYSIS TEMPLATES**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## **Purpose: To Guide State Consent Policy Analysis**

This Guide is intended 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 health information in a health information exchange (HIE) system. Throughout this document, this concept is referred to as “consumer consent.” The guide describes how the North Carolina and California teams from the Intrastate and Interstate Consent Policy Options Collaborative developed, adapted and used templates to review and analyze consent alternatives in specific health care scenarios, such as e-prescribing, laboratory tests, emergency departments, mental health, and others. Your state Collaborative can use this guide as a framework within which to conduct your state’s analysis of consumer consent alternatives. Doing so will enable your state to compare its findings with those of other states that use the templates. The templates were designed to be flexible and may be modified to reflect your state’s specific areas of interest, stakeholder composition, time and resources, and desired outcomes.

## **How to Use the Documents and Templates:**

If used effectively, the templates can assist your state in pursuing a deliberative, objective analysis of the complex issues surrounding consumer consent. These documents also are useful in consensus building and in identifying and reconciling points of disagreement. There are three categories of templates: (1) research; (2) analysis; and (3) summary and recommendations. If the templates are used in that order, participants in the analysis will see a logical progression. The templates will assist in documenting your state’s collaborative process while demonstrating the variety and complexity of stakeholder interests surrounding consumer consent.

## **Step One: Research**

Initially, every state collaborative initiating an analysis of consumer consent alternatives must determine the breadth and depth of the study. Each state must decide which consent alternatives to analyze and through research must gain an appreciation of the stakeholder interests affected by the alternatives selected for review. To ensure that these decisions are made deliberately, the participating stakeholders should acknowledge and be well informed of the various perspectives and interests of consumers, providers, vendors, payers, and health information exchange organizations. Additionally, stakeholders must consider the applicable federal and state laws as well as various stakeholder practices regarding the use and disclosure of personal health information. For these reasons a literature review is suggested.

Two templates can assist in succinctly distributing pertinent facts and information summarized from available literature. The primary purpose of these templates is to share available knowledge with stakeholders so that they have a common understanding of the issues surrounding consumer consent.

**1a Summary of Pertinent Facts:** Use this template to create and provide a summary of key information from a single source. This is particularly helpful to stakeholders who are too busy to read all of the research compiled by the Collaborative.

**1b Executive Summary of Pertinent Facts:** Use this template to collect and disseminate a compilation of summaries of pertinent facts on a single topic. For example, this template can compile and compare all the summaries from a single research source on the topic of federal laws governing use and disclosure of personal health information.

Your state Collaborative can create a web portal where these templates may be posted and accessed by stakeholders.

## **Step Two: Analysis**

Once your state Collaborative has gathered and disseminated the summaries of its research findings, consider how to use the following templates and documents. You will need to select and define the stakeholder interest areas that will be evaluated for each consent alternative analyzed. These templates can guide and document stakeholder input on which issues are deemed key to your state's analysis. They are numbered in a logical sequence that can lead you through the decision making. The analysis step represents a major portion of the work involved in addressing consent in your state and there are several templates and documents from which to choose.

**2a Developing Consent Policy Stakeholder Issues for Analysis.** We recommend you use document 2a first to frame the scope of the analysis and identify the specific issues. This will form the left-hand column of the analysis documents you choose to utilize. You need to define the strategy of your approach to consent. Will you discuss consent alternatives in general or specific to identified health care scenarios? To what extent will you utilize the consent analyses of other states? Will you analyze the five alternatives to consent selected by the Intrastate and Interstate Consent Policy Options Collaborative, or identify or develop others? Will you build from the analyses of other states and use their findings to start your state discussion on consent? Or will you complete your own analysis covering the same topics? Answering these questions will form the foundation for how you choose what documents are used and/or adapted.

You want to have a broad spectrum of stakeholders involved in the process of selecting consent alternatives. As consent alternatives are identified, this document may be used to stimulate discussion and identify other potential consent alternatives. During these discussions, identify which consent alternatives are to be considered.

In addition to assisting your state Collaborative in selecting consent alternatives to analyze, the template can help your state determine which stakeholder issues or interest areas to evaluate. In making this determination, your state must weigh the scope of the consent analysis it would like to initiate against the time and resources that are available for the effort. Consumer consent is a very complex issue, and stakeholders have a broad range of legitimate interests that will be affected differently by each consent alternative. If your state has limited resources, you can use the document to narrow the scope of the analysis. For example, you can limit the number of consent alternatives considered, or you can look at consent in a limited number of health care scenarios, such as public health, HIV, or e-prescribing. Similarly, instead of analyzing the impact of each consent alternative on eight or ten stakeholder issues or interests in a given health care scenario, you can select a limited number of stakeholder issues or interests and prioritize them.

**2b Alternative Solution Analysis.** Use this template to guide and document the input from diverse stakeholders involved in the analysis of a single consent alternative. A majority of the stakeholder Collaborative discussion, time, and effort will be captured here. The template captures the pros and cons of the one alternative in a specific health care scenario. Try to avoid the tendency to jump to other consent alternatives in the discussion. Remind stakeholders that the other consent alternatives will be discussed separately. This completed template can be quite lengthy, depending on the size and diversity of your stakeholder Collaborative. You may want to capture all major perspectives shared, then go back and edit to remove redundancy and align comments.

*A few tips for using this template:* The template is intended to capture and document all predictable stakeholder polarities that will arise, such as consumer privacy interests vs.

provider access interests. The facilitator should encourage your state Collaborative participants to strive for objectivity and to complete the form by capturing all identified pros and cons for each consent alternative in relation to the identified stakeholder issues or interests. To avoid long debates over the meaning of terms, ensure that all definitions in the template are clear and understood by all stakeholders before starting the analysis. The information on this form will be used to provide input into the Comparative Summary Analysis template.

Revisit the strategy you identified in 2a when reviewing the following templates related to the comparative summary analysis. Which templates you choose will be based on your strategy. Templates 2c through 2fx, as well as 2h and 2i can be used for a more detailed, resource rich approach where the findings are presented to an oversight board or committee. Template 2g is an adapted version of 2c; it includes fewer stakeholder issues or interests but supports covering more health care scenarios. This can then be combined in summary templates 3a and 3b, and presented to an oversight board or committee. Although each template need not list the agreed-upon privacy and security principles, the principles should be reviewed from time to time to remind everyone of the inherent privacy and security risks of HIE.

**2c Comparative Summary Analysis (CSA)** specific to a health care scenario. Use this template to effectively combine all stakeholder input, including commentary regarding the positive, negative, or neutral impact of each of the consent alternatives on each stakeholder issue or interest for the identified health care scenario. Strive to eliminate redundant or similar statements. Use of this template can assist your state Collaborative in comparing the relative effect of each consent alternative on each stakeholder issue or interest for each health care scenario. As mentioned above, before using this template to document a comparative analysis, it is important to clarify terms and to reach stakeholder consensus about the meaning of the terms and assumptions used in the template. Standardizing the ranking terms is also critical; for example, some Collaborative members prefer to rank items using pros and cons, and others prefer using symbols such as +’s, -’s and •’s (which indicate a neutral position). Use this template in evaluating each consent alternative in a specific health care scenario. The primary purpose of this template is to ensure analytical process consistency. Use a separate template for each health care scenario and each consent alternative selected.

Choose one or more health care scenario most relevant to your state’s experience. At the top of the template is a space to include a description of the health care scenario, such as e-prescribing, and a list of limitations and assumptions pertaining to that scenario (e.g., the purpose of the HIE, etc.) Include in the top row of the template a description or definition of each of the consent alternatives (or you can use the definitions this Collaborative has identified). In the far left column of the template, describe each of the specific issues or interests to be evaluated as defined by your stakeholders.

If you complete document 2b, you can use those findings to populate 2c. If you skip 2b, you can take comments directly from your diverse stakeholder discussions for this template. Another option is to complete 2b for one general health care scenario, such as e-prescribing, and then generalize those comments as appropriate to related health care scenarios, such as laboratories and emergency departments. Your state will complete a Comparative Summary Analysis using either template 2c or 2g for each health care scenario chosen.

**2d Comparative Summary Analysis EXAMPLE.** This document is an example of the CSA. It illustrates where information is required and provides examples of definitions, assumptions, and some detailed pros, cons, and neutral statements of five consent alternatives by specific issue or interest.

**2e Summary CSA specific to a health care scenario.** This template is simply a portion of a CSA, which includes the top part of the form, the summary row, and the definitions. It is useful as a one-page handout to provide an overview to your board or committee.

**2f Health care scenario steps.** This template provides a way to cross check your analysis contained in the CSA. Instead of examining consent alternatives by specific issues, the template leads stakeholders through an analysis by steps in a health care scenario. This was developed to analyze how each consent alternative measures up to the original goal of HIE in the identified health care scenario; for example, how e-prescribing HIE will reduce adverse drug interactions (increased quality of care). Using this template requires identification of each step in the scenario. This template fits well with the Summary of Laws template (2h).

**2fx Emergency Department scenario steps EXAMPLE.** Template 2fx is an example of an Emergency Department scenario to test against “Increased Quality of Care.” Note that health care scenarios are not perfect and certain assumptions need to be made in order to move forward with the analysis.

**2g Comparative Summary Analysis Modified.** This template is a modification of CSA 2c. It has the same format but fewer specific issues or interests were identified based on state preference. Also note the state specific definitions of the alternatives. This format was used to facilitate analysis of multiple health care scenarios when resources of stakeholders and time were limited. Using this approach facilitated the state to further develop the analysis between health care scenarios, as captured in the summary templates 3a and 3b.

**2h Summary of Laws.** This template arranges the state’s applicable laws by steps in the scenario. Once steps in a scenario have been identified, they can be used for both templates 2f and 2h. Federal and state law is identified and summarized by each step in the scenario with the citation provided for reference. The obligations column identifies the legal obligation between the parties involved in the health information being exchanged in each specific step of the scenario. A completed Summary of Laws template is included in Appendix C of the Intrastate and Interstate Consent Policy Options final report.

**2i CSA Public Mental Health.** This template is another version of a CSA, but is specific to the health care scenario of public mental health. When the health care scenario involves sensitive information some aspects of the analysis different. For example, there are subtle word changes, such as from patient to client, and the order of the specific issues is changed. Many health care scenarios, such as e-prescribing, laboratories, and emergency departments, are very similar. But it is the dissimilar health care scenarios, specifically sensitive health care scenarios, that will define the ends of the bell curve which must be addressed before interoperable HIE can be achieved.

### **Step Three: Summary and Recommendations**

Once your state has completed its analysis of the consent alternatives in each health care scenario, use the following templates to compare analyses between health care scenarios and to make a recommendation.

**3a Summary of Pros and Cons.** Use this template to compile and report stakeholder input across all of the health care scenarios. The template can be used to summarize your state’s CSA findings by consent alternative, for each state specified issue. For example, you would combine all “Provider Business Impact” by consent alternative in all health care scenarios analyzed.

**3b Summary of Findings.** Use this template to compile and report stakeholder input across all of the health care scenarios. The template can be used to report an overall summary of your state’s CSA findings regarding the pros and cons identified. For example, you would combine all “Quality of Care” by consent alternative in all health care scenarios analyzed.

**3c Issue Recommendation.** If your state decides to formulate a recommendation to present to an oversight Advisory Board or Steering Committee, use this fairly simple and straightforward template. The template identifies the committee or group which is presenting the recommendation to the oversight body and provides space to describe the issue. The template also provides for inclusion of the recommended consent alternative, support for the finding, recommended implementation strategies and any dissenting opinions (summarized). Although it will be difficult to reach consensus, do strive for compromise. However, it is important to provide a process for stakeholders to put their dissenting opinions on the record, and any dissenting opinions should be submitted in writing.

**FORM 1A**  
**SUMMARY OF PERTINENT FACTS**

**INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS**  
**COLLABORATIVE**  
**SUMMARY OF PERTINENT FACTS**  
**Related to**  
**ONE SOURCE**

*(Limit to one page for each source, if possible)*

<b>Committee:</b>			
<b>Issue:</b>			
<b>Document Title:</b>			
<b>Web Link:</b>			
<b>Key Word(s) Searched</b>			
<b>Document Source:</b> (Organization/ Publisher, etc.)		<b>Author</b>	
		<b>Document Date</b>	
<b>Bullets of Pertinent Facts Relating to Issue:</b>			<b>Page Number</b>

**FORM 1B**  
**EXECUTIVE SUMMARY OF PERTINENT FACTS**



**FORM 2A  
DEVELOPING CONSENT POLICY STAKEHOLDER ISSUES FOR  
ANALYSIS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## DEVELOPING CONSENT POLICY STAKEHOLDER ISSUES FOR ANALYSIS

**Purpose** The purpose of this form is to identify criteria within specific areas that relate to the issue of your task group. This criteria will be used help formulate viable alternative solutions to the issue under consideration.

**Instructions** Identify specific laws, business processes, and solutions from other standards below that specifically pertain to a task group issue as it relates to HIE in your state.

This list should contain anything pertinent to the Task Group discussion of viable alternative solutions for the Task Group issue.

The criteria below are *suggested* areas. Add, delete, or modify as necessary.

### Task Group Issue—Enter Task Group Name Here

#### Laws

- State law changes
- State regulation changes
- Federal law/regulation changes
- Federal policy changes
- IT software solutions
- IT hardware solutions
- Inventory or tracking mechanism
- Publicity campaigns to change social drivers
- Training/education

#### Business Processes

- Business practice changes
- Tools and/or templates
- Contract language
- Certification standards increased resources
- Business missions or core values adoptions/recommendations
- Increased resources
- Business missions or core values adoptions/recommendations

## Solutions from Other Standards

- The Markle Foundation Connection to Health standards
- Health Information Portability and Accountability Act (HIPAA)  
<http://www.hhs.gov/ocr/hipaa/>
- The Privacy Act of 1974
- Organization of Economic Cooperation Development Privacy Guidelines  
[http://www.oecd.org/document/18/0,2340,en\\_2649\\_34255\\_1815186\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/18/0,2340,en_2649_34255_1815186_1_1_1_1,00.html)
- United Nation Guidelines Concerning Personalized Computer Files
- European Union Data Protection Directive 95-46/EC
- Canadian Standards Association Model Code
- U.S. FTC Statement of Fair Information Practices Principles
- U.S./EU Safe Harbor Privacy Principles
- Australian Privacy Act—National Privacy Principles
- Japan Personal Information Protection Act
- Asia-Pacific Economic Cooperation Privacy Framework
- American Health Information Community (AHIC)
- American Health Information Management Association (AHIMA) Position Statements  
<http://www.ahima.org/>
- Health Information Technology Security Panel (HITSP)  
[http://www.ansi.org/standards\\_activities/standards\\_boards\\_panels/hisb/hitsp.aspx?menuid=3](http://www.ansi.org/standards_activities/standards_boards_panels/hisb/hitsp.aspx?menuid=3)
- State Alliance for E-Health—Health Information Protection Task Force  
<http://www.nga.org/portal/site/nga/menuitem.1f41d49be2d3d33eacdcbbeb501010a0/?vgnnextoid=5066b5bd2b991110VgnVCM1000001a01010aRCRD>
- Health Information Security and Privacy Collaboration
- Certification Commission for Health Information Technology (CCHIT) Certification Standards <http://www.cchit.org/>
- National Institute of Standards and Technology (NIST) standards  
<http://www.nist.gov/>
- Information Security Organization (ISO) standards  
[http://www.iso.com/index.php?option=com\\_frontpage&Itemid=965](http://www.iso.com/index.php?option=com_frontpage&Itemid=965)
- Federal Information Processing Standards (FIPS) <http://www.itl.nist.gov/fipspubs/>
- State Administrative Manual (SAM) <http://sam.dgs.ca.gov/TOC/default.htm>
- State Information Management Manual (SIMM)  
<http://www.dof.ca.gov/OTROS/StatewideIT/SIMM/SIMM.asp>
- Other states standards

**Enforcement Alternatives**

- Penalties
- Sanctions
- Inability to Utilize System

**FORM 2B  
ALTERNATIVE SOLUTION ANALYSIS**

**INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS  
COLLABORATIVE**

# **Alternative Solution Analysis**

<b>COMMITTEE</b>				Date:
<b>ISSUE</b>				
<b>ALTERNATIVE</b>				
		<b>PROS</b>	<b>CONS</b>	
	Stakeholder Impact			
	Business Practice Impact			
	Consumer Impact			
	Cost			
	Economic Impact			
	Legal Liability			
	Federal/State Law Conflict			
	Technology Compatibility			
	Public Acceptance/ Confidence			
	Consistent with Other Standards			
	Risks/Threats			

**FORM 2C**  
**COMPARATIVE SUMMARY ANALYSIS (CSA)**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## COMPARATIVE SUMMARY ANALYSIS [HEALTH CARE SCENARIO]

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available because patient information will be in the system except for those patients choosing to opt out and the information patients choose to exclude.
  - *Opt In*—this choice will result in *less* information being available because patients will need to take an action to be included in the system.

**NOTE**

Consent: A patient's informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

**Form 2c—Table 1A. Patient Quality of Care**

**Quality of Care** based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Patient</b> wants effective treatment balanced with protection of their information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 1B. Provider Quality of Care**

**Quality of Care** based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants to deliver effective treatment in the most efficient and cost-effective way.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 2A. Patient Level of Trust**

**Level of Trust in HIE**—Influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Patient</b> wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 2B. Provider Level of Trust**

**Level of Trust in HIE**—Influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants other provider in HIE to safeguard information and provide accurate and complete information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 3A. Savings and Cost Avoidance**

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, savings in long term, better quality of care, quicker reimbursements, accessing payer info for claims & eligibility.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 3B. Investment**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient choice (ongoing). <ul style="list-style-type: none"> <li>• Cost of enforcement effort (design and implementation).</li> <li>• Secondary process for those patients not participating in exchange or for sensitive info.</li> <li>• Sustainability and success of HIE system affected by the percentage of participating patients and providers.</li> </ul>	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 4. Technology**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Compatibility, integration, and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 5. National Efforts**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Markle—Connecting for Health and the NCVHS—National Commission on Vital and Health Statistics address patient consent to access their information, not patient consent to control the input of their information into an HIE or for exchange.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 6. Liability and Laws**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 7. Principles**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Consistency or inconsistency with your State Principles.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]
1. Openness					
2. Health Information Quality					
3. Individual Participation					
4. Collection Limitation					
5. Use Limitation					
6. Purpose Limitation					
7. Security Safeguards					
8. Accountability					

**Form 2c—Table 8. Summary**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**FORM 2D  
COMPARATIVE SUMMARY ANALYSIS EXAMPLE**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **INTRASTATE COMPARATIVE SUMMARY ANALYSIS EXAMPLE [HEALTH CARE SCENARIO]**

**Date**

### **COMMITTEE**

[Insert the name of the committee or working body that is completing the analysis.]

### **ISSUE**

[Put your issue statement here. For example, Patient consent to exchange laboratory information through a Health Information Exchange, for treatment. This issue analysis will examine how the consent options will affect clinician and laboratory business processes, public perception, and legal liabilities of all parties involved.]

### **BACKGROUND**

[Put your background statement here. It can be whatever length is appropriate to support stakeholder collaborative review and analysis. For example, consent is not currently required for sharing some prescription and laboratory information among healthcare providers/payers under HIPAA and California law.]

### **ASSUMPTIONS**

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- Treating physician and various providers (labs, pharmacies, other physicians) can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing clinical information will be used for treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less

- data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
- *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

## NOTES

- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.
- Consent: A patient’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system. [CMS ePrescribing Medicare regulations]

**Please note: A State using this template can choose to adapt Specific Issues to reflect your State landscape. Italic text in the five alternative columns has been left in as an example and place holder for your own State identified text. Likewise, you can identify your own explanations of 1. Quality of Care and 2. Level of Trust in HIE.**

**Form 2d—Table 1A. Patient—Quality of Care**

**Specific Issue:** Patient wants effective treatment balanced with protection of their information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care. Patient receives effective, appropriate treatment, avoids unnecessary risk. Expediting referrals increases quality of care. Scarce resources are available when needed.	+ More quality of care (portion IN the HIE)	– Least quality of care (portion not IN the HIE); patient receives unnecessary treatment that over-utilizes scarce resources. Unsafe situation if cath lab is unavailable to someone who really needs that treatment.	<ul style="list-style-type: none"> <li>• Some quality of care (portion not IN the HIE)</li> <li>+ More patient choice specificity</li> </ul>	<ul style="list-style-type: none"> <li>– Less quality of care (portion not IN the HIE)</li> <li>– Less patient choice (IN or OUT)</li> </ul>
+ Has the most patient participation	<ul style="list-style-type: none"> <li>• Has the potential for more patient participation</li> <li>• For patients who do not opt out</li> </ul>	<ul style="list-style-type: none"> <li>– Has the potential for the least patient participation.</li> <li>• For patients who do not opt in</li> <li>• For patients who choose to restrict significant information</li> </ul>	<ul style="list-style-type: none"> <li>• Has the potential for some patient participation</li> <li>• For patients who do not opt out</li> <li>• For patients who choose to restrict significant information</li> </ul>	<ul style="list-style-type: none"> <li>• Has the potential for lesser patient participation</li> <li>• For patients who do not opt in</li> </ul>
NA	NA	NA	NA	NA
– No patient choice	<ul style="list-style-type: none"> <li>• Some patient choice (OUT or IN)</li> </ul>	+ Most patient choice and specificity in choice	NA	NA

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Form 2d—Table 1B. Provider—Quality of Care**

**Specific Issue:** Provider wants to deliver effective treatment in the most efficient and cost-effective way.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care (portion IN)	– Least quality of care (portion not IN)	• Some quality of care (portion IN)	– Less quality of care (portion not IN)
+ Most cost-effective	• Somewhat cost-effective	– Least cost-effective	– Least cost-effective	– Less cost-effective
– Most safeguards required to protect patient information due to volume information	• Some safeguards required to protect patient information due to volume information	+ Least safeguards required to protect patient information due to volume information	+ Fewest safeguards required to protect patient information due to volume information	• Less safeguards required to protect patient information due to lesser volume
+ Fewest safeguards required to protect patient information due to lack of complexity	• Some safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	• Some safeguards required to protect patient information due to lack of complexity

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Form 2d—Table 2A. Patient—Level of Trust: HIE**

**Specific Issue:** Patient wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.<sup>1</sup> (Trust the HIE and health care providers regarding protection of their information.)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least need for education due to complexity	+ Lesser need for education due to complexity	– Most need for education due to complexity	– Most need for education due to complexity	• More need for education due to complexity and availability
– No patient choice, low trust	• Some degree of patient choice/trust	+ Most patient choice/trust	+ Most patient choice/trust	+ More patient choice/trust
+ Least potential errors due to volume of information	• Some potential errors due to volume of information	– Most potential errors due to least volume of information and complexity	– Most potential errors due to less volume of information and complexity	– More potential errors due to volume of information
– Most need to protect patient information due to volume	• Less need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Some need to protect patient information due to volume	• Some need to protect patient information due to volume
+ Least need to protect patient information due to complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	• Lesser need to protect patient information due to complexity

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and by whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information. [Errors amplified as carried forward through HIE. Increased professional responsibility.] This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug, and alcohol, minors, sexually transmitted diseases, and family planning.

<sup>1</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

**Form 2d—Table 2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.<sup>2</sup> (Trust between providers)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least potential errors due to volume	+ Less potential errors somewhat due to volume	– Most potential errors due to volume and complexity	– Most potential errors due to complexity and somewhat due to volume	– More potential errors due to volume
– Most need to protect patient information due to volume	– More need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Medium need to protect patient information due to volume	+ Less need to protect patient information due to volume
+ Least need to protect patient information due to complexity	+ Less need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	+ Less need to protect patient information due to complexity
+ Least need for staff and patient education due to complexity	• Some need for staff and patient education	– Most need for staff and patient education	– Most need for staff and patient education	– More need for staff and patient education

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information<sup>3</sup> [Errors amplified as carried forward through HIE. Increased professional responsibility.]

<sup>2</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

<sup>3</sup> This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.

**Form 2d—Table 3A. Savings and Cost Avoidance**

**Specific Issue:** Savings and cost avoidance—provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests, increased accuracy and effectiveness, long-term savings, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.

Risk analysis—could affect a small number of cases, but if the adverse outcome is death, etc., it could have a costly outcome.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most savings from business processes impacts due to volume and complexity. Costs are appropriate and minimal.	+ More savings from business processes impact due to volume and complexity	– Over-utilizes scarce and expensive resources of helicopter and cardiac cath lab	– Least savings from business processes impact due to volume and complexity	• Less savings from business processes impact due to volume and complexity
+ Most savings from access to complete information, payments, increased accuracy and quality of care	+ More savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Less savings from access to complete information, payments, increased accuracy and quality of care
– Most cost to educate due to volume	– More cost to educate due to volume	+ Least cost to educate due to volume	+ Least cost to educate due to volume	• Some cost to educate due to volume
+ Least cost to educate due to complexity	• Some cost to educate due to complexity	– Most cost to educate due to complexity	– Most cost to educate due to complexity	– More cost to educate due to complexity and outreach
NA	NA	– Least savings from business processes impact due to volume and complexity	NA	NA

**Form 2d—Table 3B. Investment**

**Specific Issue:** Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient consent choices (ongoing): (1) cost of enforcement effort (design and implementation); (2) second process for those patients not participating in exchange or for sensitive information; (3) sustainability and success of HIE system affected by the percentage of participating patients and providers.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least cost of process improvement	• Lesser cost of process improvement	– Most cost of process improvement	– Most cost of process improvement	• More cost of process improvement
– Most cost to address sensitive information—requires secondary process	– Most cost to address sensitive information—requires secondary process	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	– Most cost to address sensitive information—requires secondary process
+ Most sustainable	+ More sustainable	– Least sustainable	– Less sustainable	• Somewhat sustainable

**Form 2d—Table 4. Technology**

**Specific Issue:** Technology—compatibility, integration and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least complex	• Somewhat complex	– Most complex	– Most complex	– More complex
+ Least challenge to small practice providers	• Some challenge to small practice providers	– Most challenge to small practice providers	– Most challenge to small practice providers	• More challenge to small practice providers

**Form 2d—Table 5. National Efforts**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

**Form 2d—Table 6. Liability and Laws**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Some legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.

**Form 2d—Table 7. CalPSAB Principles**

**Specific Issue:** Consistency or inconsistency with the CalPSAB principles: (1) openness, (2) health information quality, (3) individual participation, (4) collection limitation, (5) use limitation, (6) purpose limitation, (7) security safeguards—NA, and (8) accountability—NA.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Consistent with health information quality	+ Consistent with health information quality	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>
- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with health information quality	- Inconsistent with health information quality	- Inconsistent with health information quality

**Form 2d—Table 8. Summary**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care	- Least quality of care	• Some quality of care	- Less quality of care
+ Least costly/most sustainable	+ Less costly/most sustainable	- Most costly/most sustainable	- Most costly/most sustainable	• More costly/most sustainable
• Some legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk
- Inconsistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles
- Least patient choice	• Some patient choice	+ Most patient choice	+ Most patient choice	+ More patient choice

**FORM 2E**  
**SUMMARY CSA SPECIFIC TO A HEALTH CARE SCENARIO**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## [HEALTH CARE SCENARIO] SUMMARY

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

### NOTES

- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

- **Consent:** A patient's informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

**Form 2e—Table 1. Summary**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Put the summary row of the complete Comparative Summary Analysis in this row.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2e—Table 2. Definitions of Alternatives**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Patients 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.	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.	Patients’ prescription records are <b>not</b> automatically placed into the HIE system and exchange is <b>not</b> 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.	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 information be removed from the electronic exchange.	Patients 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.

**FORM 2F**  
**HEALTH CARE SCENARIO STEPS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## [HEALTH CARE SCENARIO] SCENARIO STEPS

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

**Form 2f—Table 1. Scenario Steps**

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**FORM 2FX  
EMERGENCY DEPARTMENT SCENARIO STEPS EXAMPLE**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **EMERGENCY DEPARTMENT SCENARIO STEPS INCREASED QUALITY OF CARE**

### **Date**

#### **COMMITTEE**

PRIVACY—Consent for Sharing Clinical Information in an Emergency Department Setting

#### **ISSUE**

Patient consent to have their clinical information shared through an electronic Health Information Exchange (HIE) for treatment. This issue analysis will examine how the consent alternatives affect provider business processes, public perception, and legal liabilities of all parties involved. Scenario is to test the consent alternatives relative to quality of care.

#### **BACKGROUND**

Currently consent is not required for sharing clinical information among healthcare providers/payers under HIPAA and California law.

#### **ASSUMPTIONS**

- Treating physician and various providers (labs, pharmacies, other physicians) can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing clinical information will be used for treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those patients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.

- *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
- *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
- *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
- *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

### **Story or Scenario**

Calvin P. Sab, 65 years of age, was in an auto accident. Ambulance Emergency Medical Technician (EMT) conducts partial medical screening. Patient is extremely short of breath, incoherent, and having chest pains. Available demographics, vitals, etc. taken, low blood pressure is identified. Calvin is transported to the nearest hospital Emergency Department (ED). Calvin's last annual physical was February 2007. Three weeks ago his physician, Dr. P, referred Calvin to the following specialists:

- + Dr. C, cardiologist for chest pains, EKG ordered, anti-hypertension medication prescribed. Cardiac catheterization last year, stents placed for anterior wall MI.
- + Dr. D, endocrinologist for diabetes, medication prescribed
- + Dr. R, rheumatologist for rheumatoid arthritis, medication prescribed

**ALLERGY ALERT:** Severe anaphylactic reaction to Vancomycin. Alert information accessible through the HIE.

**Form 2fx—Table 1. Emergency Department Scenario Steps—Example**

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Patient presents at scene of accident	Calvin has no choice, Calvin’s health information is accessible through HIE.	Calvin chose to opt out, his health information is NOT accessible through HIE.	Calvin chose to opt in with restrictions, his health information is accessible through HIE, except for rheumatoid arthritis information.	Calvin chose to opt out except for general medical information. Much of his specific health information is NOT accessible through HIE.	Calvin chose to opt in, Calvin’s health information is NOT accessible through HIE.
Transported to emergency department	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.
Transported to emergency department	His records are available through HIE.	No additional information is available.	His records are available through HIE minus Rheumatoid Arthritis information	Only his general information is available through HIE.	His records are available through HIE.
Admitted to emergency department	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).
Admitted to emergency department	His records are available through HIE.	His records are not available through HIE.	His records are available through HIE, minus the rheumatoid arthritis information.	His general medical information is available but not specialist information through HIE.	His records are available through HIE.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Admitted to emergency department	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.
Emergency department physician	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.
Emergency department physician	All Calvin’s information is available through HIE.	No information on Calvin is available through HIE.	Calvin’s information is available through HIE, minus the rheumatoid arthritis information.	Calvin’s general medical information only is available through HIE.	All Calvin’s information is available through HIE.
Emergency department physician	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Emergency department physician	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.
Laboratory	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).
Patient status	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.
Lab results	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Diagnoses	Negative drug interaction with rheumatoid arthritis medication and angina based on unchanged EKG from previous cardiologist’s study. Heart issue ruled out.	Pneumonia with sepsis confirmed. Heart issue—evidence of prior STEMI (ST segment elevation myocardial infarction). Previous EKG information not available.	Pneumonia with sepsis confirmed—rheumatoid arthritis medication information not available. Heart issue ruled out, previous EKG information available.	Pneumonia with sepsis confirmed. Heart issue—evidence of prior STEMI (ST segment elevation myocardial infarction). Previous EKG information not available.	Negative drug interaction with rheumatoid arthritis medication and angina based on unchanged EKG from previous cardiologist’s study. Heart issue ruled out.
Treatment prescribed	Cease use of rheumatoid arthritis medication and prescribed alternate anti-inflammatory administered through IV to flush patient’s system. Monitor.	—	Antibiotic therapy ordered with alternative therapy given due to Vancomycin allergy. Suggest transfer Calvin to cardiac catheterization laboratory for further workup on heart issue.	Vancomycin antibiotic therapy ordered. Suggest transfer Calvin to cardiac catheterization laboratory for further workup on heart issue.	Antibiotic therapy ordered with alternative therapy given due to Vancomycin allergy.
Patient response to treatment	Patient is stabilized. Blood pressure normal. Responding well IV with alternate anti-inflammatory medication. Calvin is transferred to the ICU for continuing care and monitoring of new anti-inflammatory medication.	—	Calvin’s blood pressure normal, heart attack still possible diagnosis, no hives. Patient transferred to cardiac catheterization lab for further workup.	Calvin develops hives and increasing ventilator settings are required to maintain oxygenation and ventilation. Patient is immediately transferred via helicopter to cardiac catheterization lab for further workup and alternative ventilation therapy.	Benadryl IV is prescribed and given, but there is still difficulty breathing. Increasing ventilator settings are required to maintain oxygenation and ventilation.

Scenario Step	No Consent (Patient Info IN)	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Outcome	Treatment plan is effective and appropriate for Calvin. Quality of care is high. Costs are appropriate and minimal. Chest pain is accurately diagnosed as Angina based on comparison to the cardiologist’s study results in HIE.	—	Rheumatoid arthritis medication drug interaction identified in general health information in HIE, so hives and decreased breathing drug reaction avoided. But, Calvin receives unnecessary treatment that over utilizes scarce cardiac catheterization lab resources. Increased costs to system. Unsafe situation if catheterization lab is unavailable to someone who really needs that treatment.	Treatment plan is not effective and harmful to Calvin. Quality of care is lower without HIE. Dangerous drug reaction to Vancomycin occurs. Helicopter and cardiac catheterization lab utilization increase costs and makes those resources unavailable to patient actually in need.	Treatment plan only partially effective. Although heart attack is ruled out, the drug interaction involving the rheumatoid arthritis medication with another recent medication prescribed was not identified. Calvin remained in the emergency department, more tests ordered to determine the cause of breathing problem. Calvin referred to ICU to be stabilized for the negative drug interaction. Increased costs.

**FORM 2G**  
**COMPARATIVE SUMMARY ANALYSIS MODIFIED**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **COMPARATIVE SUMMARY ANALYSIS (MODIFIED VERSION)**

**Date**

### **COMMITTEE**

[Insert the name of the committee or working body that is completing the analysis.]

### **SCENARIO ONE**

[Insert scenario here.]

### **ASSUMPTIONS**

[Insert assumptions here.]

### **BACKGROUND**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Form 2g—Table 1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Definitions	<p><b>Auto In.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission and regardless of consumer preferences. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization.</p>	<p><b>Auto In with Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i></p>	<p><b>Auto Out with Granular Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.</p>	<p><b>Auto In with Granular Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed; and/or (iii) what specific health information may be placed in their EHR.</p>	<p><b>Auto Out with Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i></p>

**Form 2g—Table 2. Quality of Care**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 3. Business Practice Impact**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 4. Public Confidence—Trust in HIE**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 5. Health Care Cost Avoidance**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 6. Liability and Laws**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**FORM 2H  
SUMMARY OF LAWS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## SUMMARY OF LAWS [HEALTH SCENARIO]—APPLICABLE LAWS

**Form 2h—Table 1. Health Scenario**

Step in the Case Scenario	Area of Concern	Applicable Law Citation	Obligations
—	—	—	—
—	—	—	—

**FORM 2I**  
**CSA PUBLIC MENTAL HEALTH**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## COMPARATIVE ANALYSIS PUBLIC MENTAL HEALTH SCENARIO

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

## NOTES

- (1) Preferred Terms—clients/consumers rather than patient. (2) Client Philosophy—client prefers to manage and control his/her mental health information and may not wish to have the information shared.
- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.
- **Consent:** A client’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

[Note—Since this format was used for a public mental health treatment situation the order of the issues is different. Laboratories, e-prescribing, and emergency departments treatment situations were similar, but mental health subject matter experts put the issues into a different priority.]

**Form 2i—Table 1. Client—Public Acceptance/Social Drivers**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Client—public acceptance/ social drivers	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Client—public acceptance/ social drivers	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 2. Principles**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Principles	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Principles	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 3. Quality of Care**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
<b>Provider</b> wants to deliver effective treatment in the most efficient way.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Provider</b> wants to deliver effective treatment in the most efficient way.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]
<b>Client</b> wants effective treatment balanced with protection of their information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Client</b> wants effective treatment balanced with protection of their information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 4. Level of Trust in HIE**

Influenced by Client Choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard client information, ability to provide extra protections of sensitive information [errors amplified as carried forward through HIE, increased professional responsibility].

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants other Provider in HIE to safeguard information and provide accurate and complete information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Provider</b> wants other Provider in HIE to safeguard information and provide accurate and complete information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]
<b>Client</b> wants to be informed and know that the Provider and HIE will provide accurate information for treatment and will safeguard information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Client</b> wants to be informed and know that the Provider and HIE will provide accurate information for treatment and will safeguard information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 5a. Savings and Cost Avoidance**

Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, savings in long term, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Savings and cost avoidance	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Savings and cost avoidance	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 5b. Investment**

Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing client choice (ongoing).

- Cost of enforcement effort (design and implementation)
- Secondary process for those clients not participating in exchange or for sensitive information
- Sustainability and success of HIE system affected by the percentage of participating clients and providers.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Investment	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Investment	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 6. Technology**

Compatibility, integration, and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Technology	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Technology	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 7. National Efforts**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
National efforts	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
National efforts	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 8. Political Viability**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Political viability	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Political viability	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 9. Liability and Laws**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Liability and laws	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Liability and laws	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**FORM 3A**  
**SUMMARY OF PROS AND CONS**

**Form 3a—Table 1. Quality of Care**

Quality of Care	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p><b>GOAL:</b> High quality of health care resulting from timely access to a high volume of complete and accurate EHRs, and high level of consumers involvement in the management of their own health care</p> <p><b>FACTORS:</b></p> <ul style="list-style-type: none"> <li>• Amount of reliable information available to providers through HIE</li> <li>• Consumer participation in HIE</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 2. Provider Business Impact**

Provider Business Impact	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p><b>GOAL:</b> A consent policy that:</p> <ul style="list-style-type: none"> <li>• is easy and cost effective to implement and administer</li> <li>• is inexpensive to train staff and consumers</li> <li>• ensures cost savings from HIE</li> <li>• ensures consumer participation</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 3. Confidence in HIE**

<b>Confidence in HIE</b>	<b>No Choice</b>	<b>Opt Out</b>	<b>Opt In with Restrictions</b>	<b>Opt Out with Exceptions</b>	<b>Opt In</b>
<p><b>GOAL:</b> A consent policy that:</p> <ul style="list-style-type: none"> <li>instills consumer confidence and trust in HIE</li> <li>instills provider confidence and willingness to participate in HIE</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 4. Liability and Laws**

<b>Liability and Laws</b>	<b>No Choice</b>	<b>Opt Out</b>	<b>Opt In with Restrictions</b>	<b>Opt Out with Exceptions</b>	<b>Opt In</b>
<p>How will current federal and state laws about release of information and consent (and liability for breaches of those laws) likely affect the risk/advisability of each consent option?</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**FORM 3B  
SUMMARY OF FINDINGS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## SUMMARY OF FINDINGS

### Date

#### COMMITTEE

[Insert the name of the committee or working body.]

#### FACTORS

[Put your factors here.]

#### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

#### CONSENT OPTIONS

**NO CHOICE: Auto In.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission and regardless of consumer preferences. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization.

**OPT OUT: Auto In with Choice.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization *unless and until the consumer chooses to opt out.*

**OPT OUT WITH EXCEPTIONS: Auto In with Granular Choice.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization *unless and until the consumer chooses to opt out.* In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed, and/or (iii) what specific health information may be placed in their EHR.

**OPT IN: Auto Out with Choice.** Consumer's health information is **not** automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization *unless and until the consumer opts in.*

**OPT IN WITH RESTRICTIONS: Auto Out with Granular Choice.** Consumer’s health information is **not** automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization *unless and until the consumer opts in*. In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.

**Form 3b—Table 1. Quality of Care**

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 3b—Table 2. Provider Business Impact**

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Design and implementation: [Insert text here.]				
Provider business process: [Insert text here.]				
Patient and provider education: [Insert text here.]				

**Form 3b—Table 3. Liability and Laws**

Where the law requires advance consumer consent to exchange health information through HIE, consent is not a policy option.

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Release of info: [Insert text here.]				
Malpractice liability: [Insert text here.]				

**FORM 3C  
ISSUE RECOMMENDATION**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## ISSUE RECOMMENDATION

Date

<b>COMMITTEE:</b>		<b>DATE:</b>	
<b>ISSUE:</b>			
<b>INSTRUCTIONS:</b>	Identify the recommended alternative, supporting information for selecting the alternative and the recommendation for how the alternative would be implemented.		
<b>RECOMMENDATION:</b>	Alternative #:		
<b>SUPPORT FOR FINDING:</b>			
<b>RECOMMENDED IMPLEMENTATION STRATEGIES:</b>			
<b>DISSENTING OPINION:</b>			

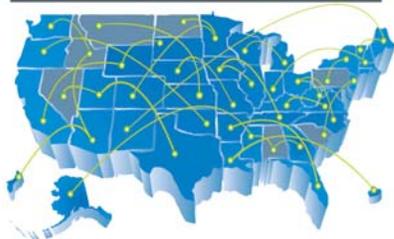
Created by CALIFORNIA PRIVACY AND SECURITY ADVISORY BOARD

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## Appendix L: Interstate Guidebook

Health Information Security & Privacy

**COLLABORATION**



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## Purpose

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This guidebook provides directions for states interested in researching state-driven legal mechanisms to resolve barriers to the interstate electronic exchange of health information and have conflicting laws and requirements governing patient consent.<sup>1</sup> This guidebook will also assist states in determining how each mechanism may (1) serve as a model for addressing a major barrier to the electronic exchange of protected health information (PHI), or (2) clarify which states' laws take precedence when PHI disclosures are requested between states with conflicting laws.

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## Background

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The Intrastate and Interstate Consent Policy Options Collaborative (the Collaborative) explored the viability of four legal mechanisms that states could use to resolve barriers to interstate electronic health information exchange. The four specific legal mechanisms reviewed included:

**Uniform state law**—A uniform state law is a legislative proposal approved by the National Conference of Commissioners of Uniform State Law (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**—A 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 they may adopt only a portion of the model act.

**Choice of law**—A choice of law provision is a provision that states could adopt to specify which state's law governs consent when PHI is requested to be exchanged between states with conflicting laws.

**Interstate compact**—An interstate compact is a voluntary agreement between two or more states which is designed to meet common problems of the parties concerned. Compacts that usurp federal power receive consent of the U.S. Congress as specified in Article I, Section 10 of the Constitution.

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<sup>1</sup> As used in this guide, "consent" means the patient's signed approval for the use or disclosure of PHI, which may also be referred to as an "authorization" or "permission" under HIPAA or other applicable federal or state laws.

Compacts usually address issues such as conservation, boundary problems, education, port control, flood control, water rights, and penal matters. An interstate compact addressing consent to the interstate exchange of PHI would supersede conflicting laws between states that join the compact.

The Collaborative researched each of these approaches to assess their relative abilities to streamline electronic health information exchange among the states. Through the use of this guidebook, states are provided with a systematic process for choosing a mechanism that may best align their consent requirements with those of other states that have conflicting privacy laws.

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## Template Development

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To assist states in conducting their research, the Collaborative developed Interstate Analysis Templates (Appendix L-1). 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 for pursuing a specific legal mechanism.

Several questions may arise regarding how to complete the templates, and this guidebook will provide a suggested approach, with interpretive guidance of the evaluation terms used for each reviewing state's consideration.

As mentioned previously, for the purpose of consistency each evaluation template uses the same review criteria. A specific definition of each criteria 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 some guidance, the following interpretations represent common points of consideration of each review criteria when conducting the analysis and review.

### **1. *Process for Developing the Option***

For each of the four proposed mechanisms, identify the implementation processes your state must complete. The processes may help identify the pros and cons of using a proposed mechanism and may well 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 various stakeholder communities in different ways. The intent is to identify affected stakeholders and the impact that 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 your state. Identify the relative merits of each mechanism in resolving these liability concerns.

#### **7. *Ramifications of Acceptance/Rejection***

Based upon the anticipated impact within your 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, there is wide license 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 in order 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 PHI. Based on your state's laws and regulations, describe the applicable infrastructure for the proposed mechanism and the rules for state participation.

- Are there any specific enablers or quirks in your state's legal or regulatory scheme that might affect the development and implementation of the mechanism?
- Assuming that a particular mechanism is enacted by your state, evaluate any foreseeable barriers to administering and enforcing each proposed mechanism.

**10. Process for Withdrawal**

Assuming that 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 catchall 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.

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**Recommended Approach**


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Based upon the experience of the Intrastate and Interstate Consent Policy Options Collaborative, the following approach is recommended to accomplish the review of legal mechanisms. **Exhibit A** presents a general overview of this approach.

1. While your state may have a steering or governing committee, it's equally important to establish a legal review work group to conduct the research and analysis. This work group should be comprised of members representing as many stakeholders of the health care delivery system as possible, including both the public and private sectors. While attorneys represent a key component of this work group, you should also include non-attorneys for stakeholder group representation. In addition, the work group should include a project coordinator to assign and track progress.
2. Reach a consensus on the legal mechanisms the state will review. The Intrastate and Interstate Consent Policy Options Collaborative identified four legal mechanisms; however, your state may identify additional legal mechanisms to evaluate. The nature of the templates is such that the number of alternatives is irrelevant as long as the review criteria used for the evaluation remains consistent.

3. Develop a research agenda in consultation with the steering or governing committee and the legal review work group. Research is essential to an effective evaluation process.

**Tip**

Search out those persons with firsthand knowledge of the research subject. For example, each state has commissioners who belong to the Uniform Law Commission. An interview with one of these commissioners can provide valuable information for the Uniform Law or Model Act mechanisms.

4. Review the “definitions” and “assumptions” sections to agree on a consistent approach to the analyses.
5. Come to an agreement on the expectations involving the review criteria.
6. The legal review work group, in consultation with a steering committee when appropriate, should determine how the analysis process should be undertaken.
  - Should the review be assigned to a sub-group focused on each mechanism? If so, it is recommended that at least one representative from each stakeholder community participate in the evaluation of each mechanism. To ensure an unbiased review, it is recommended that no single representative participate in more than two review groups.

**Tip**

Allow the initial reviews to be conducted by a sub-group of the entire legal work group. This will allow the analysis of multiple mechanisms to be conducted in parallel, creating a more efficient evaluation process.

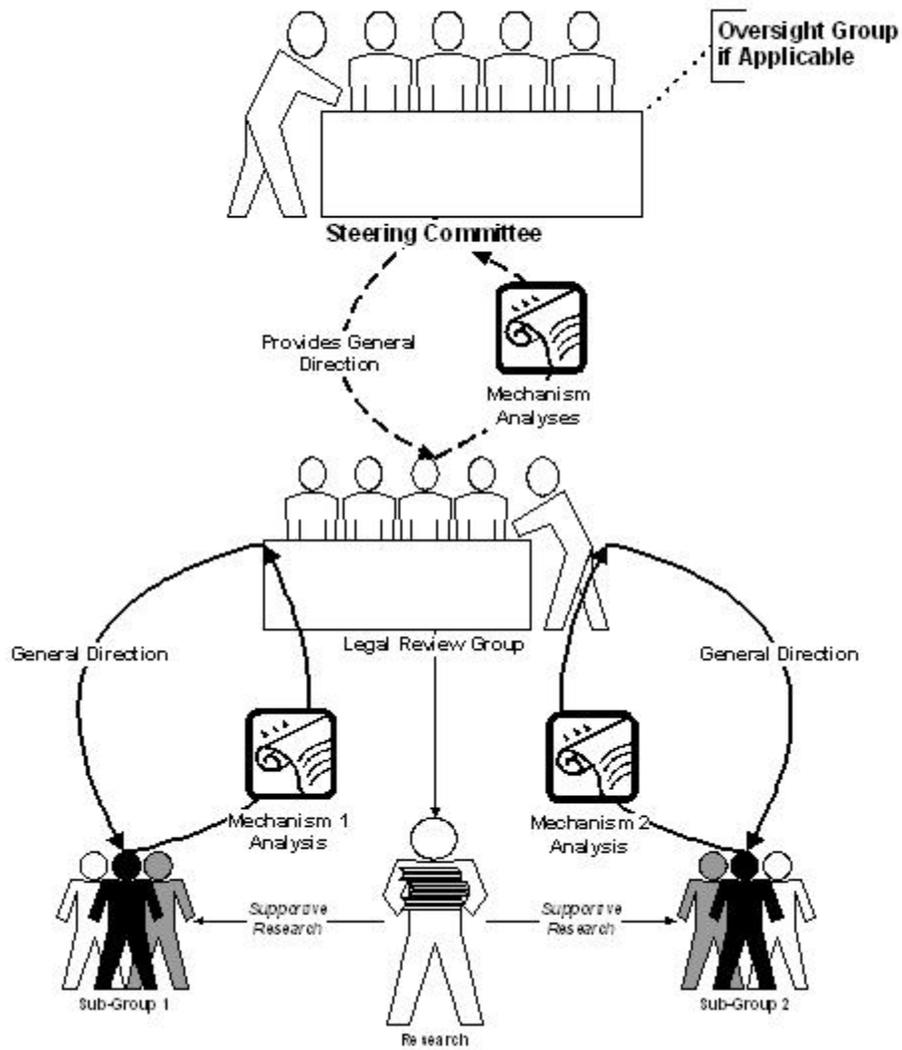
7. Each legal mechanism should be analyzed against the review criteria such that the pros and cons of the mechanism as well as the implementation considerations are identified and well documented for the comparative summary analysis.
8. If developed by a sub-group, submit the reviews to the entire work group for input, questions, comment, as well as guidance in the preparation of the conclusion of each of the selected mechanisms.

**Tip**

Prior to submitting draft populated templates to the entire legal working group for review, reconvene the subgroup representatives to fully vet the populated templates and make any necessary revisions.

9. Compile all the comments collected from the analysis of each mechanism onto a single template to eliminate redundancies and leave a unique set of considerations for each legal mechanism.
10. The reviews should then be presented to the steering committee or other oversight group for approval, if applicable.

**Exhibit A. Overview of Interstate Analysis Approach**



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## Success

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By following these steps, each state conducting the analysis will:

- Develop a clear understanding of the legal options and how they affect the state.
- Generate consensus on the best solution based on the analysis being conducted by a broad stakeholder base.
- Understand the legislative challenges associated with implementing the legal mechanisms.
- Create collaboration with neighboring states interested in similar exchange principles.
- Establish a replicable process that can be used to conduct similar analysis of the requirements for intrastate exchange between state agencies and private exchange initiatives.

## **Appendix L-1: Interstate Analysis Templates**

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## INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

### UNIFORM LAW ANALYSIS [ENTER STATE NAME]

## Introduction

One focus of the Intrastate and Interstate Consent Policy Options Collaborative is to explore the viability of four options that states could enact to resolve barriers to the exchange, including electronic, of protected health information (PHI) among states that have conflicting state laws governing consent to use or disclose PHI. These barriers can be summarized as the civil or criminal liability that may accrue to health information exchange (HIE) organizations or health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether a “uniform law” could eliminate these barriers. A uniform law would offer states the option to enact the same law governing consent issues, which would supersede any conflicting laws between adopting states.

“A uniform state law is a statute that has been promulgated by the Uniform Law Commission [ULC]. Although other organizations may adopt the term ‘uniform’ when describing their own acts, generally, when the term ‘uniform’ is used, it is highly likely that it is a law that has been drafted and approved by the ULC. . . . A uniform act is one in which uniformity of the provisions of the act among the various jurisdictions is a principal and compelling objective.”<sup>2</sup>

## Definitions/Assumptions

To ensure consistency in the analysis of the four options, the collaborative has adopted a uniform set of definitions and assumptions.

### Definitions:

- Authentication—means the method or methods to verify the identity of a person or entity authorized to access PHI.

<sup>2</sup> Frequently Asked Questions about NCCUSL, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>

- Authorization—means the level of access an individual or entity has to PHI and includes a management component—an individual or individuals must be designated to authorize access and manage access once access is approved.
- Consent—means the patient’s signed approval for the use or disclosure of PHI, which may also be referred to as an “authorization” or “permission” under HIPAA or other state laws.
- Health—is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.<sup>3</sup>
- Health care—is the prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical, nursing, and allied health professions.<sup>4</sup>
- Health information exchange (HIE)—the electronic movement of health-related information among organizations according to nationally recognized standards.
- Requesting state—the state that is requesting medical information.
- Responding state—the state that has received the request for medical information and is responding.
- Protected health information (PHI)—is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to (1) the past, present, or future physical or mental health or condition of an individual; (2) provision of health care to an individual; or (3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

**Assumptions: The purpose of these assumptions is to lay the framework for the analysis effort.**

- For purposes of this initiative, HIE represents the processes involved in the exchange of consent and is not intended to represent a specific entity.
- The record holder of the responding state may release and have access to the patient’s record in conformance with federal and state consent laws for the release of PHI.
- The **responding state** and the **requesting state** will have an agreement that addresses:
  - The exchange of PHI regarding persons authorized to access PHI
  - The authentication of users
- The **responding state** has more stringent consent laws for the release of PHI than the patient’s **requesting state**. (Assuming the reverse would not be relevant to this analysis in that the patient’s PHI would not be available for exchange unless the patient had already executed the required—more expansive—consent.)

<sup>3</sup> World Health Organization, <http://www.who.int/about/definition/en/index.html>

<sup>4</sup> Wikipedia definition, [http://en.wikipedia.org/wiki/Health\\_care](http://en.wikipedia.org/wiki/Health_care)

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## **Process for Developing the Option**

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### **Discussion**

**Pros**

**Cons**

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## **Length of Time Required to Formulate**

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### **Discussion**

**Pros**

**Cons**

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## **Implementation Requirements**

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### **Discussion**

**Pros**

**Cons**

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## **Impact on Stakeholder Communities**

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### **Discussion**

**Positive Impact**

**Negative Impact**

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**Feasibility**

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**Discussion**

**Arguments for Feasibility**

**Arguments Against Feasibility**

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**Does the Option Address Liability Concerns**

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**Discussion**

**Pros**

**Cons**

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**Ramifications of Acceptance/Rejection**

---

**Discussion**

**Acceptance**

**Rejection**

---

**Conflicts With State or Federal Laws**

---

**Discussion**

**Pros**

**Cons**

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## **Legal Framework/Rules of Engagement**

---

**Discussion**

**Pros**

**Cons**

---

## **Process for Withdrawal**

---

**Discussion**

**Pros**

**Cons**

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## **State Responsibilities**

---

**Discussion**

**Pros**

**Cons**

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## **State's Rights**

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### **Discussion**

**Pros**

**Cons**

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## **Enforcement**

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### **Discussion**

**Pros**

**Cons**

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## **Other Considerations**

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## **Conclusion**

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## INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

### MODEL ACT ANALYSIS [ENTER STATE NAME]

## Introduction

One focus of the Intrastate and Interstate Consent Policy Options Collaborative is to explore the viability of four options that states could enact to resolve barriers to the exchange, including electronic, of protected health information (PHI) among states that have conflicting state laws governing consent to use or disclose PHI. These barriers can be summarized as the civil or criminal liability that may accrue to health information exchange (HIE) organizations or health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether a “model act” could eliminate these barriers. A model act would offer states the option to enact a similar act governing consent issues, which would address conflicting acts between adopting states.

A model state act is promulgated by the Uniform Law Commission (ULC): “An act may be designated as ‘model’ if the principal purposes of the act can be substantially achieved even though it is not adopted in its entirety by every state.”<sup>5</sup>

## Definitions/Assumptions

To ensure consistency in the analysis of the four options, the collaborative has adopted a uniform set of definitions and assumptions.

### Definitions:

- Authentication—means the method or methods to verify the identity of a person or entity authorized to access PHI.
- Authorization—means the level of access an individual or entity has to PHI and includes a management component—an individual or individuals must be designated to authorize access and manage access once access is approved.

<sup>5</sup> Frequently Asked Questions about NCCUSL, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>

- Consent—means the patient’s signed approval for the use or disclosure of PHI, which may also be referred to as an “authorization” or “permission” under HIPAA or other state laws.
- Health—is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.<sup>6</sup>
- Health care—is the prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical, nursing, and allied health professions.<sup>7</sup>
- Health information exchange (HIE)—the electronic movement of health-related information among organizations according to nationally recognized standards.
- Requesting state—the state that is requesting medical information.
- Responding state—the state that has received the request for medical information and is responding.
- Protected health information (PHI)—is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to (1) the past, present, or future physical or mental health or condition of an individual; (2) provision of health care to an individual; or (3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

**Assumptions: The purpose of these assumptions is to lay the framework for the analysis effort.**

- For purposes of this initiative, HIE represents the processes involved in the exchange of consent and is not intended to represent a specific entity.
- The record holder of the responding state may release and have access to the patient’s record in conformance with federal and state consent laws for the release of PHI.
- The **responding state** and the **requesting state** will have an agreement that addresses:
  - The exchange of PHI regarding persons authorized to access PHI
  - The authentication of users
- The **responding state** has more stringent consent laws for the release of PHI than the patient’s **requesting state**. (Assuming the reverse would not be relevant to this analysis in that the patient’s PHI would not be available for exchange unless the patient had already executed the required—more expansive—consent.)

<sup>6</sup> World Health Organization, <http://www.who.int/about/definition/en/index.html>

<sup>7</sup> Wikipedia definition, [http://en.wikipedia.org/wiki/Health\\_care](http://en.wikipedia.org/wiki/Health_care)

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## **Process for Developing the Option**

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### **Discussion**

**Pros**

**Cons**

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## **Length of Time Required to Formulate**

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### **Discussion**

**Pros**

**Cons**

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## **Implementation Requirements**

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### **Discussion**

**Pros**

**Cons**

---

## **Impact on Stakeholder Communities**

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### **Discussion**

**Positive Impact**

**Negative Impact**

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**Feasibility**

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**Discussion**

**Arguments for Feasibility**

**Arguments Against Feasibility**

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**Does the Option Address Liability Concerns**

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**Discussion**

**Pros**

**Cons**

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**Ramifications of Acceptance/Rejection**

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**Discussion**

**Acceptance**

**Rejection**

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**Conflicts With State or Federal Laws**

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**Discussion**

**Pros**

**Cons**

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## **Legal Framework/Rules of Engagement**

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**Discussion**

**Pros**

**Cons**

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## **Process for Withdrawal**

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**Discussion**

**Pros**

**Cons**

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## **State Responsibilities**

---

**Discussion**

**Pros**

**Cons**

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## **State's Rights**

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### **Discussion**

**Pros**

**Cons**

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## **Enforcement**

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### **Discussion**

**Pros**

**Cons**

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## **Other Considerations**

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## **Conclusion**

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## INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

### CHOICE OF LAW ANALYSIS [ENTER STATE NAME]

## Introduction

One focus of the Intrastate and Interstate Consent Policy Options Collaborative is to explore the viability of four options that states could enact to resolve barriers to the exchange, including electronic, of protected health information (PHI) among states that have conflicting state laws governing consent to use or disclose PHI. These barriers can be summarized as the civil or criminal liability that may accrue to health information exchange (HIE) organizations or health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether a “choice of law provision” could eliminate these barriers. A choice of law provision is a provision that states could adopt to specify which state law governs consent when PHI is requested to be exchanged between states with conflicting laws on whether and what consent is needed for such exchange.

A **choice of law provision** may be a **clause** in a contract which specifies which law (i.e., the law of which state) will be applied to resolve any disputes arising under the contract. It may also be a statute or codified preference for which state’s laws apply to a given circumstance (usually, it is the enacting state’s laws). It may also be a codified general preference for the application of a particular state’s laws.

## Definitions/Assumptions

To ensure consistency in the analysis of the four options, the collaborative has adopted a uniform set of definitions and assumptions.

### Definitions:

- Authentication—means the method or methods to verify the identity of a person or entity authorized to access PHI.
- Authorization—means the level of access an individual or entity has to PHI and includes a management component—an individual or individuals must be designated to authorize access and manage access once access is approved.

- Consent—means the patient’s signed approval for the use or disclosure of PHI, which may also be referred to as an “authorization” or “permission” under HIPAA or other state laws.
- Health—is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.<sup>8</sup>
- Health care—is the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions.<sup>9</sup>
- Health information exchange (HIE)—the electronic movement of health-related information among organizations according to nationally recognized standards.
- Requesting state—the state that is requesting medical information.
- Responding state—the state that has received the request for medical information and is responding.
- Protected health information (PHI)—is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to (1) the past, present, or future physical or mental health or condition of an individual; (2) provision of health care to an individual; or (3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

**Assumptions: The purpose of these assumptions is to lay the framework for the analysis effort.**

- For purposes of this initiative, HIE represents the processes involved in the exchange of consent and is not intended to represent a specific entity.
- The record holder of the responding state may release and have access to the patient’s record in conformance with federal and state consent laws for the release of PHI.
- The **responding state** and the **requesting state** will have an agreement that addresses:
  - The exchange of data regarding persons authorized to access PHI
  - The authentication of users
- The **responding state** has more stringent consent requirements for the release of PHI than the patient’s **requesting state**. (Assuming the reverse would not be relevant to this analysis in that the patient’s PHI would not be available for exchange unless the patient had already executed the required—more expansive—consent.)

<sup>8</sup> World Health Organization, <http://www.who.int/about/definition/en/index.html>

<sup>9</sup> Wikipedia definition, [http://en.wikipedia.org/wiki/Health\\_care](http://en.wikipedia.org/wiki/Health_care)

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## **Process for Developing the Option**

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### **Discussion**

**Pros**

**Cons**

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## **Length of Time Required to Formulate**

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### **Discussion**

**Pros**

**Cons**

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## **Implementation Requirements**

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### **Discussion**

**Pros**

**Cons**

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## **Impact on Stakeholder Communities**

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### **Discussion**

**Positive Impact**

**Negative Impact**

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**Feasibility**

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**Discussion**

**Arguments for Feasibility**

**Arguments Against Feasibility**

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**Does the Option Address Liability Concerns**

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**Discussion**

**Pros**

**Cons**

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**Ramifications of Acceptance/Rejection**

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**Discussion**

**Acceptance**

**Rejection**

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**Conflicts With State or Federal Laws**

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**Discussion**

Pros

Cons

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### **Legal Framework/Rules of Engagement**

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Discussion

Pros

Cons

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### **Process for Withdrawal**

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Discussion

Pros

Cons

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### **State Responsibilities**

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Discussion

Pros

Cons

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## **State's Rights**

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### **Discussion**

**Pros**

**Cons**

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## **Enforcement**

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### **Discussion**

**Pros**

**Cons**

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## **Other Considerations**

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## **Conclusion**

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## INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

### INTERSTATE COMPACT ANALYSIS [ENTER STATE NAME]

## Introduction

One focus of the Intrastate and Interstate Consent Policy Options Collaborative is to explore the viability of four options that states could enact to resolve barriers to the exchange, including electronic, of protected health information (PHI) among states that have conflicting state laws governing consent to use or disclose PHI. These barriers can be summarized as the civil or criminal liability that may accrue to health information exchange (HIE) organizations or health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether an “interstate compact” could eliminate these barriers. An interstate compact may accomplish this goal by establishing a framework for resolving conflicts, which member states agree to adopt.

The Council of State Governments defines an interstate compact as “a contract between two or more states. It carries the force of statutory law and allows states to perform a certain action, observe a certain standard or cooperate in a critical policy area. Generally speaking, interstate compacts:

- establish a formal, legal relationship among states to address common problems or promote a common agenda;
- create independent, multistate governmental authorities (such as commissions) that can address issues more effectively than a state agency acting independently, or when no state has the authority to act unilaterally; and
- establish uniform guidelines, standards or procedures for agencies in the compact’s member states.”<sup>10</sup>

## Definitions/Assumptions

To ensure consistency in the analysis of the four options, the collaborative has adopted a uniform set of definitions and assumptions.

<sup>10</sup> Fact Sheet, Council of State Governments, National Center for Interstate Compacts at <http://www.csg.org/> (keyword: interstate compacts).

**Definitions:**

- Authentication—means the method or methods to verify the identity of a person or entity authorized to access PHI.
- Authorization—means the level of access an individual or entity has to PHI and includes a management component—an individual or individuals must be designated to authorize access and manage access once access is approved.
- Consent—means the patient’s signed approval for the use or disclosure of PHI, which may also be referred to as an “authorization” or “permission” under HIPAA or other state laws.
- Health—is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.<sup>11</sup>
- Health care—is the prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical, nursing, and allied health professions.<sup>12</sup>
- Health information exchange (HIE)—the electronic movement of health-related information among organizations according to nationally recognized standards.
- Requesting state—the state that is requesting medical information.
- Responding state—the state that has received the request for medical information and is responding.
- Protected health information (PHI)—is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to (1) the past, present, or future physical or mental health or condition of an individual; (2) provision of health care to an individual; or (3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

**Assumptions: The purpose of these assumptions is to lay the framework for the analysis effort.**

- For purposes of this initiative, HIE represents the processes involved in the exchange of consent and is not intended to represent a specific entity.
- The record holder of the responding state may release and have access to the patient’s record in conformance with federal and state consent laws for the release of PHI.
- The **responding state** and the **requesting state** will have an agreement that addresses:
  - The exchange of PHI regarding persons authorized to access PHI
  - The authentication of users

<sup>11</sup> World Health Organization, <http://www.who.int/about/definition/en/index.html>

<sup>12</sup> Wikipedia definition, [http://en.wikipedia.org/wiki/Health\\_care](http://en.wikipedia.org/wiki/Health_care)

- The **responding state** has more stringent consent requirements for the release of PHI than the patient's **requesting state**. (Assuming the reverse would not be relevant to this analysis in that the patient's PHI would not be available for exchange unless the patient had already executed the required—more expansive—consent.)

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## Process for Developing the Option

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### Discussion

### Pros

### Cons

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## Length of Time Required to Formulate

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### Discussion

### Pros

### Cons

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## Implementation Requirements

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### Discussion

### Pros

### Cons

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## **Impact on Stakeholder Communities**

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Discussion

Positive Impact

Negative Impact

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## **Feasibility**

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Discussion

Arguments for Feasibility

Arguments Against Feasibility

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## **Does the Option Address Liability Concerns**

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Discussion

Pros

Cons

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## **Ramifications of Acceptance/Rejection**

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Discussion

Acceptance

**Rejection**

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**Conflicts With State or Federal Laws**

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**Discussion**

**Pros**

**Cons**

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**Legal Framework/Rules of Engagement**

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**Discussion**

**Pros**

**Cons**

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**Process for Withdrawal**

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**Discussion**

**Pros**

**Cons**

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**State Responsibilities**

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**Discussion**

**Pros**

**Cons**

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## **State's Rights**

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**Discussion**

**Pros**

**Cons**

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## **Enforcement**

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**Discussion**

**Pros**

**Cons**

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## **Other Considerations**

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## **Conclusion**

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# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE—FINAL REPORT**

## **APPENDIX M: CONSOLIDATED SUMMARY—ANALYSIS OF INTERSTATE MECHANISMS**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## 1. Process for Developing the Option

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

### Interstate Compact

Legislatively authorized or appointed commissioners are chosen to develop a compact. Informal group with subject matter expertise. Eventually, need legislative support.

The Council of State Governments (CSG) defines an interstate compact as “a contract between two or more states. It carries the force of statutory law and allows states to perform a certain action, observe a certain standard, or cooperate in a critical policy area. Generally speaking, interstate compacts:

- establish a formal, legal relationship among states to address common problems or promote a common agenda;
- create independent, multistate governmental authorities (such as commissions) that can address issues more effectively than a state agency acting independently, or when no state has the authority to act unilaterally; and
- establish uniform guidelines, standards, or procedures for agencies in the compact's member states.”<sup>1</sup>

CSG outlined the following key steps in the development process of a regulatory compact:

- *Advisory group:* Composed of state officials and other critical stakeholders, an advisory group examines the realm of the problem, suggests possible solutions, and makes recommendations as to the structure of the interstate compact. Typically, an advisory group is composed of approximately 20 individuals, each representative of various groups and states. An advisory group would likely meet one or two times over a period of 2 to 3 months, with their work culminating in a set of recommendations as to what the final compact product should look like.
- *Drafting team:* While an advisory group enjoys thinking about the issue from a macro-level, a drafting team pulls the thoughts, ideas, and suggestions of the advisory group into a draft compact. The drafting team, composed of five to eight compact and issue experts, will craft the recommendations, as well as their own thoughts and expertise, into a draft compact that will be circulated to state officials for comment. The document will also be open for comments from a wide swath of stakeholders and the public. Following these comment periods, the compact will be revised as needed and released finally back to an advisory group for final review to ensure it meets the original spirit of the group's recommendations. A drafting team

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<sup>1</sup> Fact sheet, Council of State Governments, National Center for Interstate Compacts at <http://www.csg.org/> (keyword: interstate compacts).

would meet three to four times over a period of 10 to 14 months, with significant staff work and support between sessions.

- *Education:* Once completed, the interstate compact would be available to states for legislative approval. During this phase of the initiative, state-by-state technical assistance and on-site education are keys to rapid success. A majority of state legislators have limited knowledge about interstate compacts, and with such a major issue being addressed, legwork on the ground in each state is crucial. Previous interstate compact efforts have convened end-of-the-year legislative briefings for state officials to educate them on the solutions provided by the interstate compact. Education occurs before and during state legislative sessions.
- *Enactment:* A majority of interstate compacts did not become active right away. Rather, interstate compacts typically activate when triggered by a preset number of states joining the compact. For instance, the Interstate Compact for Adult Offender Supervision (Adult Compact) required 35 state enactments before it could become active. This number was chosen for two reasons. A membership of 35 ensures that a majority of states are in favor of the agreement and that a new compact would not create two conflicting systems. Moreover, a sense of urgency for states was created because the first 35 jurisdictions to join would meet soon thereafter and fashion the operating rules of the compact. Most interstate compacts take up to 7 years to reach critical mass. However, the most recent effort managed by CSG, the Adult Compact, reached critical mass just 30 months from its first date of introduction in 2000.
- *Transition:* Following enactment by the required minimum number of states, the new compact becomes operational and, dependent upon the administrative structure placed in the compact, goes through standard start-up activities such as state notification; planning for the first commission or state-to-state meetings; and, if authorized by the compact, hiring of staff to oversee the agreement and its requirements. A critical component of the transition will be the development of rules, regulations, forms, standards, etc. by which the compact will need to operate. Typically, transition activities run for between 12 and 18 months before the compact body is independently running.<sup>2</sup>

The process would begin with a negotiated agreement between the participating states. Initially, an advisory group composed of state officials, stakeholders, and issue experts will examine the issues and current policy. The group will work to identify best practices and alternative structures. Ultimately, the advisory group should establish recommendations for the content. Thereafter, a drafting team composed of a smaller number of officials, stakeholders, and experts will draft a compact based upon the advisory board recommendations. The committee's draft agreement may be circulated to representatives of the states and stakeholders any number of times for review, comment, and revisions. At each round, the drafting team will consider and incorporate the comments it receives, and will eventually send its final product back to the advisory board before the compact is released to the states for consideration.

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<sup>2</sup> 10 Frequently Asked Questions, Council of State Governments, National Center for Interstate Compacts website. Available at <http://www.csg.org/programs/ncic/resources.aspx>.

Common characteristics of an interstate compact which would have to be negotiated include: (a) the creation of an independent joint regulatory organization or body; (b) uniform guidelines, standards, or procedures conditioned on action by the other states involved; (c) the states are not free to modify or repeal their laws unilaterally; and (d) statutes requiring reciprocity.

Lastly, consideration will have to be given to whether the interstate compact would require congressional approval. Article I, Section 10, Clause 3 of the U.S. Constitution provides that “No State shall, without the consent of Congress . . . enter into agreement or compact with another State. . . .”

This language appears to require that all interstate compacts require congressional approval, but the U.S. Supreme Court has clarified that congressional approval is not required in all instances: *Virginia v. Tennessee*, 148 U.S. 503, 518–522 (1893). Rather, to determine whether congressional approval is necessary, courts typically look to determine (a) whether the agreement affects the balance of power between the federal government and the states; or (b) intrudes on an area reserved or of interest to the federal government. Based upon these criteria, it appears that congressional approval would be necessary before the compact could take effect.

Congressional consent may take the form of an act or joint resolution of Congress stating that it consents. Or, Congress may consent in advance to the creation of an interstate compact.

Alternatively, congressional approval may be implied by its actions after the states have formally entered into the compact.

Congressional consent may have the effect of transforming the compact into federal law. In *Cuyler v. Adams*, 449 U.S. 433, 440 (1981), the U.S. Supreme Court concluded that “where Congress has authorized the States to enter into a cooperative agreement, and where the subject matter of that agreement is an appropriate subject for congressional legislation, the consent of Congress transforms the State’s agreement into federal law under the Compact Clause.”

*Education and enactment:* The states will need to be educated on the necessity for and the terms of the compact. To that end, a comprehensive resource kit and other promotional materials, support documents, and Internet resources will likely need to be developed. In addition, a national symposium or briefing to educate state legislators and other key state officials may need to be convened.

State support will be created through a network of champions (officials, legislators, governors, etc.). Informational testimony will need to be offered to the state legislative committees considering the compact. Then, as each state enacts the compact, focus will need to shift toward transition and implementation of the compact.

Additional support and education efforts will also be required at the federal level if congressional approval is determined to be required.

*Transition and operation:* Once the enactment threshold is met, states should be notified that the compact has taken effect, and an interim executive board of the interstate commission will need to be appointed. Information systems will likely need development at this point (including the creation of standards, establishment of security procedures, and selection of vendors).

Once the compact is fully up and running, an eye must be kept on technological advancements, law changes, or other issues that may require reconvening the advisory committees and revising the compact language.

There are three foreseeable approaches where an interstate compact can address this conflict between the two states.

### ***Approach 1—Responding State Prevails***

Under this approach, the member states in the compact agree that health information that is properly consented in the responding state will be accepted by the requesting state, the requesting state's consent laws notwithstanding. Most state laws currently require providers in the responding state to comply with their own laws, so this approach is closest to the status quo. Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in "Assumptions") would receive and be permitted to use protected health information (PHI) if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the health information organization [HIO] received a "blanket" consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state determined what the responding state's consent laws were and presented the responding state with a consent that fulfilled these more stringent laws. Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in "Assumptions") would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a "blanket" consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state presented the responding state with a consent that fulfilled the responding state's consent laws, which could presumably be done by using a consent from the requesting state because its laws are more stringent.

### ***Approach 2—Requesting State Prevails***

This approach has the compact member states agreeing that the consent laws of the requesting state would prevail. Before PHI could be sent to the requesting state, a patient consent must meet the requirements of the requesting state. This approach requires

requesting states to be familiar with only their own state’s laws, instead of being prepared to obtain consents that satisfy various responding states’ laws.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in “Assumptions”) would receive and be permitted to use PHI if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws even if they were less stringent than the responding state; or (b) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state). Presumably, if the responding state’s laws were satisfied, the requesting state’s laws would also be satisfied. Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI only if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws; or (b) the responding state obtains the information by voluntarily obtaining a more stringent consent that also fulfills the laws of the requesting state.

### ***Approach 3—Compact Defined Consent***

The third approach would be the adoption by compact of a consent policy that would apply to all member states. This policy would be incorporated in the terms of the compact that is enacted by member states. This could result in a compromise between the requirements of the requesting state and those of the responding states. PHI would be exchanged if the requirements of the compact were met.

### **Uniform Law**

The process for creating a uniform law begins with the National Conference of Commissioners on Uniform State Laws (NCCUSL) Committee on Scope and Program. It receives suggestions from a variety of sources, such as the uniform law commissioners, state government entities, the organized bar, interest groups, and private individuals. This committee can then create a study committee to review the issue and report back or make recommendations to the Executive Committee.

Although another organization may refer to a legislative proposal as being “uniform,” uniform laws are generally understood to be those adopted by NCCUSL—also referred to as the Uniform Law Commission (ULC). NCCUSL’s standing as promulgator of uniform laws stems from the direct participation of every state in its deliberations.<sup>3</sup> It was created more than 116 years ago when the state of New York invited other states to participate in a

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<sup>3</sup> Frequently Asked Questions about NCCUSL, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

conference to draft uniform laws.<sup>4</sup> Each state provides financial support to the organization and sends a contingent of “commissioners.” Illinois law<sup>5</sup> provides for the appointment of nine commissioners to represent the state on the ULC. According to Katie Robinson, Communications Officer, NCCUSL, most states have 3 to 5 commissioners, while others have more than 10.

The process for creating a uniform law begins with the Committee on Scope and Program.<sup>6</sup> It receives suggestions from a variety of sources, such as the uniform law commissioners, state government entities, the organized bar, interest groups, and private individuals. This committee can then create a study committee to review the issue and report back or make recommendations to the Executive Committee.<sup>7</sup>

With the approval of the Executive Committee, a drafting committee is selected or created. The drafting committee is appointed from the membership of the ULC. “Each draft receives a minimum of 2 years consideration, sometimes much longer. Drafting committees meet throughout the year. The open drafting process draws on the expertise of state-appointed commissioners, legal experts, and advisors and observers representing the views of other legal organizations or interests that will be subject to the proposed laws.”<sup>8</sup> The drafting committee drafts the act and revisits the decision whether to designate the act as a uniform or model act.<sup>9</sup>

“Draft acts are submitted for initial debate of the entire Uniform Law Commission at an annual meeting.”<sup>10</sup> “Each act must be considered section by section, at no less than two annual meetings, by all commissioners sitting as a Committee of the Whole. Once the Committee of the Whole approves an act, the final step is a vote by states—one vote per state. A majority of the states present, and no less than 20 states, must approve an act before it can be officially adopted for consideration by the states.”<sup>11</sup>

Approval of an act as a uniform act obligates commissioners from each state to promote verbatim adoption by their respective legislatures.<sup>12</sup> Approval of an act as a model act

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<sup>4</sup> State of Illinois Report of the Illinois Delegation to the National Conference of Commissioners on Uniform State Laws (NCCUSL), November 28, 2007, Legislative Reference Bureau, p. 1, [http://www.ilga.gov/commission/lrb/NCCUSL\\_2007.pdf](http://www.ilga.gov/commission/lrb/NCCUSL_2007.pdf).

<sup>5</sup> Section 5.07 of the Legislative Reference Bureau Act, 25 ILCS 135/5.07.

<sup>6</sup> Proposals and Criteria, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

<sup>7</sup> Ibid.

<sup>8</sup> Frequently Asked Questions about the Uniform Law Commission, Uniform Law Commission website, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>9</sup> Proposals and Criteria, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

<sup>10</sup> Introduction, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=0&tabid=11>.

<sup>11</sup> Frequently Asked Questions about the Uniform Law Commission, Uniform Law Commission website, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>12</sup> Proposals and Criteria, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

obligates commissioners from each state to promote adoption to achieve necessary and desirable uniformity, but without as much emphasis on verbatim adoption.<sup>13</sup>

After a uniform law has been approved by the ULC, commissioners advocate for the adoption of the new act. Publication of a uniform act or model act is no guarantee of acceptance by individual state legislatures. Each uniform or model act undergoes the same legislative process as other bills. In fact, under the Illinois Bill Drafting Manual promulgated by the Legislative Reference Bureau, bill titles should not begin with the word “model” or indicate that an act may be cited as a model act, although use of the word “uniform” is permitted for NCCUSL Uniform Acts.<sup>14</sup> There have been exceptional instances in which uniform or model acts have been overwhelmingly rejected by state legislatures. For example, the Uniform Computer Information Transactions Act (UCITA) was approved by NCCUSL as a uniform act but was adopted in only two states.<sup>15</sup> A number of states rejected UCITA, and some even adopted measures contrary to UCITA.<sup>16</sup> Ultimately, NCCUSL ceased promoting UCITA.<sup>17</sup>

Even if state legislatures incorporate a uniform or model act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently. Often, a court will emphasize prior case law more heavily than the terms of the statute. For example, even though the UCC has been widely adopted verbatim by various states, there are dramatic differences in application that affect the rights of parties under the UCC. One such area is the formation of warranties through representations by the seller, in which the buyer’s right to enforce a warranty varies widely from state to state under identical UCC provisions.

The ULC has established a Study Committee on Health Care Information Interoperability (W. Grant Callow, Chair). The Study Committee is to “study various state law impediments to the effective exchange of health care information (electronic and otherwise) between and among health care providers, insurers, government entities, and other actors within the health care system, and in coordination with ongoing state and federal efforts in this area will assess whether state statutory reform is needed.”<sup>18</sup> At the July 19–20, 2008, Annual Meeting of the Committee on Scope and Program of the Uniform Law Commission, the Study Committee provided this report:

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<sup>13</sup> Ibid.

<sup>14</sup> Illinois Bill Drafting Manual, Legislative Resource Bureau, §20.5.

<sup>15</sup> A Few Facts about the Uniform Computer Information Transactions Act, National Conference of Commissioners on Uniform State Laws, 2002. Available at [http://www.nccusl.org/Update/uniformact\\_factsheets/uniformacts-fs-ucita.asp](http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-ucita.asp).

<sup>16</sup> What is UCITA? Americans for Fair Electronic Commerce Transactions. Available at [http://www.ucita.com/what\\_history.html](http://www.ucita.com/what_history.html).

<sup>17</sup> Letter from NCCUSL President to Commissioners dated August 1, 2003, Americans for Fair Electronic Commerce Transactions. Available at <http://www.ucita.com/pdf/Nccusl2003UcitaKingLetP1.pdf>.

<sup>18</sup> Study Committees, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=1&tabid=40>.

“Commissioner Nichols reported briefly on the committee’s work, noting that at midyear 2008 Scope decided to continue this committee until reports from outside organizations were released, including a report by the National Governor’s Association. Commissioner Grant Callow addressed the committee and confirmed that no report has been issued. Commissioner Callow noted that he has been in touch with a member of the ABA Privacy and Security Project which is working on a project to harmonize state privacy laws, and requested that the study committee be continued in order to receive additional input from interested groups. The Committee on Scope and Program agreed to continue the study committee, and expects a further report at its midyear meeting in January 2009.”<sup>19</sup>

## Model Law

There are different processes for developing model laws, based upon the different drafting entities. The process for creating a model law could be a lengthy process. Then it is up to the states to determine what parts of the model laws they choose to enact. And the model law would go through the legislative process.

Unlike a “uniform law,” model acts can be those adopted by NCCUSL—or by other associations and interest groups. NCCUSL’s standing as promulgator of uniform laws and model acts stems from the direct participation of every state in its deliberations.<sup>20</sup> It was created more than 116 years ago when the state of New York invited other states to participate in a conference to draft uniform laws.<sup>21</sup> Each state provides financial support to the organization and sends a contingent of “commissioners.” Illinois law<sup>22</sup> provides for the appointment of nine commissioners to represent the state on the ULC. According to Katie Robinson, Communications Officer, NCCUSL, most states have 3 to 5 commissioners, while others have more than 10.

An example of another organization that has developed model acts is the Turning Point National Collaborative on Public Health Statute Modernization. “The Collaborative is a partnership between the Turning Point states of Alaska, Oregon, Nebraska, Wisconsin, and Colorado; and a number of federal agencies and national organizations, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the American Public Health Association, the National Governors’ Association, the National Conference of State Legislatures, the National Indian Health Board, the Association of State and Territorial Health Officials, and the National Association of County

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<sup>19</sup> Scope and Program Committee, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/Minutes/scope071908mn.pdf>.

<sup>20</sup> Frequently Asked Questions about NCCUSL, National Conference of Commissioners on Uniform State Laws, 2002. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>21</sup> State of Illinois Report of the Illinois Delegation to the National Conference of Commissioners on Uniform State Laws (NCCUSL), November 28, 2007, Legislative Reference Bureau, p. 1. Available at [http://www.ilga.gov/commission/lrb/NCCUSL\\_2007.pdf](http://www.ilga.gov/commission/lrb/NCCUSL_2007.pdf).

<sup>22</sup> Section 5.07 of the Legislative Reference Bureau Act, 25 ILCS 135/5.07.

and City Health Officials.”<sup>23</sup> This collaborative developed the “Turning Point Model State Public Health Act to serve as a tool for state, local, and tribal governments to use to revise or update public health statutes and administrative regulations.”<sup>24</sup>

Government, more specifically, the Centers for Disease Control and Prevention (CDC) has been the initiator of model acts, two of which have been reviewed for this paper. One proposal, the Model State Public Health Privacy Act, “was developed by Lawrence O. Gostin and James G. Hodge, Jr., in 1999 under the auspices of the CDC and with significant input from an expert advisory group.”<sup>25</sup> This model act addresses privacy and security issues regarding identifiable health information collected by public health agencies.

“In October 2001, CDC commissioned the Center for Law and the Public’s Health to produce the Model State Emergency Health Powers Act.”<sup>26</sup> This model act was completed in December 2001. The Center for Law and the Public’s Health’s website includes information on the state adoption of the model act up to July 15, 2006. According to the site, “thirty-eight (38) states . . . and DC have passed a total of 66 bills or resolutions that include provisions from or closely related to the Act.”<sup>27</sup>

Because of the number of different entities that propose model acts, this paper will limit its discussion to the process used by NCCUSL. For that organization, the creation of a model act begins with the Committee on Scope and Program.<sup>28</sup> It receives suggestions from a variety of sources, such as the commissioners, state government entities, the organized bar, interest groups, and private individuals. When a party proposes an act, it is asked to demonstrate that the act will meet various NCCUSL criteria, including whether the subject matter is appropriate for state legislation in view of federal versus state jurisdiction; and whether the subject matter is consistent with NCCUSL’s objective to promote uniformity in state law on subjects where uniformity is desirable and practicable. Each act must: (1) have an obvious reason that makes it a practical step toward uniformity of state law or at least toward minimizing its diversity; (2) have reasonable probability of being accepted and enacted into law by a substantial number of jurisdictions, or, if not, will promote uniformity indirectly; and, (3) produce significant benefits to the public or avoid significant disadvantages arising from diversity of state law. The Committee on Scope and Program

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<sup>23</sup> Turning Point National Collaborative on Public Health Statute Modernization. Available at [http://www.hss.state.ak.us/dph/improving/turningpoint/the\\_collaborative.htm](http://www.hss.state.ak.us/dph/improving/turningpoint/the_collaborative.htm).

<sup>24</sup> Centers for Law and the Public’s Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSPHA.php>.

<sup>25</sup> Centers for Law and the Public’s Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSPHA.php>.

<sup>26</sup> James G. Hodge, Jr., and Lawrence O. Gostin, *The Model State Emergency Health Powers Act—A Brief Commentary* (January 2002), p. 3. Available at <http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf>.

<sup>27</sup> Centers for Law and the Public’s Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSEHPA.php>.

<sup>28</sup> *Proposals and Criteria*, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

determines whether the proposed act merits consideration by NCCUSL and makes a recommendation to the Executive Committee. The Executive Committee refers the proposal to a Standing or Special Study Committee (the Study Committee) to review the issue and report back or make recommendations to the Executive Committee. The Study Committee recommends whether to draft an act and whether to designate it as a “uniform” act or a “model” act.<sup>29</sup>

With the approval of the Executive Committee, a drafting committee is selected or created.<sup>30</sup> The drafting committee is appointed from the membership of the ULC. “Each draft receives a minimum of two years consideration, sometimes much longer. Drafting committees meet throughout the year. The open drafting process draws on the expertise of state-appointed commissioners, legal experts, and advisors and observers representing the views of other legal organizations or interests that will be subject to the proposed laws.”<sup>31</sup> The drafting committee drafts the act and revisits the decision whether to designate the act as a uniform or model act.<sup>32</sup>

“Draft acts are submitted for initial debate of the entire Uniform Law Commission at an annual meeting.”<sup>33</sup> “Each act must be considered section by section, at no less than two annual meetings, by all commissioners sitting as a Committee of the Whole. Once the Committee of the Whole approves an act, the final step is a vote by states—one vote per state. A majority of the states present, and no less than 20 states, must approve an act before it can be officially adopted for consideration by the states.”<sup>34</sup>

Approval of an act as a uniform act obligates commissioners from each state to promote verbatim adoption by their respective legislatures.<sup>35</sup> Approval of an act as a model act obligates commissioners from each state to promote adoption to achieve necessary and desirable uniformity, but without as much emphasis on verbatim adoption.<sup>36</sup>

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<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

<sup>31</sup> Frequently Asked Questions about the Uniform Law Commission, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>32</sup> Proposals and Criteria, National Conference of Commissioners on Uniform State Laws, 2002. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

<sup>33</sup> Introduction, National Conference of Commissioners on Uniform State Laws, 2002. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=0&tabid=11>.

<sup>34</sup> Frequently Asked Questions about the Uniform Law Commission, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>35</sup> Proposals and Criteria, National Conference of Commissioners on Uniform State Laws, 2002. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=3&tabid=42>.

<sup>36</sup> Ibid.

cited as a model act (although use of the word “uniform” is permitted for NCCUSL Uniform Acts).<sup>37</sup> There have been exceptional instances in which uniform or model acts have been overwhelmingly rejected by state legislatures. For example, UCITA was approved by NCCUSL as a uniform act, but was adopted in only two states.<sup>38</sup> A number of states rejected UCITA, and some even adopted measures contrary to UCITA.<sup>39</sup> Ultimately, NCCUSL ceased promoting UCITA.<sup>40</sup>

Even if state legislatures incorporate a uniform or model act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently. Often, a court will emphasize prior case law more heavily than the terms of the statute. For example, even though the UCC has been widely adopted verbatim by various states, there are dramatic differences in application that affect the rights of parties under the UCC. One such area is the formation of warranties through representations by the seller, in which the buyer’s right to enforce a warranty varies widely from state to state under identical UCC provisions.

Generally, as compared to uniform acts, model acts are expected to be subject to greater variation when adopted (or not) by the various states. According to the ULC, an act may be designated as “model” if the principal purposes of the act can be substantially achieved even though it is not adopted in its entirety by every state. By comparison, a uniform act is one in which uniformity of the provisions of the act among the various jurisdictions is a principal and compelling objective. Legislatures are urged to adopt uniform acts exactly as written, to “promote uniformity in the law among the states.”<sup>41</sup> Model acts are designed to serve as guideline legislation, which states can borrow from or adapt to suit their individual needs and conditions.

Proposals for new acts are considered by the ULC Committee on Scope and Program, which accepts suggestions from the organized bar, state governments, private interest groups, uniform law commissioners, and private individuals. It may assign a suggested topic to a study committee which studies the topic and reports back to the Committee. The Scope and Program Committee sends its recommendations to the Executive Committee. A proposed act need not be designated as “uniform” or “model” until a draft is actually submitted to the Executive Committee for consideration at its annual meeting. With the ULC Executive

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<sup>37</sup> Illinois Bill Drafting Manual, Legislative Resource Bureau, §20.5.

<sup>38</sup> A Few Facts about the Uniform Computer Information Transactions Act, National Conference of Commissioners on Uniform State Laws, 2002. Available at [http://www.nccusl.org/Update/uniformact\\_factsheets/uniformacts-fs-ucita.asp](http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-ucita.asp).

<sup>39</sup> What is UCITA? Americans for Fair Electronic Commerce Transactions. Available at [http://www.ucita.com/what\\_history.html](http://www.ucita.com/what_history.html).

<sup>40</sup> Letter from NCCUSL President to Commissioners dated August 1, 2003, Americans for Fair Electronic Commerce Transactions. Available at <http://www.ucita.com/pdf/Nccusl2003UcitaKingLetP1.pdf>.

<sup>41</sup> About NCCUSL, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=0&tabid=11>.

Committee's approval, a drafting committee is selected from the membership, and a reporter/drafter—an expert in the field—is hired.

Each draft receives a minimum of 2 years' consideration, sometimes much longer. Drafting committees meet throughout the year. The open drafting process draws on the expertise of state-appointed commissioners, legal experts, and advisors and observers representing the views of other legal organizations or interests that will be subject to the proposed laws.

Draft acts are submitted for initial debate of the entire Uniform Law Commission at an annual meeting. Each act must be considered section by section, at no less than two annual meetings, by all commissioners sitting as a Committee of the Whole. Once the Committee of the Whole approves an act, the final step is a vote by states—one vote per state. A majority of the states present, and no less than 20 states, must approve an act before it can be officially adopted for consideration by the states.

The ULC has established a Study Committee on Health Care Information Interoperability (W. Grant Callow, Chair). The Study Committee is to "study various state law impediments to the effective exchange of health care information (electronic and otherwise) between and among health care providers, insurers, government entities, and other actors within the health care system, and in coordination with ongoing state and federal efforts in this area will assess whether state statutory reform is needed."<sup>42</sup> At the July 19–20, 2008, Annual Meeting of the Committee on Scope and Program of the Uniform Law Commission, the Study Committee provided this report: "Commissioner Nichols reported briefly on the committee's work, noting that at midyear 2008 Scope decided to continue this committee until reports from outside organizations were released, including a report by the National Governor's Association. Commissioner Grant Callow addressed the committee and confirmed that no report has been issued. Commissioner Callow noted that he has been in touch with a member of the American Bar Association (ABA) Privacy and Security Project which is working on a project to harmonize state privacy laws, and requested that the study committee be continued in order to receive additional input from interested groups. The Committee on Scope and Program agreed to continue the study committee, and expects a further report at its midyear meeting in January 2009."<sup>43</sup>

The American Law Institute (ALI) and the ABA also promulgate model acts. The ALI and ABA do not have the same procedures and timelines as the ULC. For the ALI, each proposed act is assigned to a "reporter" who prepares the various drafts to be reviewed by ALI subcommittees and ALI membership. Once a model act is approved, the reporter prepares ALI's official version for publication. The ABA, through its various sections, divisions,

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<sup>42</sup> Study Committees, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=1&tabid=40>.

<sup>43</sup> Scope and Program Committee, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/Minutes/scope071908mn.pdf>.

forums, and committees, pursues the improvement of various laws, including the drafting of model acts, via similar procedures.

We are not aware of any unusual processes, enablers, or quirks that would impact the adoption and implementation of a model act. As discussed above in the Process for Developing the Option and the Implementation Requirements, a number of hurdles will need to be overcome and ground rules will need to be established, but from a legal process standpoint, passage of a model act is possible.

Foreseeable barriers to administering and enforcing the model act will be operational in nature. The move to a model act could include the adoption of a uniform consent form. Given the vast number of health care providers and the wide variance of size and sophistication, ensuring that all health care providers adopt the uniform consent form will be a challenge. Also, part of the model act should address how to handle exchange of information with states that have not adopted the model act. This issue will undoubtedly arise, so states should be prepared how address it.

Unlike a “uniform law,” model acts can be those adopted by NCCUSL—or by other associations and interest groups.

NCCUSL’s standing as promulgator of uniform laws and model acts stems from the direct participation of every state in its deliberations. It was created more than 116 years ago when the state of New York invited other states to participate in a conference to draft uniform laws. Each state provides financial support to the organization and sends a contingent of “commissioners.” Illinois law provides for the appointment of nine commissioners to represent the state on the ULC. According to Katie Robinson, Communications Officer, NCCUSL, most states have 3 to 5 commissioners, while others have more than 10.

An example of another organization that has developed model acts is the Turning Point National Collaborative on Public Health Statute Modernization. “The Collaborative is a partnership between the Turning Point states of Alaska, Oregon, Nebraska, Wisconsin, and Colorado; and a number of federal agencies and national organizations, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the American Public Health Association, the National Governors’ Association, the National Conference of State Legislatures, the National Indian Health Board, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials.” This collaborative developed the “Turning Point Model State Public Health Act to serve as a tool for state, local, and tribal governments to use to revise or update public health statutes and administrative regulations.”<sup>44</sup>

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<sup>44</sup> Turning Point Model State Public Health Act, Centers for Law and the Public Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSPHA.php>.

Government, more specifically, CDC, has been the initiator of model acts, two of which have been reviewed for this paper. One proposal, the Model State Public Health Privacy Act, “was developed by Lawrence O. Gostin and James G. Hodge, Jr., in 1999 under the auspices of the CDC and with significant input from an expert advisory group.”<sup>45</sup> This model act addresses privacy and security issues regarding identifiable health information collected by public health agencies.

“In October 2001, CDC commissioned the Center for Law and the Public’s Health to produce the Model State Emergency Health Powers Act.”<sup>46</sup> This model act was completed in December 2001.

The Center for Law and the Public’s Health’s website includes information on the state adoption of the model act up to July 15, 2006. According to the site, “thirty-eight (38) states . . . and DC have passed a total of 66 bills or resolutions that include provisions from or closely related to the Act.”<sup>47</sup>

Because of the number of different entities that propose model acts, this paper will limit its discussion to the process used by the NCCUSL. For that organization, the creation of a model act begins with the Committee on Scope and Program. It receives suggestions from a variety of sources, such as the commissioners, state government entities, the organized bar, interest groups, and private individuals. When a party proposes an act, it is asked to demonstrate that the act will meet various NCCUSL criteria, including whether the subject matter is appropriate for state legislation in view of federal versus state jurisdiction; and whether the subject matter is consistent with NCCUSL’s objective to promote uniformity in state law on subjects where uniformity is desirable and practicable. Each act must: (1) have an obvious reason that makes it a practical step toward uniformity of state law or at least toward minimizing its diversity; (2) have reasonable probability of being accepted and enacted into law by a substantial number of jurisdictions, or, if not, will promote uniformity indirectly; and, (3) produce significant benefits to the public or avoid significant disadvantages arising from diversity of state law. The Committee on Scope and Program determines whether the proposed act merits consideration by NCCUSL and makes a recommendation to the Executive Committee. The Executive Committee refers the proposal to a Standing or Special Study Committee (the “Study Committee”) to review the issue and report back or make recommendations to the Executive Committee. The Study Committee recommends whether to draft an act and whether to designate it as a “uniform” act or a “model” act.

With the approval of the Executive Committee, a drafting committee is selected or created. The drafting committee is appointed from the membership of the ULC. “Each draft receives

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<sup>45</sup> Ibid.

<sup>46</sup> Model State Emergency Health Powers Act, Centers for Law and the Public Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSEHPA.php>.

<sup>47</sup> Ibid.

a minimum of 2 years consideration, sometimes much longer. Drafting committees meet throughout the year. The open drafting process draws on the expertise of state-appointed commissioners, legal experts, and advisors and observers representing the views of other legal organizations or interests that will be subject to the proposed laws.”<sup>48</sup> The drafting committee drafts the act and revisits the decision whether to designate the act as a uniform or model act.

“Draft acts are submitted for initial debate of the entire Uniform Law Commission at an annual meeting. Each act must be considered section by section, at no less than two annual meetings, by all commissioners sitting as a Committee of the Whole. Once the Committee of the Whole approves an act, the final step is a vote by states—one vote per state. A majority of the states present, and no less than 20 states, must approve an act before it can be officially adopted for consideration by the states.”<sup>49</sup>

Approval of an act as a uniform act obligates commissioners from each state to promote verbatim adoption by their respective legislatures. Approval of an act as a model act obligates commissioners from each state to promote adoption to achieve necessary and desirable uniformity, but without as much emphasis on verbatim adoption.

Publication of a uniform act or model act is no guarantee of acceptance by individual state legislatures. Each uniform or model act undergoes the same legislative process as other bills. In fact, under the Illinois Bill Drafting Manual promulgated by the Legislative Reference Bureau, bill titles should not begin with the word “model” or indicate that an act may be cited as a model act (although use of the word “uniform” is permitted for NCCUSL Uniform Acts). There have been exceptional instances in which uniform or model acts have been overwhelmingly rejected by state legislatures. For example, UCITA was approved by NCCUSL as a uniform act but was adopted in only two states. A number of states rejected UCITA, and some even adopted measures contrary to UCITA. Ultimately, NCCUSL ceased promoting UCITA.

Even if state legislatures incorporate a uniform or model act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently. Often, a court will emphasize prior case law more heavily than the terms of the statute. For example, even though the UCC has been widely adopted verbatim by various states, there are dramatic differences in application that affect the rights of parties under the UCC. One such area is the formation of warranties through representations by the seller, in which the buyer’s right to enforce a warranty varies widely from state to state under identical UCC provisions.

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<sup>48</sup> Frequently Asked Questions, Uniform Law Commission website. Available at <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>.

<sup>49</sup> Ibid.

Health care providers, HIOs, and other health-related organizations must comply with applicable state and federal requirements when disclosing a person's PHI. These requirements can create barriers or inefficiencies to disclosure of PHI, particularly when the organizations sharing the PHI reside in different states.

Before disclosing PHI to any entity (within or without the state), a disclosing organization must comply with the state and federal laws applicable to the disclosing organization. For instance, a disclosing organization in Illinois must comply with Illinois and federal laws, even if the request comes from another state. Similarly, a disclosing organization residing in another state must comply with federal laws and the laws of its state, even if an organization in Illinois requests the information. In effect, the current status of the law is that the responding state's laws control the disclosure.

As a result, the requesting organization must be familiar with, and comply with, the state consent laws of each different jurisdiction from which it desires to obtain PHI. In practice, this is typically done by using forms or documents that the disclosing entity provides and has already determined comply with its law. Failure to provide a consent that complies with the laws applicable to the responding state will result in rejection of the request, unless the disclosure is otherwise permitted without a consent. Similarly, inconsistencies in state laws including, without limitation, restrictions on secondary disclosure of PHI could lead to potential liability.

Uses and disclosures of PHI by organizations located within the jurisdiction of the state of Illinois must satisfy the federal Health Insurance Portability and Accountability Act (HIPAA) and certain Illinois state statutes. These statutes include the following:

- **General Medical Records:** Physicians, health care providers, health services corporations, agents and employees of hospitals, and insurance companies are prohibited from disclosing the nature or details of services provided to patients, except to: (a) the patient; (b) the patient's representative responsible for treatment decisions; (c) parties directly involved in *providing treatment* or *processing the payment* for such treatment; (d) parties responsible for peer review, utilization review, and quality assurance; and (e) parties required to be notified under certain other acts (such as for reporting child abuse or certain sexually transmitted diseases) or where otherwise authorized or required by law.
- **HIV/AIDS Test Results:** Illinois law prohibits persons from disclosing the identity of any person upon whom an HIV test is performed, or the results of such a testing in a manner which permits identification of the subject of the test, except to certain persons under certain conditions. These conditions include "[a]n authorized agent or employee of a health facility or health care provider if . . . the agent or employee *provides patient care* . . . , and the agent or employee has a need to know such information."<sup>50</sup>
- **Genetic Testing Information:** "[G]enetic testing and information derived from genetic testing is confidential and privileged and may be released only to the

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<sup>50</sup> 410 ILCS 305/9 (2008).

individual tested and to persons specifically authorized, in writing . . . ,” with certain exceptions, including to “[a]n authorized agent or employee of a health facility or health care provider if . . . the agent or employee *provides patient care*, and the agent or employee has a need to know the information in order to conduct the tests or provide care of treatment.”<sup>51</sup>

- **Mental Health and Developmental Disabilities:** “Records and communications may be disclosed . . . only with the written consent of those persons who are entitled to inspect and copy a recipient’s record.”<sup>52</sup> (Note: this list of people does not include a health care provider.)
- **Alcohol or Drug Abuse:** Records “may be disclosed only in accordance with the provisions of federal law and regulations concerning the confidentiality of alcohol and drug abuse patient records.”<sup>53</sup> These generally do not permit the disclosure of these records, except in emergencies, unless there is written consent.

In addition, each state may have inconsistent consent requirements, including those that apply specifically to certain individuals. For example, states may define minors differently by age or have different requirements for emancipation, which determines when they may legally consent.

For this analysis, there are two scenarios: (1) Scenario 1, in which the responding state has more stringent consent requirements for the release of PHI than that of the requesting state; and (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state. The difference in consent requirements establishes an impediment to the efficient delivery of health information needed to treat the patient because health providers in the responding and requesting state may not be able to disclose or access the information, respectively, without opening themselves up to civil or criminal liability.

The commissioners drafting a model act to address these conflicts between the two states may consider three possible approaches.

### ***Approach 1—Responding State Prevails***

The commissioners could recommend a model act that provides that health information properly consented in the *responding* state will be accepted by the requesting state, the requesting state’s consent laws notwithstanding. Most state laws currently require providers in the responding state to comply with their own laws so this approach is closest to the status quo.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in “Assumptions”) would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state

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<sup>51</sup> 410 ILCS 513/15 (2008).

<sup>52</sup> 740 ILCS 110/5 (2008).

<sup>53</sup> 20 ILCS 301/30-5(bb) (2008).

(i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state determined what the responding state’s consent laws were and presented the responding state with a consent that fulfilled these more stringent laws.

Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state presented the responding state with a consent that fulfilled the responding state’s consent laws, which could presumably be done by using a consent from the requesting state because its laws are more stringent.

### ***Approach 2—Requesting State Prevails***

The commissioners could recommend a model act that provides that the consent laws of the requesting state would govern the exchange of PHI (i.e., before PHI could be sent to the requesting state, a patient consent must meet the requirements of the requesting state). This approach requires requesting states to be familiar with only their own state’s laws, instead of being prepared to obtain consents that satisfy various responding states’ laws.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in “Assumptions”) would receive and be permitted to use PHI if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws even if they were less stringent than the responding state; or (b) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state). Presumably, if the responding state’s laws were satisfied, the requesting state’s laws would also be satisfied.

Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI only if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws; or (b) the responding state obtains the information by voluntarily obtaining a more stringent consent that also fulfills the laws of the requesting state.

### ***Approach 3—Uniform Consent***

NCCUSL could determine that the best solution would be a uniform consent requirement that would govern the interstate exchange of PHI. PHI would be exchanged if the requirements of the model act were met.

## Choice of Law

A choice of law provision in a contract, between entities that are exchanging PHI interstate, would require an analysis of the laws to the two states, and consistency. Statutory choice of law would require consensus building to develop an inclusive choice of law, or the choice of law could be designed to only support state law.

Choice of law provisions are a mechanism for eliminating uncertainty and can prevent potential disputes regarding the law that governs a particular transaction. Choice of law provisions might be simple or complex. For example, the provision may simply select one state's labor, discrimination, and similar laws to govern all disputes that may arise out of the transaction. Or, the drafters could establish a completely new set of such laws through negotiation and collaboration to address every aspect of the health information exchange (HIE) transaction. Alternatively, the provision may simply establish which state's (i.e., the responding state or the requesting state's) laws apply in a given situation. And of course, there are a myriad of options that span across a spectrum that includes these various options.

If one state's laws are chosen to govern all transactions, another important issue that will need to be addressed includes whether the law which is chosen is to remain static or if it will change as the chosen state's laws are amended. The choice of law provision could adopt an implicit or explicit modification of the applicable law if the underlying state's law is subsequently modified.

A contractual provision only governs conduct between the parties, and does not take precedence over statutory law. For example, if a state consent statute prohibits a disclosure, the parties to a contract cannot violate such prohibition in that state on the basis of having agreed contractually to apply a different state's laws that would permit the disclosure. The contractual choice of law provision would offer little or no protection from criminal or civil liability for violation of an applicable state statute.

A second approach to the choice of law option would be to have the states pass a statute specifying the choice of law in PHI exchanges. The statutory choice of law provision could work so long as both the responding state and the requesting state enact a consistent choice of law provision.

The choice of law provision (either by contract or by statute) could specify that the law of the requesting state should apply, which, per the scenarios in the "Assumptions," would mean that, in some cases, the more stringent consent laws would apply, and in others, that the less stringent consent laws would apply. In Scenario 1, the consent presented to the HIO member would be less stringent than the requirements of the HIO member's state, so the HIO member would want the assurance of a choice of law provision to make the disclosure without risk of civil or criminal liability. In Scenario 2, the consent presented to

the HIO member in the responding state for the release of PHI would be more stringent than the requirements of the HIO member's state, so the HIO member could make the disclosure confident that no civil or criminal liability would accrue.

Alternatively, the choice of law could specify that the responding state's law would apply. This approach is the current practice, as each responding party reviews disclosure requests and consent forms to ensure that they are compliant with the laws applicable to the responding party. Currently, if the consent does not satisfy the responding state's laws, the disclosure is delayed while the requesting party obtains and submits a satisfactory consent. To avoid such a delay, the requesting state would need to remain familiar with each responding state's laws and each change to them.

Note that the structure of the HIO also impacts the disclosure and consent process. If the HIO as an entity makes the disclosure, then it is also an actor that could potentially incur liability, and it may be located in, and subject to the laws of, a third state. In this situation, having an agreement among all the parties to use the requesting state's law avoids the added complexity of having a third state's laws apply to information collected under one state's laws and being requested for disclosure under a second state's laws.

Choice of law provisions are a mechanism for eliminating uncertainty and can prevent potential disputes regarding the law that governs a particular transaction. Choice of law provisions might be simple or complex. For example, the provision may simply select one state's labor, discrimination, and similar laws to govern all disputes that may arise out of the transaction. Or, the drafters could establish a completely new set of such laws through negotiation and collaboration to address every aspect of the HIE transaction. Alternatively, the provision may simply establish which state's (i.e., the responding state or the requesting state's) laws apply in a given situation. And of course, there are a myriad of options that span across a spectrum that includes these various options.

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### **Interstate Compact—Pro**

- + Informal development will foster expertise, and legislatively approved development will foster sponsors.
- + Allows the states (as opposed to the federal government) to draw the parameters, not only for participation in the compact, but also for developing dispute resolution procedures. This can lead to increased effectiveness and efficiency, as well as flexibility and autonomy. While the threat of federal preemption or mandates is

lessened, it is important to note (as set forth below) that congressional consent will likely transform the final product into federal law.

- + The process for developing interstate compacts, described by the CSG, was determined to be a reasonable and appropriate process by which standardization of disparate state consent processes could be achieved. Being able to work through a number of state legislatures would allow for the main relevant issues to surface during the drafting process. This process allows for the issues to be examined in depth during the process. The requirement for enacting an interstate compact only after a preset number of states join the compact may help to promote widespread adoption.
- + If an interstate compact is successfully adopted by multiple states, standard provisions could be used by a large number of states. The adoption of standard provisions would be a benefit to organizations attempting to disclose PHI across state lines to other organizations in an HIO network.

### ***Approach 1—Responding State Prevails***

- May be easiest to implement because it is closest to the status quo and does not require the responding state to be familiar with any other state’s requirements.
- Could be implemented by a responding state obtaining a consent at the time it collects the information from patients rather than at the time of the request from the requesting state. If consent obtained in the responding state allows for broad disclosure to other states for treatment (or even for other purposes), information could flow quickly once the requesting state submits a request that meets the responding state’s requirements.
- In Scenario 1 (the responding state has *more* stringent consent laws), if the consent was obtained at the time of collection, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- In Scenario 1 (the responding state has *more* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- In Scenario 2 (the responding state has *less* stringent consent laws), information could flow easily and quickly if the requesting state complies with its own, more stringent laws, which are those with which it is most likely to be familiar.

### ***Approach 2—Requesting State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- In Scenario 1 (the responding state has *more* stringent consent laws), information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure.

- This approach requires requesting states to be familiar with only their own state’s laws, instead of being prepared to obtain consents that satisfy various responding states’ laws.

### ***Approach 3—Compact Defined Consent***

- A uniform process enacted by the states will be easier to understand in the context of interstate exchange of PHI.
- A uniform consent form would be developed, and each state could become familiar with a consistent set of documentation to permit access and disclosure of information.

### **Uniform Law—Pro**

- + NCCUSL is uniquely organized and qualified to draft any uniform or model state laws that might be recommended.
- + With the support of the State Alliance and National Governors Association (NGA), such acts could be efficiently and expediently produced and enacted by the states.
- + The process for the adoption of a uniform law, by including the opportunity for comment and feedback by representatives from all 50 states and the favorable vote by at least a majority of the states present (and not less than 20 states), makes it more likely that an act will receive favorable treatment when finally presented to each state legislature.
- + The NCCUSL has representation from every state, including Illinois, which currently has 11 commissioners participating. The process allows for the issues to be examined in depth by the commissioners, who work toward consensus. The requirement that the act is approved by a large number of states before being recommended may help to promote widespread adoption. In addition, the NCCUSL is a respected organization, and its endorsement of an act may influence states to adopt it.

In the current situation, working with the NCCUSL to draft and endorse a uniform act does provide an avenue by which standardization of disparate state consent processes could be achieved. If a uniform act is successfully drafted and supported by the NCCUSL, standard provisions could be adopted verbatim or in consistent principle by a large number of states. Such adoption of standard provisions would be a benefit to organizations attempting to disclose PHI across state lines to other organizations in an HIO network. Standardized provisions will be in place for all states that adopt the uniform act. Also, more effort might be made by other credible organizations, in addition to NCCUSL, as part of the drafting process and thus bring more opportunity to bring forward best possible solutions.

### **Model Law—Pro**

- + NCCUSL is uniquely organized and qualified to draft any uniform or model state laws that might be recommended.
- + Different organizations can draft model laws.
- + States can adapt what best fits their needs.

- + The procedures for adoption of model acts, like those for the adoption of uniform laws, involve a significant amount of participation by state representatives and make it more likely that the model act will be well received by the individual states when submitted for adoption. In addition, if a proposed uniform law becomes too controversial to be adopted as a uniform law, it may find better success as a model act.
- + The NCCUSL has representation from every state, including Illinois, which currently has 11 commissioners participating. The process allows for the issues to be examined in depth by the commissioners, who work toward consensus. The requirement that the act is approved by a large number of states before being recommended may help to promote widespread adoption. In addition, the NCCUSL is a respected organization, and its endorsement of an act may influence states to adopt it.
- + In the current situation, working with the NCCUSL to draft and endorse a model act does provide an avenue by which standardization of disparate state consent processes could be achieved. If a model act is successfully drafted and supported by the NCCUSL, standard provisions could be adopted verbatim or in consistent principle by a large number of states. Such adoption of standard provisions would be a benefit to organizations attempting to disclose PHI across state lines to other organizations in an HIO network. Standardized provisions will be in place for all states that adopt the model act. Also, more effort might be made by other credible organizations, in addition to NCCUSL, as part of the drafting process and thus bring more opportunity to bring forward best possible solutions.
- + May be easiest to implement because it is closest to the status quo and does not require the responding state to be familiar with any other state’s requirements.
- + Could be implemented by a responding state obtaining a consent at the time it collects the information from patients rather than at the time of the request from the requesting state. If consent obtained in the responding state allows for broad disclosure to other states for treatment (or even for other purposes), information could flow quickly once the requesting state submits a request that meets the responding state’s requirements.
- + In Scenario 1 (the responding state has *more* stringent consent laws), if the consent was obtained at the time of collection, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- + In Scenario 1 (the responding state has *more* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- + In Scenario 2 (the responding state has *less* stringent consent laws), information could flow easily and quickly if the requesting state complies with its own, more stringent, laws, which are those with which it is most likely to be familiar.
- + In Scenario 2 (the responding state has *less* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- + In Scenario 1 (the responding state has *more* stringent consent laws), information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that

complies with its own laws. It would be irrelevant that the responding state's laws would not have permitted the disclosure.

- + This approach requires requesting states to be familiar with only their own state's laws, instead of being prepared to obtain consents that satisfy various responding states' laws.
- + A uniform process enacted by the states will be easier to understand in the context of interstate exchange of PHI.
- + A uniform consent form would be developed, and each state could become familiar with a consistent set of documentation to permit access and disclosure of information.

## **Choice of Law—Pro**

### ***Contractual Provisions***

- + Ease of negotiating terms.
- + Many entities already doing it.
- + Can customize it to fit unique situations.
- + A contractual choice of law provision is relatively simple to enact and does not require legislative action. The parties need only to write a suitably worded provision into their agreement after selecting the law.

### ***Statutory Provision***

- + Uniform for state.
- + More buy-in and open to the consumer and community.
- + Easily understood process.
- + A statutory choice of has the force of the law behind it and, if implemented appropriately, could be relied upon by parties exchanging PHI.
- + A choice of law provision will protect the justified expectations of the parties and make it possible for them to foretell with accuracy what will be their rights and liabilities in a given situation. This is even more true if one state's laws are selected, as there would be a complete and coherent set of norms that apply. In other words, rather than assimilating norms and provisions from various sources, a "single source" approach would bring with it a unitary and integrated set of laws to the table.
- + Regardless of whether a single state's laws are chosen, or if multiple states' laws are assimilated into a new framework, the selection could focus on state laws that have already been interpreted by the courts, thereby allowing a greater degree of certainty about what those laws mean.
- + By establishing a choice of law provision, each party presumably would be precluded from later arguing (or litigating) that the law of its own state is to apply. Without such a clause, the parties will need to be aware of the panoply of problems they are creating by having no legal norms and no means of defined, adequate redress for the affected parties.

### **Interstate Compact—Con**

- California would need to have a strong presence to ensure development is consistent with California ideals.
- Congressional approval may have the effect of transforming the interstate compact into federal law. Accordingly, the compact’s language and interpretation could be at the mercy of the federal government, including the federal courts. Courts could hold unenforceable state laws that are inconsistent with federal and interstate interests.
- Enactment of an interstate compact requires working with a number of state legislatures, which could become difficult with a long negotiation process. For instance, issues such as privacy issues, identifying responsible parties, and other items related to compiling comments and research could be time consuming with various legislators. The education phase would require the building of buy-in, potentially across a number of very different state stakeholders. In addition to the work required for enactment, the transition process could also become bogged down if there is not early agreement on the development of rules, regulations, forms, standards, etc. by which the compact will need to operate.
- The process also seems like a lot of work which may not be ultimately successful if it does not get adopted by a majority of states. There is no requirement that states ultimately adopt an interstate compact so a significant amount of effort could be made to draft language that is ultimately not adopted by enough states. This would mean that a barrier to HIE would still exist between compact member states and nonmember states.

### ***Approach 1—Responding State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), there is a lesser focus on privacy concerns which could be objectionable to privacy advocates.
- In Scenario 1 (the responding state has *more* stringent consent laws), the responding state will require compliance with its own state laws before permitting the disclosure. This may delay the release of the PHI if the requesting state submits a consent that does not meet the higher standards of the responding state. A more stringent consent would need to be obtained from the patient unless the responding state has already obtained an appropriate consent at the time the information was collected.

### ***Approach 2—Requesting State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), access to PHI in the requesting state will be delayed while health care providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards. This may impede or delay the provision of needed health care.
- Health care providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- In Scenario 1 (the responding state has *more* stringent consent laws), this approach may raise objections from responding states that do not wish to release PHI under less demanding consent requirements.

- The approach cannot be implemented in advance because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information.

### ***Approach 3—Compact Defined Consent***

- The drafting group may have difficulty finding agreeable consensus language, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approach 1 or 2.
- If the compact defined consent is not implemented properly, the failure to provide adequate education on new requirements would result in confusion by health care providers over required procedures.
- For states that have fairly lenient consent requirements, this approach could be objectionable if the compact defined consent imposes new, more stringent requirements.
- For states that have fairly robust consent requirements, this approach could be objectionable to privacy advocates if the compact defined consent imposes less stringent requirements and reduces the emphasis on privacy.

### **Uniform Law—Con**

- States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. The process seems like a lot of work which may not be ultimately successful if it does not get adopted by a majority of states. There is no requirement that states ultimately adopt the uniform law so a significant amount of effort could be made to draft an act that is ultimately not enacted by enough states.
- By requiring so much participation by the representatives of each state, the act of promulgating a uniform law can be sidelined by opposition by several states and can be delayed if the act needs to be redrafted to meet various objections. In addition, because the uniform law is intended to be adopted without changes, it may meet more resistance to adoption by states than the more flexible model law.

### **Model Law—Con**

- The process is lengthy and potentially contentious, even though NCCUSL is uniquely organized and qualified to draft any uniform or model state laws that might be recommended.
- The largest drawback to the model act approach is the greater likelihood that there will be significant variations from state to state—which although unlikely to be as diverse as the current situation, would not appear to be as useful as a uniform act in addressing the need for uniform standards for the electronic movement of health-related information among organizations.
- States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. The process seems like a lot of work which may not be ultimately successful if it does not get adopted by a majority of states. There is no requirement that states ultimately adopt the model act so a significant amount of effort could be made to draft an act that is ultimately not enacted by enough states.

- The lack of emphasis on verbatim adoption of the model act may result in confusion as even small word changes can make a big difference. The NCCUSL might recommend language for the model act, but there is no requirement for the act to contain certain terms. The process has also too much opportunity for states to adopt conflicting rules, since recommendations could potentially come from a wide variety of groups.
- In Scenario 2 (the responding state has *less* stringent consent laws), there is a lesser focus on privacy concerns which could be objectionable to privacy advocates.
- In Scenario 1 (the responding state has *more* stringent consent laws), the responding state will require compliance with its own state laws before permitting the disclosure. This may delay the release of the PHI if the requesting state submits a consent that does not meet the higher standards of the responding state. A more stringent consent would need to be obtained from the patient unless the responding state has already obtained an appropriate consent at the time the information was collected.
- In Scenario 2 (the responding state has *less* stringent consent laws), access to PHI in the requesting state will be delayed while health care providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state's higher standards. This may impede or delay the provision of needed health care.
- Health care providers in the responding state will be required to determine the requirements of the requesting state's laws before they release the information, which could delay the release of data for HIE purposes.
- In Scenario 1 (the responding state has *more* stringent consent laws), this approach may raise objections from responding states that do not wish to release PHI under less demanding consent requirements.
- The approach cannot be implemented in advance because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information.
- If the uniform consent is not implemented properly, the failure to provide adequate education on new requirements would result in confusion by health care providers over required procedures.
- For states that have fairly lenient consent requirements, this approach could be objectionable if the uniform consent imposes new, more stringent requirements.
- For states that have fairly robust consent requirements, this approach could be objectionable to privacy advocates if the uniform consent imposes less stringent requirements and reduces the emphasis on privacy.

## **Choice of Law—Con**

### ***Contractual Provisions***

- May not resolve legal liability issues.

### ***Statutory Provision***

- Complexity of legislative process and nonuniformity in adoption by other states.

- Less nimble than contracts.
- If too California-centric, may hinder exchange.
- Passing a choice of law statute could be difficult and time consuming, and could include undesired modifications and amendments during the legislative process.
- Note that a statutory choice of law provision will only work if all parties to the exchange also enact a consistent choice of law. In addition, since the choice of law only determines which state's laws will apply to the exchange of PHI, it will also be crucial that the laws that already govern PHI exchange be consistent.
- Increased time for negotiation and development of an appropriate choice of law provision, particularly given each state's interest in protecting the health information of its citizens.

## 2. Length of Time Required to Formulate

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

### Interstate Compact

An advisory committee would be expected to take at least 1 year to draft compact language. Timing of the presentation to the states would be critical since some do not have annual legislative sessions. The language of the compact may require a minimum number of states to ratify before it can become effective. Depending upon the scope of the compact, congressional approval could be required.

Unfortunately, there is no clear answer regarding the length of time required to formulate a compact, but based upon past Ohio experience, it appears that from the initial meeting of the advisory committee to the time the compact takes effect could take several years.

CSG provided the following insight into the time frame for adopting interstate compacts:

"A study of 65 interstate compacts, conducted in the early 1960s, indicated that the average amount of time required to launch a new compact was almost 5 years. But that study was admittedly skewed by the unusually long time required for the approval of several compacts that dealt with controversial natural resource issues. In fact, the average time required to enact 19 compacts covering river management and water rights was almost 9 years.

More recently, however, interstate compacts have enjoyed great rapidity in their adoption. The Interstate Compact for Adult Offender Supervision was adopted by 35 states in just 30 months. Other recent compacts, including the new Interstate Insurance Product Regulation Compact are enjoying fast success, gaining quick adoptions over a period of 2–3 years.

In recent years, there have been some remarkable success stories. For example, in December 1989, a committee of the Midwestern Legislative

Conference approved draft language for the Midwestern Higher Education Compact and began circulating it to lawmakers in the 12 Midwestern states that were eligible to participate. Just 13 months later, the compact became effective.”<sup>54</sup>

Only under the most ideal circumstances could adoption of an interstate compact relating to the interstate exchange of health information occur in 2 years. Three years would be an optimistic estimate for adoption.

An examination of PHI requests may reveal that the vast majority of requests involving Illinois providers are with entities in only a small number of states. The compact may wish to address a limited number of states initially, rather than attempt national acceptance.

### **Uniform Law**

Drafting a uniform law generally takes 3 to 5 years, according to NCCUSL. This time frame would also be affected either way by the deliberations of a study committee. The NCCUSL created the Study Committee on Health Care Information Interoperability a few years ago to look at the issue.

Under the best of circumstances, adoption of the uniform law among a meaningful number of states will take at least another 2 years—for a total of 5 to 7 years. According to Katie Robinson, NCCUSL Communications Officer, if the NCCUSL drafts in an area where Congress does not draft, where there is a clear and timely need in states, there is a good chance for success.

### **Model Law**

Depending on the group chosen to develop the model law, this process can take years to complete. Once the model law is formed, then it will take even more time for each state to figure out what part they want to adopt and then to go through the legislative process to adopt it. Further implementation may require the adoption of regulations.

None of the organizations which could promulgate a model act is likely to take less than several years. Once promulgated by an organization, a model act is officially offered for consideration by the states. Model acts are designed to serve as guideline legislation, which states can borrow from or adapt to suit their individual needs and conditions.

Drafting a model act generally takes 3 to 5 years, according to NCCUSL Communications Officer Katie Robinson. A longer formulation process would be expected if a study committee were established. The NCCUSL created the Study Committee on Health Care Information Interoperability a few years ago to look at the issue. According to W. Grant Callow, Chair, the committee has been waiting for the NGA to give them a report that

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<sup>54</sup> Compacts as a Tool of the Game, Council of State Governments website. Available at <http://www.csg.org/programs/ncic/resources.aspx>.

summarizes NGA’s recommendation on the best legal mechanism to address electronic exchange of PHI.

In the Turning Point National Collaborative on Public Health Statute Modernization example discussed previously, that collaborative’s model act was “released on September 16, 2003 after 3 years of development and a national commentary period.”<sup>55</sup>

Under the best of circumstances, adoption of the model act among a meaningful number of states will take at least another 2 years for a total of 5 to 7 years from the start of development until formal adoption.

### **Choice of Law**

Health Information Security and Privacy Collaboration (HISPC) collaboratives have done research on commonality of the laws and contract language, which could speed up the formulation process.

A contractual agreement could be performed relatively quickly, depending on the amount of time the organization desires for review and execution by the approving authority. Potentially, a contractual agreement could be negotiated and reviewed in a matter of weeks or less. It should be noted, however, that if different parties to the contractual agreement have different interests to protect, the negotiation process could be longer.

A statute to address the issue would be subject to the legislative process and would be scheduled for review and action, the same as any other legislation. There is no method to estimate the time required to introduce and pass legislation. Potentially, legislation could be proposed, pass committee review, be scheduled for the required readings, approved, and promptly signed into law. More likely, the legislation would advance in fits and starts as more major bills, such as appropriations, command the attention of the legislature. Often, legislation is left incomplete at the end of the legislative term and dies without having been acted upon. As a result, the time required to obtain approval of a statute could exceed 1 year.

Deciding which laws should apply and drafting the appropriate language will obviously lengthen the negotiation and drafting processes and could delay agreement as the interested parties would need to come to decisions on a whole new set of issues. Because every state has its own health care laws, and often laws governing confidentiality and other HIE-related issues, this may be an extensive process.

### **Interstate Compact—Pro**

- + The more that policy makers are interested, the quicker it will get done.

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<sup>55</sup> Centers for Law and the Public’s Health website. Available at <http://www.publichealthlaw.net/ModelLaws/MSPHA.php>.

- + While formulating an effective interstate compact is expected to be a lengthy process, the end result will be a negotiated agreement among the participating states, which would hopefully offset later delays occasioned by individual states' objections to the provisions of the compact. In other words, presumably the states that agree to and execute the compact will not thereafter seek to challenge its terms.

### **Uniform Law—Pro**

- + NCCUSL has successfully drafted and enacted many diverse laws.
- + Given the multiyear drafting and adoption timeline, multiple reviewers will have the opportunity to look at the model language and create the best solution. If the consent law drafted was simple, with a limited amount of revision to existing consent requirements, this might take less time to develop and be more quickly adopted by a majority of states.
- + The process for the adoption of a uniform law, by including the opportunity for comment and feedback by representatives from all 50 states and the favorable vote by at least a majority of the states present (and not less than 20 states), makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Ohio has been generally accepting of uniform laws.
- + One of the more recent examples is the adoption of the Uniform Electronic Transactions Act.

### **Model Law—Pro**

- + The procedures for adoption of model acts, like those for the adoption of uniform laws, involve a significant amount of participation by state representatives, which make it more likely that the model act will be reasonably well received by the individual states when submitted for adoption.
- + There is the possibility that a model act can be moved through on an expedited basis (i.e., on about 1 year's timetable). For instance, in summer 2008, the Uniform Interstate Family Support Act was considered and approved on an expedited basis in order to effectuate the Hague Convention on Maintenance. The Convention's federal enacting legislation states that a version of this act must be passed by the states by 2010, and so the ULC agreed to create and pass a model act for states on an expedited basis.
- + The general subject of expedited review was the subject of some extended discussion at the ULC's annual meeting in July 2008. The conference has done a good job of being very efficient and nimble where time is of the essence for certain acts, but such review has occurred only a few times. The consensus was that, given the ever-quickening pace of change and advancements (particularly in the realms of technology and international transactions), there would likely be a need for the conference to be willing to consider expedited review more frequently.
- + Given the multiyear drafting and adoption timeline, multiple reviewers will have the opportunity to look at the model language and create the best solution. If the consent law drafted was simple, with a limited amount of revision to existing consent requirements, this might take less time to develop and be more quickly adopted by a majority of states.

## **Choice of Law—Pro**

### ***Contractual Provision***

- + Significantly less time consuming than legislation.
- + Spending additional time on the “front end” establishing the applicable choice of law provision will likely lead to less time on the “back end” deciding which laws apply to a given dispute.

## **Interstate Compact—Con**

- Resolution of the issue and effective transfer of health and medical information will not be immediate under this process. By way of example, the negotiation and approval of the Great Lakes–St. Lawrence River Basin Water Resources Compact took 7 years from the initial stages through congressional approval in August 2008.

## **Uniform Law—Con**

- States have different legislative processes and calendars, so the time frame could be inconsistent and prolonged.
- Five to 7 years from development until adoption is a lengthy process, and multiple reviewers may also slow down the process more. Adoption by a significant number of states is not guaranteed. The process is lengthy and has the potential for limited success. Additional time will be required to bring state laws into alignment with the adopted uniform act. In addition, given the emphasis on patient privacy, it is likely that numerous interest groups would want input into the creation of a uniform act, thereby increasing the length of time for final adoption by states.

## **Model Law—Con**

- Time estimates are unknown and variable.
- States have different legislative processes and calendars, so the time frame could be inconsistent and prolonged.
- As indicated by the report of the ULC’s Study Committee, the process can take several years before the decision is made to begin the process to promulgate a model act. The actual process of promulgating a model act will take an additional 2 years at a minimum. The process of adoption by individual states will likely take several more. Other approaches may be quicker.
- Five to 7 years from development until adoption is a lengthy process, and multiple reviewers may also slow down the process more. Adoption by a significant number of states is not guaranteed. The process is lengthy and has the potential for limited success. Additional time will be required to bring state laws in alignment with the adopted model act. In addition, given the emphasis on patient privacy, it is likely that numerous interests groups would want input into the creation of a model act, thereby increasing the length of time for final adoption by states.

## Choice of Law—Con

### *Contractual Provision*

- Writing a choice of law provision might raise additional issues that the drafting committee or participating states may prefer to keep closed for the sake of getting the compact, model act, or uniform law finished.

### *Statutory Provision*

- Time consuming and will probably require additional regulations to implement.

## 3. Implementation Requirements

Identify the 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 appear necessary to implement each proposed mechanism.

### **Interstate Compact**

Typically, implementation steps would include the work of:

- Advisory group
- Drafting team
- Education
- Enactment
- Transition

A state enters into an enforceable and binding interstate compact when it follows the entry provisions set out in the compact. States need to explicitly follow the procedures for entry that are stated in the compact language.

In Ohio, there appear to be two mechanisms for approving an interstate compact. The General Assembly may authorize the governor or other official to execute the compact. See, for example, R.C. 2151.56 (Interstate Compact on Juveniles); R.C. 5101.141 (authorizing the director of the department of job and family services to enter into interstate compacts for the provision of medical assistance and other social services to children in certain circumstances).

More commonly, the General Assembly enacts the compact's language as Ohio law. See, for example, R.C. 109.971 (National Crime Prevention and Privacy Compact); R.C. 921.60 (Pest Control Compact); R.C. 1503.41 (Middle Atlantic Interstate Forest Fire Protection Compact); R.C. 1514.30 (Interstate Mining Compact); R.C. 1522.01 (Great Lakes–St. Lawrence River Basin Water Resources Compact); R.C. 3301.48 (Interstate Compact for Education); R.C.

3747.01 (Midwest Interstate Compact and Commission on Low-level Radioactive Waste); R.C. 3915.16 (Interstate Insurance Product Regulation Compact); R.C. 5103.20 (Interstate Compact for the Placement of Children); R.C. 5119.50 (Interstate Compact on Mental Health); R.C. 5149.21 (Interstate Compact for Adult Offender Supervision). In either event, it appears the General Assembly has typically enacted the language of the compact and required that the final version be “substantially” the same as the language it has enacted. And the General Assembly may enact companion statutes at the same time as part of the legislation. See, for example, R.C. 3747.02-.03 (related to the Midwest Interstate Compact and Commission on Low-level Radioactive Waste); R.C. 1522.02-.08 (related to the Great Lakes–St. Lawrence River Basin Water Resources Compact).

In addition, the compact may include language setting forth many parameters, including: (a) the number of states that must agree to the compact before it will take effect; (b) the necessity for congressional consent; (c) the method by which a state must consent to the compact (e.g., signature or legislative enactment).

### **Uniform Law**

The implementation requirements will be dependent on many variables. If the uniform law sets a specific consent policy, then implementation would require the review of any existing contracts that may be contrary to the uniform law. In drafting new agreements, a uniform law would alleviate the obligation to determine the consent policy and could be implemented when the other terms of the agreement are reached. If the negotiating partner comes from a state that has not adopted the uniform law, then the parties would be in the same position they are now.

Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the governor, or an override by the legislature if the governor would veto the bill. Illinois has enacted over 95 uniform and model acts according to NCCUSL.

***Illinois Law Concerning PHI Disclosures:*** Health care providers, HIOs, and other health-related organizations must comply with applicable state and federal requirements when disclosing a person’s PHI. These requirements can create barriers or inefficiencies to disclosure of PHI, particularly when the organizations sharing the PHI reside in different states.

Before disclosing PHI to any entity (within or without the state), a disclosing organization must comply with the state and federal law applicable to the disclosing organization. For instance, a disclosing organization in Illinois must comply with Illinois and federal laws, even if the request comes from another state. Similarly, a disclosing organization residing in another state must comply with federal laws and the laws of its state, even if an

organization in Illinois requests the information. In effect, the current status of the law is that the responding state's laws control the disclosure.

As a result, the requesting organization must be familiar with, and comply with, the state consent laws of each different jurisdiction from which it desires to obtain PHI. In practice, this is typically done by using forms or documents that the disclosing entity provides and has already determined comply with its law. Failure to provide a consent that complies with the laws applicable to the responding state will result in rejection of the request, unless the disclosure is otherwise permitted without consent.

Similarly, inconsistencies in state laws including, without limitation, restrictions on secondary disclosure of PHI could lead to potential liability.

Uses and disclosures of PHI by organizations located within the jurisdiction of the state of Illinois must satisfy the federal HIPAA and certain Illinois state statutes. These statutes include the following:

**General Medical Records:** Physicians, health care providers, health services corporations, agents and employees of hospitals, and insurance companies are prohibited from disclosing the nature or details of services provided to patients, except to: (a) the patient; (b) the patient's representative responsible for treatment decisions; (c) parties directly involved in *providing treatment or processing the payment* for such treatment; (d) parties responsible for peer review, utilization review, and quality assurance; and (e) parties required to be notified under certain other acts (such as for reporting child abuse or certain sexually transmitted diseases) or where otherwise authorized or required by law.

**HIV/AIDS Test Results:** Illinois law prohibits persons from disclosing the identity of any person upon whom an HIV test is performed, or the results of such a testing in a manner which permits identification of the subject of the test, except to certain persons under certain conditions. These conditions include "[a]n authorized agent or employee of a health facility or health care provider if . . . the agent or employee *provides patient care* . . . , and the agent or employee has a need to know such information."<sup>56</sup>

**Genetic Testing Information:** "[G]enetic testing and information derived from genetic testing is confidential and privileged and may be released only to the individual tested and to persons specifically authorized, in writing . . . ," with certain exceptions, including to "[a]n authorized agent or employee of a health facility or health care provider if . . . the agent or employee *provides patient care*, and the agent or employee has a need to know the information in order to conduct the tests or provide care of treatment."<sup>57</sup>

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<sup>56</sup> 410 ILCS 305/9 (2008).

<sup>57</sup> 410 ILCS 513/15 (2008).

***Mental Health and Developmental Disabilities:*** “Records and communications may be disclosed . . . only with the written consent of those persons who are entitled to inspect and copy a recipient’s record.”<sup>58</sup>

***Alcohol or Drug Abuse:*** Records “may be disclosed only in accordance with the provisions of federal law and regulations concerning the confidentiality of alcohol and drug abuse patient records.”<sup>59</sup> These generally do not permit the disclosure of these records, except in emergencies, unless there is written consent.

In addition, each state may have inconsistent consent requirements including those that apply specifically to certain individuals. For example, states may define minors differently by age or have different requirements for emancipation, which determines when they may legally consent.

For this analysis, there are two scenarios:

- (1) Scenario 1, in which the responding state has more stringent consent requirements for the release of PHI than that of the requesting state; and
- (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state. The difference in consent requirements establishes an impediment to the efficient delivery of health information needed to treat the patient because health providers in the responding and requesting state may not be able to disclose or access the information, respectively, without opening themselves up to civil or criminal liability.

The commissioners drafting a uniform law to address these conflicts between the two states may consider three possible approaches.

### ***Approach 1—Responding State Prevails***

The commissioners could recommend a uniform law that provides that health information properly consented in the responding state will be accepted by the requesting state, the requesting state’s consent laws notwithstanding. Most state laws currently require providers in the responding state to comply with their own laws, so this approach is closest to the status quo.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in “Assumptions”) would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state determined what the responding state’s consent laws were and presented the responding state with a consent that fulfilled these more stringent laws.

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<sup>58</sup> 740 ILCS 110/5 (2008).

<sup>59</sup> 20 ILCS 301/30-5(bb) (2008).

Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state presented the responding state with a consent that fulfilled the responding state’s consent laws, which could presumably be done by using a consent from the requesting state because its laws are more stringent.

### ***Approach 2—Requesting State Prevails***

The commissioners could recommend a uniform law that provides that the consent laws of the requesting state would govern the exchange of PHI (i.e., before PHI could be sent to the requesting state, a patient consent must meet the requirements of the requesting state). This approach requires requesting states to be familiar with only their own state’s laws, instead of being prepared to obtain consents that satisfy various responding states’ laws.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in “Assumptions”) would receive and be permitted to use PHI if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws even if they were less stringent than the responding state; or (b) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a “blanket” consent from patients that permitted disclosure for the purposes requested by the requesting state).

Presumably, if the responding state’s laws were satisfied, the requesting state’s laws would also be satisfied.

Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI only if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws; or (b) the responding state obtains the information by voluntarily obtaining a more stringent consent that also fulfills the laws of the requesting state.

### ***Approach 3—Uniform Consent***

NCCUSL could determine that the best solution would be a uniform consent requirement that would govern the interstate exchange of PHI. PHI would be exchanged if the requirements of the uniform law were met.

In order to implement a uniform law in Ohio, we would need to identify General Assembly proponent(s), prepare and provide proponent testimony as necessary in both houses, obtain a majority in each house, and obtain the governor’s signature (or an override, if vetoed).

The implementation could use the existing connections between members of the Ohio HISPC and the Legal Work Group (LWG).

In working with the General Assembly, we could liaison with existing infrastructure for lobbying and analysis through medical and legal associations. For example, the General Assembly often turns to the Ohio State Bar Association (OSBA), the Ohio State Medical Association, the Ohio Hospital Association, and local medical and hospital societies for advice and counsel on health care legislation, so support and understanding from these groups would be key. The OSBA Health Care Law Committee would be a good forum to work within as that group includes many of our LWG members and is an existing vehicle for input to the OSBA, which in turn is highly regarded by the legislature for legal analysis.

In addition, our many LWG members from state agencies (Ohio Department of Health [ODH], Ohio Department of Job and Family Services [ODJFS], Ohio Bureau of Workers' Compensation [BWC]) and our members who sit on the governor's Health Information Partnership Advisory Board (HIPAB), a component of Governor Strickland's health information technology (IT) plan, could serve as liaisons to develop support at the executive branch strategy.

After adoption, the uniform law would need likely need implementing regulations, which would be handled by a government agency. The government agency would need to be sufficiently empowered and funded to ensure that the uniform law is appropriately implemented.

### **Model Law**

The implementation requirements will be dependent on many variables. If the model law sets a specific consent policy, then implementation would require the review of any existing contracts that may be contrary to the model law. In drafting new agreements, a model law would alleviate the obligation to determine the consent policy and could be implemented when the other terms of the agreement are reached. If the negotiating partner comes from a state that has not adopted the model law, then the parties would be in the same position in which they are now.

In order to implement a model act in Ohio, we would need to identify General Assembly proponent(s), prepare and provide proponent testimony as necessary in both houses, obtain a majority in each house, and obtain the governor's signature (or an override, if vetoed). The implementation could use the existing connections between members of the Ohio HISPC and the LWG.

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After adoption, the model act would likely need implementing regulations, which would be handled by a government agency. The government agency would need to be sufficiently empowered and funded to ensure that the model act is appropriately implemented.

Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the governor, or an override by the legislature, if the governor would veto the bill. Illinois has enacted over 95 uniform and model acts according to NCCUSL.

### **Choice of Law**

If the "choice of law" is determined statutorily, such as a provision that declares California privacy rights cannot be waived by contract or otherwise impinged; then implementation would require the review of any existing contracts that may be contrary to California law.

In the absence of statutorily mandated choice of law, the parties are free to negotiate terms that will permit them to customize the flow of information to accommodate the laws of their state and, if needed, with the consent of the individual.

Contractual provisions can be implemented immediately after approval, in the time required to disseminate modified policies and procedures for consents, and to train the responsible staff in their use.

Implementation of a statute requires passage of the legislation, after which the statute may be implemented anytime after its effective date. The HIOs can implement compliance measures at any time, provided that such compliance measures do not conflict with other applicable laws. Often, statutes include requirements for implementation activities such as the creation of a training program and development of forms and procedures that implement elements of the statute.

With respect to issues of consent, the implementation requirements should be forthright. The requesting party could generate a consent form that satisfied the statutes applicable in their state, and ensure that each patient completed it prior to requesting such patient's PHI. Alternatively, the HIO members could identify the state with the most stringent consent requirements, and agree contractually to implement a consistent system that is compliant with the most stringent criteria and compliant with all other HIO states' statutes as well. In

this case, all the HIO member states could use a single consent form that was mutually compliant with each of the other states' consent requirements. If a state from outside the HIO requested PHI and had more stringent consent requirements, that state could be responsible for obtaining such consent from the patient.

A choice of law provision may implement two possible approaches.

### ***Approach 1—Responding State Prevails***

The choice of law provision could provide that health information properly consented in the responding state will be accepted by the requesting state, the requesting state's consent laws notwithstanding. Most state laws currently require providers in the responding state to comply with their own laws, so this approach is closest to the status quo.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in "Assumptions") would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a "blanket" consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state determined what the responding state's consent laws were and presented the responding state with a consent that fulfilled these more stringent laws. Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in "Assumptions") would receive and be permitted to use PHI if: (a) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a "blanket" consent from patients that permitted disclosure for the purposes requested by the requesting state); or (b) the requesting state presented the responding state with a consent that fulfilled the responding state's consent laws, which could presumably be done by using a consent from the requesting state because its laws are more stringent.

### ***Approach 2—Requesting State Prevails***

The choice of law provision could provide that the consent laws of the requesting state would govern the exchange of PHI (i.e., before PHI could be sent to the requesting state, a patient consent must meet the requirements of the requesting state). This approach requires requesting states to be familiar with only their own state's laws, instead of being prepared to obtain consents that satisfy various responding states' laws.

Under this approach, the requesting state with *less* stringent consent laws (Scenario 1 in "Assumptions") would receive and be permitted to use PHI if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state's consent laws, even if they were less stringent than the responding state; or (b) the responding state had already fulfilled its own consent laws that authorized a disclosure to the requesting state (i.e., the HIO received a "blanket" consent from patients that permitted disclosure for

the purposes requested by the requesting state). Presumably, if the responding state’s laws were satisfied, the requesting state’s laws would also be satisfied.

Under this approach, the requesting state with *more* stringent consent laws (Scenario 2 in “Assumptions”) would receive and be permitted to use PHI only if: (a) the requesting state presented the responding state with a consent that fulfilled the requesting state’s consent laws; or (b) the responding state obtains the information by voluntarily obtaining a more stringent consent that also fulfills the laws of the requesting state.

Establishing a choice of law provision will first require a survey or research of the possible candidates for the applicable law, followed by negotiation and drafting by the stakeholders as they create the choice of law provision. Such a survey may be less necessary if the choice of law provision simply establishes that the requesting state’s (or responding state’s) law applies in all circumstances.

### **Interstate Compact—Pro**

- + Many states have expressed interest in the development of a compact to resolve interstate exchanges of health information.
- + Because the implementation process is set out as part of the compact language, participating states should be able to reach some consensus in advance as to the most effective way to get state participation as early as possible. However, it is likely that not each state will have the same preferred process, which may make ratification by some states more difficult than others.
- + Legislatures are familiar with the process of developing interstate compacts, and the General Assembly in Illinois has successfully participated in a significant number.

### **Uniform Law—Pro**

- + States can adopt those portions of the uniform law that fit their issues, especially if the state law is more stringent.
- + The proposed law must be enacted through the state legislature with public involvement.
- + If the uniform law is simple, the state will simply repeal the old language and replace it with the new act, limiting the amount of additional work.

### ***Approach 1—Responding State Prevails***

- May be easiest to implement because it is closest to the status quo and does not require the responding state to be familiar with any other state’s requirements.
- Could be implemented by a responding state obtaining a consent at the time it collects the information from patients rather than at the time of the request from the requesting state. If consent obtained in the responding state allows for broad disclosure to other states for treatment (or even for other purposes), information could flow quickly once the requesting state submits a request that meets the responding state’s requirements.

- In Scenario 1 (the responding state has *more* stringent consent laws), if the consent was obtained at the time of collection, it would be irrelevant that the requesting state's consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- In Scenario 1 (the responding state has *more* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- In Scenario 2 (the responding state has *less* stringent consent laws), information could flow easily and quickly if the requesting state complies with its own, more stringent laws, which are those with which it is most likely to be familiar.

### ***Approach 2—Requesting State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- In Scenario 1 (the responding state has *more* stringent consent laws), information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state's laws would not have permitted the disclosure.
- This approach requires requesting states to be familiar with only their own state's laws, instead of being prepared to obtain consents that satisfy various responding states' laws.

### ***Approach 3—Uniform Consent***

- A uniform process enacted by the states will be easier to understand in the context of interstate exchange of PHI.
- A uniform consent form would be developed and each state could become familiar with a consistent set of documentation to permit access and disclosure of information.

### **Model Law—Pro**

- + Do not need all of the states to agree to have an exchange between states.
- + States can adopt those portions of the model law that fit their issues and especially if the state law is more stringent.
- + The proposed law must be enacted through the state legislature with public involvement.
- + A model act would allow any Ohio nuances to be taken into account to the extent not accounted for in a uniform law.
- + If the model act is simple, the state will simply repeal the old language and replace it with the new act, limiting the amount of additional work.

## Choice of Law—Pro

### ***Contractual Provision***

- + Easy to customize to situation.
- + With a properly defined choice of law provision, future disputes can be resolved more expeditiously by the courts, or through a defined dispute resolution process.

### ***Statutory Provision***

- + Uniformity throughout state; unclear for interstate unless similar laws.
- + More accessible, terms are available for research and adoption by other states, in contracts.
- + Implementation via a central repository that was responsible for operationalizing the disclosure would be the easiest method if the technology would allow for the determination of whether the consent laws are met prior to disclosure. Providers will have less uncertainty about which form to use and what rules to apply once it is settled which state law applies.
- + It may be possible to have a generically drafted choice of law provision that is adopted by each state, such as “requestors follow the consent laws of the responding states and responders follow the consent laws of the responding state.” Another current example is a multistate regional health information organization (RHIO) that is contractually agreeing to a more stringent disclosure, with providers in the less stringent states not violating their own law, just being overly compliant. If (a) a contractual choice of law provision is consistently with the laws of all of the states that adopt the contractual choice of law provision; or (b) the statutory choice of law provision is enacted consistently by multiple states in a consistent manner and all of the states have consistent state laws that address use and disclosure of PHI, there are possible advantages.

### ***Approach 1—Responding State Prevails***

- May be easiest to implement because it is closest to the status quo and does not require the responding state to be familiar with any other state’s requirements.
- Could be implemented by a responding state obtaining a consent at the time it collects the information from patients rather than at the time of the request from the requesting state. If consent obtained in the responding state allows for broad disclosure to other states for treatment (or even for other purposes), information could flow quickly once the requesting state submits a request that meets the responding state’s requirements.
- In Scenario 1 (the responding state has *more* stringent consent laws), if the consent was obtained at the time of collection, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- In Scenario 1 (the responding state has *more* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.

- In Scenario 2 (the responding state has *less* stringent consent laws), information could flow easily and quickly if the requesting state complies with its own, more stringent laws, which are those with which it is most likely to be familiar.

### **Approach 2—Requesting State Prevails**

- In Scenario 2 (the responding state has *less* stringent consent laws), privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- In Scenario 1 (the responding state has *more* stringent consent laws), information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure.
- This approach requires requesting states to be familiar with only their own state’s laws, instead of being prepared to obtain consents that satisfy various responding states’ laws.

### **Interstate Compact—Con**

- Will need to be enacted by a significant number of states to effectuate a nationwide exchange.
- Ohio’s experience has been that even when the proper “champions” are on board with the compact’s purpose and language, individual legislators can hold up the process by injecting their own concerns. For example, in considering the Great Lakes Water Compact, members of the Ohio Senate held up enactment of the compact in Ohio for months over concerns that the compact language could infringe upon private property rights. Thus, education efforts and support activities are critical at each stage of the process.
- The ratification process could delay implementation as we wait for either Illinois or the other states to trigger the effective date of the compact. If the minimum number of states required to adopt the pact is large, this could significantly delay implementation.
- During the transition period, providers will need to be educated, which will be both costly and time consuming. This will add another layer of analysis for the provider, as they will need to learn the requirements of the interstate compact in addition to understanding their current state consent law for release of PHI.

### **Uniform Law—Con**

- Will need to be adopted by a significant number of states to effectuate a nationwide exchange.
- Depending on the makeup of the drafting committee, state representation may differ.
- If the uniform law is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time consuming. There is no guarantee that courts in various jurisdictions will interpret a uniform law consistently, thereby reducing its effectiveness as a solution for inconsistent laws.

- A strategy to involve consumers must be developed to supplement the strong provider base that has developed. Again, using existing consumer advocacy groups and individuals from HIPAB, HISPC, and state agency ombudspersons would be an effective way to network with this important group. Developing a consensus for issues when strong (sometimes emotional) ideas are held will be challenging (e.g., use and disclosure of sensitive health information).

### ***Approach 1—Responding State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), there is a lesser focus on privacy concerns which could be objectionable to privacy advocates.
- In Scenario 1 (the responding state has *more* stringent consent laws), the responding state will require compliance with its own state laws before permitting the disclosure.
- This may delay the release of the PHI if the requesting state submits a consent that does not meet the higher standards of the responding state. A more stringent consent would need to be obtained from the patient unless the responding state has already obtained an appropriate consent at the time the information was collected.

### ***Approach 2—Requesting State Prevails***

- In Scenario 2 (the responding state has *less* stringent consent laws), access to PHI in the requesting state will be delayed while health care providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state's higher standards. This may impede or delay the provision of needed health care.
- Health care providers in the responding state will be required to determine the requirements of the requesting state's laws before they release the information, which could delay the release of data for HIE purposes.
- In Scenario 1 (the responding state has *more* stringent consent laws), this approach may raise objections from responding states that do not wish to release PHI under less demanding consent requirements.
- The approach cannot be implemented in advance because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information.

### ***Approach 3—Uniform Consent***

- If the uniform consent is not implemented properly, the failure to provide adequate education on new requirements would result in confusion by health care providers over required procedures.
- For states that have fairly lenient consent requirements, this approach could be objectionable if the uniform consent imposes new, more stringent requirements.
- For states that have fairly robust consent requirements, this approach could be objectionable to privacy advocates if the uniform consent imposes less stringent requirements and reduces the emphasis on privacy.

### **Model Law—Con**

- Will need to be adopted by a significant number of states to effectuate a nationwide exchange.
- The states will need to adopt similar versions of the model law to effectuate a nationwide exchange.
- Depending on the drafting entity, state representation may differ.
- The implementation of a model act may allow for state variation that defeats the stated objective of uniformity. Developing a consensus for issues when strong (sometimes emotional) ideas are held will be challenging (e.g., use and disclosure of sensitive health information).

If the model act is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time consuming. There is no guarantee that courts in various jurisdictions will interpret a model act consistently, thereby reducing its effectiveness as a solution for inconsistent laws. Significant work and time may have been spent to create a good model act, yet it can be rejected or changed by the states' legislatures.

### **Choice of Law—Con**

#### ***Statutory Provision***

- May require regulations to implement.
- Needs to be consistent with other states' choice of law so business practices can be uniform.
- May impact existing contracts.
- To the extent a choice of law provision indicates that another state's law applies, the process to repeatedly update providers (or a central repository) on existing laws in other states will be cumbersome. Given that health care laws change frequently, providers do not necessarily have the time to research any updated consent law changes in order to transfer the information in a timely manner. This could lead to confusion.
- Note that the majority of the advantages identified above assume that the choice of law provision is adopted consistently by all relevant states. This is unlikely to occur. Even if this is the case, a statutory choice of law provision would merely identify which state law applies in a particular situation and if the state laws are inconsistent, the statutory choice of law provision would not reduce the barriers to effective HIE.
- This complicates things exponentially given that there are currently 50 state consent laws which will then have an overlay of 50 choice of law provisions. Contractual choice of law cannot overrule a statutory provision. Unless all statutory provisions are consistent across states, a choice of law provision is not going to help. Also, if providers have to follow other state consent laws, they may worry that their data will get caught up in other states' rules. In addition, if a state elects to follow another state's consent law that is more stringent, this could unnecessarily slow the flow of information.

- Increased negotiation or drafting time, as this may be a major point of discussion while attempting to reach consensus among the stakeholder communities as to the appropriate guidelines for the HIE transaction.

## 4 Impact on Stakeholder Communities

This section recognizes that there are pros and cons of each proposed mechanism being considered that will affect the various stakeholder communities in different ways. The intent is to identify the stakeholders affected and the impact of adopting each proposed mechanism on each category of stakeholder.

### Interstate Compact

Patients and advocates

- Providers
- Payers
- Public health
- Research
- Regulatory agencies

Interstate compacts have proven to be fairly effective in addressing a number of inconsistent policies among states, though their impact on stakeholders appears mixed at best. The range of problems stakeholders may experience, however, could ultimately deter support and participation.

The interstate compact option gives stakeholders an opportunity to provide input in the process for developing the terms of the compact, the legislative hearings on the ratification legislation, and the governor's decision on approving the bill. Stakeholders could engage paid or unpaid lobbyists to lobby for or against its passage.

### Uniform Law

In the studying and drafting aspects, NCCUSL wants stakeholders involved from the very beginning, as much as possible, to get their input for the provisions contained in the act. Even now, stakeholders will also be involved in the legislative process considering the proposed uniform law.

The impact of the proposal on stakeholders will depend upon the approach selected by the commissioners. A uniform consent requirement would result in a change in procedures by many health care providers in states that previously had less stringent requirements.

Stakeholder communities will include consumers, providers (physicians, hospitals, labs, pharmacies, long-term care, home health, etc.), public health, payers, regional health

information organizations (RHIOs), quality improvement organizations (QIOs), and professional associations as well as particular types of professionals within health care who can provide needed expertise (chief information officers (CIOs), health information management (HIM), and risk management to name a few). All of these communities will be impacted, and a strategy to seek input from them would be helpful to ensure that any impacts, especially pertaining to patient care, are identified and addressed. The hearings that Ohio Health Information Technology (OHHIT) held in conjunction with developing the statewide IT plan would be a good forum to engage stakeholder communities, but broad-based buy-in will be necessary.

### **Model Law**

Depending on the drafting entity, the stakeholders will most likely be involved in drafting the law, by providing input, direct drafting, or reviewing. State-level stakeholders will be responsible for choosing provisions for adoption and implementing the chosen provisions. Therefore, in the political process the stakeholders will be able to express their views. Although the laws may be complex, these will be laws that are uniform across the state and there should be ample opportunity to provide education to assist the consumer and practitioners in understanding these laws.

Stakeholder communities will include consumers, providers (physicians, hospitals, labs, pharmacies, long-term care, home health, etc.), public health, payers, RHIOs, QIOs, and professional associations as well as particular types of professionals within health care who can provide needed expertise (CIOs, HIM, and risk management to name a few). All of these communities will be impacted, and a strategy to seek input from them would be helpful to ensure that any impacts, especially pertaining to patient care, are identified and addressed. The hearings that OHHIT held in conjunction with developing the statewide health IT plan would be a good forum to engage stakeholder communities, but broad-based buy-in will be necessary.

NCCUSL wants stakeholders involved from the very beginning, as much as possible, to get their input for the provisions contained in the model act. One can expect that other groups would also seek stakeholder feedback in developing their proposal.

Stakeholders will also be involved in the legislative process considering the proposed model act and could engage paid or unpaid lobbyists to lobby for or against its passage.

The impact of the proposal on stakeholders depends upon the approach selected by the commissioners. A uniform consent requirement would result in a change in procedures by many health care providers in states that previously had less stringent requirements. Stakeholders concerned about privacy would advocate an approach that imposes the more stringent consent requirements. Stakeholders concerned mostly about promoting the free

flow of information would be more likely to advocate an approach that imposes less stringent consent requirements.

### **Choice of Law**

- While contractual agreements as to choice of law may be easily created between trading partners, it lacks the transparency for the patient. Also, it places the burden on the parties to the agreement to implement in accordance with the variances in the state laws, with little to no assurances that they got it right, until after they have implemented.
- A statutorily defined choice of law has the potential to leave all the options open to the parties to decide (similar to Civil Code section 1646.5, which permits parties to choose their controlling law), or it can determine state law to be dominant and any agreement to the contrary is void and unenforceable.
- Stakeholders can be involved in the negotiation process to develop a choice of law provision that addresses their concerns. Stakeholders will also be involved in the legislative process considering the proposed choice of law provision and could engage paid or unpaid lobbyists to lobby for or against the passage.
- While no precedent was found directly on point, choice of law provisions may prove to be a prudent consideration but ultimately insufficient means to eliminate the existing barriers associated with interstate electronic information exchange.

### **Interstate Compact—Pro**

- + Depends on the scope of the compact as to the impact it will have on each stakeholder.
- + An interstate compact may offer health care providers added certainty about what law to apply when exchanging information electronically across state lines. Such certainty could reduce disputes among providers, concerns surrounding liability, and professional hesitation due to patient confidentiality obligations. The adaptive structure of interstate compacts may give health care providers a more immediate remedy than would a national solution, should modifications become necessary in light of their experience. Larger health care providers that offer their services across states or regions could realize more exponential gains by consistency in law.
- + An interstate compact may similarly offer health plans and other third-party payers some added certainty as to which law they might apply when exchanging health information electronically between states. This may be especially beneficial to larger health plans that regularly do business in multiple, adjoining states and are otherwise subject to differing laws. Health plans and third-party payers will also be impacted by time, resources, and additional compliance requirements associated with an interstate compact for interstate exchange which may differ from intrastate exchange requirements. Larger health plans and third-party payers may be less negatively impacted, however, as a result of their size.
- + State governments may retain some of their traditional sovereignty by developing an interstate compact that reflects the needs and experiences of their citizens, though some of that traditional sovereignty would necessarily be reduced in reaching the collective's objectives. The range of stratification between participating states' laws may make consensus more or less difficult to achieve.

- + Larger employers that self-insure or provide in-house health care services may experience more of the benefits associated with an interstate compact and less of the associated burdens.
- + An interstate compact would impose the same rules on states which, once implemented, would result in great connectivity across providers. Providers could implement a consent process that complies with the interstate compact and feel fairly confident in disclosing information across state lines with certainty in complying with laws. This would also assist in protecting providers from inappropriate disclosures and help them with evidentiary documentation if they are required to defend the disclosure, especially in a litigious society. It will be important to have adequate education for providers and patients about what is in the interstate compact.
- + Once implemented, an interstate compact would increase the free flow of information. This could certainly improve the quality of health care for patients and assist in more efficient delivery of health care.
- + The process gives stakeholders a voice, which may lead to a better outcome and increase the likelihood of buy-in during the legislative process. It may also make implementation easier since providers will be getting educated about the issues during the advisory team and drafting phases, eliminating potential ambiguity.

### **Uniform Law—Pro**

- + The proposed law must be enacted through the state legislature with public involvement and opportunity to comment.
- + Stakeholders can present to the NCCUSL drafting committee.
- + A uniform law would impose the same rules on states which, once implemented, would result in great connectivity across providers. Providers could implement a uniform consent and feel fairly confident in disclosing information across state lines with certainty in complying with laws since they are the same laws with which the providers are required to comply. This would also assist in protecting providers from inappropriate disclosures and help them with evidentiary documentation if they are required to defend the disclosure, especially in a litigious society. It will be important to have adequate education for providers and patients about what is in the uniform law.
- + Once implemented, a uniform law would increase the free flow of information. This could certainly improve the quality of health care for patients and assist in more efficient delivery of health care.
- + Engaging all of the stakeholder communities and understanding and cataloging their input would help expedite consensus.

### **Model Law—Pro**

- + The proposed law must be enacted through the state legislature with public involvement and opportunity to comment.
- + Stakeholders could be the drafters of the model law.
- + To the extent Ohio presents any nuances not accounted for in a uniform law, a model act will allow for more stakeholder input.

- + A model act would impose the same rules on states which, once implemented, would result in great connectivity across providers. Providers could implement a uniform consent and feel fairly confident in disclosing information across state lines with certainty in complying with laws since they are the same laws with which the providers are required to comply. This would also assist in protecting providers from inappropriate disclosures and help them with evidentiary documentation if they are required to defend the disclosure, especially in a litigious society. It will be important to have adequate education for providers and patients about what is in the model act.
- + Once implemented, a model act would increase the free flow of information. This could certainly improve the quality of health care for patients and assist in more efficient delivery of health care.
- + There is a greater opportunity for stakeholder involvement given NCCUSL process, as well as the number of groups putting together model acts. The NCCUSL commissioners also have a role as advocates to bring this back to their legislatures.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Ease to create for provider/payers.

#### ***Statutory Provision***

- + More transparent for everyone.
- + A clearly drafted choice of law provision that is adopted by all members of the HIO, if by contract, or by all relevant statutes, if a statutory provision, can make things simplified and result in expedited exchange of health information.
- + Members of the HIO wish to exchange PHI while avoiding any liability for consent issues. To the degree that contractual provisions can regulate the consent requirements between parties to the contract, the impact would be a simplification and standardization of obtaining acceptable consent documentation.
- + Some recognition by courts—Choice of law provisions have been granted some deference by courts. Therefore, their inclusion may generally offer stakeholders support in their decision making and enhance their ability to predict the outcome of potential dispute(s).
- + Reduced litigation—Creating explicit provisions may allow stakeholders to reduce any unnecessary time and expenses associated with litigating procedural matters.

### **Interstate Compact—Con**

- May make it harder to customize for unique situations; depending on state role, less influence over the results.
- Consumers will be impacted by whatever “consensus” is reached, as some states currently provide greater protection than other states and the federal government (e.g., whether disclosures for the purposes of payment or health care operations require authorization, the treatment of sensitive information, and access rights of minors and their parents).

- Consumers who experience diminished protections and rights may consequently decide to forgo necessary treatment or seek treatment from more consumer friendly states/regions.
- The uncertainty that state courts would interpret the interstate compact consistently, however, may still deter interstate exchange. The time, expense, and potential confusion experienced by health providers in complying with the interstate compact for interstate exchanges, in addition to state law for intrastate exchanges, would also be significant obstacles to interstate HIE. The negative aspects of interstate compacts may be experienced more acutely by smaller health care providers, whose resources, compliance programs, and liability concerns would all highlight the level of uncertainty an interstate compact would still allow.
- Governments which forgo their own state's traditional sovereignty may find their actions to be later questioned and politically opposed.
- Interstate compacts may also create some political tension between the various branches of state government. Tension may arise, for example, as a result of a participating state's lost ability to pass new and dissimilar laws, absent a subsequent compact or repeal with Congress's approval. Political tension may also result from executive branch appointments to the interstate council or advisory board which may be claimed by others to be unrepresentative of the state's constituency at large (Interstate Compact Analysis/HISPC-[Ohio] [Rev. 10/27/2008], pp. 7, 14). The distribution of funding requirements among participating states may be problematic, especially for those states with limited health care budgets. State agencies charged with the development and/or administration of an interstate compact would also require enhanced funding to take on the additional responsibilities associated with the interstate compact, and workforce investments would be required.
- State government health care providers and payers would likely experience the same advantages and frustrations with regard to resources, time, and compliance requirements as would their private counterparts. Health care providers and health plans may also seek reimbursement increases by the state to offset their own additional compliance costs.
- Employers may be financially impacted by the costs associated with an interstate compact through direct requests for contributions, an increase in taxes used by participating states to redistribute the costs, and potential increases in the billing and premiums used by health care providers and health plans to offset their own additional expenses.
- Statewide input may delay the approval process since a diversity of voices will be heard at multiple points. Some groups may organize against the compact and will use the process to give them ample opportunity to put their position forward. Additional negative impacts include the need for providers to adapt to the compact directives in order to ensure that information is available for patients and that providers are following the new privacy standards.
- If the interstate compact results in a less stringent environment for the exchange of information, privacy advocates' concerns may not be adequately addressed. If the interstate compact results in a more stringent environment for the exchange of information, this could inhibit the free flow of information. In addition, if the enactment of an interstate compact results in a dramatic difference between the current consent requirements and the requirements of the interstate compact,

providers and patients may not initially be familiar with the requirements to permit the exchange of data. This could result in increased confusion.

### **Uniform Law—Con**

- May make it harder to customize for unique situations; depending on state role, less influence over the results.
- The length of time required to develop and adopt a uniform law would mean a longer period of uncertainty for health care providers. Expediting the process would be beneficial, but care needs to be taken to allocate sufficient time to address the various dimensions of the problem and create appropriate solutions. If the uniform law results in a less stringent environment for the exchange of information, privacy advocates' concerns may not be adequately addressed. If the uniform law results in a more stringent environment for the exchange of information, this could inhibit the free flow of information. In addition, if the enactment of a uniform law results in a dramatic difference between the current consent requirements and the requirements of the uniform law, providers and patients may not initially be familiar with the requirements to permit the exchange of data. This could result in increased confusion.
- Since a broad cross-section of the state would be represented in these stakeholder communities, it will take significant time and effort to address the many different perspectives raised. There is no guarantee that all stakeholders will be satisfied with a uniform approach.

### **Model Law—Con**

- Again, a model act's allowance of this input may perpetuate state variances that a uniform law is better designed to address.
- The length of time required to develop and adopt a model act would mean a longer period of uncertainty for health care providers. Expediting the process would be beneficial, but care needs to be taken to allocate sufficient time to address the various dimensions of the problem and create appropriate solutions. If the model act results in a less stringent environment for the exchange of information, privacy advocates' concerns may not be adequately addressed. If the model act results in a more stringent environment for the exchange of information, this could inhibit the free flow of information. In addition, if the enactment of a model act results in a dramatic difference between the current consent requirements and the requirements of the model act, providers and patients may not initially be familiar with the requirements to permit the exchange of data. This could result in increased confusion.
- There is the possibility that a model act could be promulgated by a special interest group that does not recognize the broadest range of issues or need by all stakeholders. At the other end of the continuum, there could be multiple stakeholder groups trying to create a model act, which could result in a messy process.

### **Choice of Law—Con**

#### ***Contractual Provision***

- Not transparent for consumers, regulators, or otherwise affected entities/persons.
- Not helpful for public health or research, unless contract provides.

### **Statutory Provision**

- May make it harder to customize for unique situations; less influence over the results.
- If different states adopt different choice of law provisions, there is a conflict among these provisions. Therefore, providers and the HIO will be uncertain as to which law applies. This inconsistency will further more confusion and will not promote the exchange of information. If the choice of law provision results in a less stringent environment for the exchange of information, privacy advocates' concerns may not be adequately addressed. If the choice of law provision results in a more stringent environment for the exchange of information, this could inhibit the free flow of information. In addition, if the choice of law provision results in a dramatic difference between the current consent requirements and the requirements under the choice of law provision, providers and patients may not initially be familiar with the requirements to permit the exchange of data. This could result in increased confusion.
- Inconsistent judicial interpretation, remaining fear of liability, and deterred uptake—absent explicit, statutory action, judicial interpretation of choice of law provisions could remain uncertain enough to deter stakeholders from exchanging health information electronically across state lines—for fear of liability.
- Disparate burden and professional ethics—such uncertainty may be especially problematic for some stakeholders. Smaller health care providers, for example, might be deterred by the potential time and expenses they might incur by exchanging the information as provided for. The health care provider may also be deterred by the focus such provisions may take away from the actual provision of health care. Consumers might be even less able to represent themselves adequately should a conflict arise. The likelihood that many consumers would be less informed in negotiating such terms also increases the risk that contractual choice of law provisions would be overturned.

## **5 Feasibility**

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

### **Interstate Compact**

- Unknown costs and sources of funding; if high costs, less likely to be implemented.
- Interests are high so long as it does not disadvantage rights.
- How much does the option cost?

The CSG provides the following overview of the cost to develop and operate an interstate compact:

- No two compacts are alike, and therefore, the issues addressed by one compact require different development considerations than do others. Some compacts have enjoyed massive federal support, such as the Adult Compact, which received more

than \$1.2 million from the National Institute of Corrections. However, a more recent compact revision of the Interstate Compact for the Placement of Children will have resulted in a final compact in 10 months for approximately \$100,000 (not counting education and transition costs). Cost depends largely upon the desired timelines, the level of external stakeholder involvement, and the level of education desired within each state.

- For an interstate compact focused on addressing consent requirements for transferring health information across state lines, it is expected the only cost would be to support the developmental process. This developmental cost could be higher under Approach 3—Compact Defined Consent to support the process of drafting an agreed consent policy. Ongoing operational cost would only occur if the drafters of the compact felt the need to establish some oversight or arbitration entity.
- There is also an implementation cost to be considered. Most of this cost would fall upon the provider community. Providers would incur expenses relating to the implementation of new procedures and educational efforts. Whether government would help with this cost is an open question.

Is the option politically viable?

- Interstate compacts are mechanisms that enable states to address issues without federal interference. With respect to HIOs, it may be politically preferable to join an interstate compact rather than have a federal standard for consent that would supersede state consent laws.

Is the option technically possible?

- Regarding the creation of interstate compact relating to interstate HIE, Keith Scott of the CSG National Center for Interstate Compacts indicated that no subject matter is prohibited, everything is fair game, so difficulty as far as subject matter is not as much of an issue. He noted that difficulty does vary depending on, for instance, how regulated the subject matter already is at state and federal levels, how territorial states are regarding the subject matter (regional policies, state-to-state policies, etc.), and how many states are entering into a compact—the more states involved, the more differences there are to work out.

## Uniform Law

There are several elements to take into consideration when considering the feasibility of the option.

- How much does it cost?

A typical 1-year study and 2-year drafting process for creating a uniform law or model act cost approximately \$100,000. All the study and drafting meetings are in person, and the NCCUSL reimburses commissioners for expenses. This expense is covered by the NCCUSL, which is supported by contributions from the states.

The cost of considering/adopting the uniform law would be minimal, given that this would likely be done during a normal legislative session. However, there could be considerable cost to implementing a uniform consent requirement.

Health care providers would be expected to change forms and information systems to conform to the new consent standards. There will also be a cost associated with informing the public about the change.

- Is the option politically viable?

According to Katie Robinson, Communications Officer, NCCUSL, it is not the level of complexity that determines successful adoption but rather the level of need in the states. The approach adopted by the commissioners would be the major determinant of the political viability of the uniform law. States with less stringent consent laws may be reluctant to accept a uniform law based on a scenario where a more stringent law could apply because it could impede the free flow of information and require providers to implement additional mechanisms to obtain such consents. Similarly, states with more stringent consent laws may be reluctant to accept a uniform law based on a scenario where a less stringent law could apply because it would reduce privacy protections for patient data. Approach 3, the development of a uniform consent requirement, could be the most problematic because it would impose new requirements on the most states.

- Is the option technically possible?

One could argue that to be technically possible, the uniform law proposed by NCCUSL would need to be passed with few changes. To have the NCCUSL proposal approved by states with significant variations could defeat the purpose of overcoming conflicting consent laws to enable the efficient exchange of PHI.

On its website, Cornell University Law School's Legal Information Institute discusses the issue of the uniformity of the uniform laws proposed by NCCUSL.

"Uniform Laws: aspiration rather than reality

The phrase 'Uniform Laws' can be misleading. Upon approval by the National Conference a Uniform Law is not law anywhere in the United States. It is simply a legislative proposal addressed to fifty state legislatures. During the history of the Conference, roughly half its proposals have not been adopted by a single state.

(Examples include the Uniform Construction Lien Act (1987), the Uniform Franchise and Business Opportunities Act (1987), the Uniform Putative and Unknown Fathers Act (1988).) In addition, most of those that have enjoyed reasonable success have fallen way short of the goal of adoption by all or even a majority of the states. Furthermore, the versions of the 'Uniform Laws' passed by the states are rarely uniform. Variations occur at the outset since prior law or other special local conditions lead states to make changes; rarely do states adopt Uniform Laws verbatim. A second source of variance is the Conference itself. Having adopted a successful Uniform Law, the Commissioners are prompted, just as true legislators are, to revise it from time to time in the light of changing conditions and policies. This results in multiple versions of some Uniform Laws, and unless and until the states that adopted an earlier version enact the Commissioners' revisions in multiple

versions in effect in the states. There are, for example, at least two versions of the Uniform Probate Code in force in the states, the original code and 1989-1990 revisions which some states have not adopted and others have adopted only in part. . . . In short, uniformity has proven an elusive goal.”<sup>60</sup>

The above discussion notwithstanding, some uniform laws enjoy wide acceptance, such as: (1) the UCC, Article 9 “Secured Transactions,” adopted by 50 states, the District of Columbia, and the U.S. Virgin Islands; (2) the Uniform Electronic Transactions Act, adopted by 46 states, the District of Columbia, and the U.S. Virgin Islands; and, (3) the Uniform Transfers to Minors Act, adopted by 48 states and the District of Columbia. The 2007 legislative year was considered very successful by the Uniform Law Commission, as 105 uniform laws were enacted and 215 introduced into the legislative process. Other uniform laws that are less widely adopted are still useful in shaping legislative activity by educating lawmakers and stakeholders. Some commentators tally the number of provisions enacted by states, rather than the adoption of uniform laws verbatim, as a measure of a uniform law’s success.

Uniform laws can surface issues and considerations that would otherwise be overlooked by the various states, resulting in more complete bodies of law than would have resulted if the uniform law were not available. Even when refusing to adopt a uniform law, a state’s legislature will typically articulate its objections to the uniform law, and, as a result, such objections may be more easily addressed by the stakeholders.

A uniform law is more likely to minimize diversity of content, and therefore, the goal of sharing of information should be promoted by a uniform law rather than a model act. There is typically a 1-year study process and 2-year drafting process with no guarantee that the uniform law will be adopted by all state legislatures. This could be an expensive and ultimately unsatisfying approach.

### **Model Law**

A model act will not achieve the goals of a uniform law that will allow the sharing of information. In a model act, there is often variability in the final product which may result in some of the same roadblocks to sharing of information that the states face now.

There are several elements to take into consideration when considering the feasibility of the option.

- How much does it cost?

A typical 1-year study and 2-year drafting process for creating a uniform law or model act cost approximately \$100,000. All the study and drafting meetings are in person, and the

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<sup>60</sup> Uniform Laws, Cornell University Law School Legal Law Information Institute website. Available at <http://www.law.cornell.edu/uniform/uniform.html>.

NCCUSL reimburses commissioners for expenses. This expense is covered by the NCCUSL, which is supported by contributions from the states.

The cost of considering/adopting the model act would be minimal given that this would likely be done during a normal legislative session. However, there could be considerable cost to implementing a uniform consent requirement. Health care providers would be expected to change forms and information systems to conform to the new consent standards. There will also be a cost associated with informing the public about the change.

- Are there any foreseeable barriers to administering a model law provision?
- Is the option politically viable?

The approach adopted by the commissioners would be the major determinant of the political viability of the model act.

States with less stringent consent laws may be reluctant to accept a model act based on a scenario where a more stringent law could apply because it could impede the free flow of information and require providers to implement additional mechanisms to obtain such consents. Similarly, states with more stringent consent laws may be reluctant to accept a model act based on a scenario where a less stringent law could apply because it would reduce privacy protections for patient data.

Approach 3, the development of a uniform consent requirement, could be the most problematic because it would impose new requirements on the most states.

- Is it easily enforceable?
- Uniformity with other states?
- Is the option technically possible?

One could argue that to be technically possible, the “model act” proposed by NCCUSL would need to be passed with few changes. To have the NCCUSL proposal approved by states with significant variations could defeat the purpose of overcoming conflicting consent laws to enable the efficient exchange of PHI. On the other hand, model acts are designed to serve as guideline legislation, which states can borrow from or adapt to suit their individual needs and conditions. This flexibility can be useful for implementation.

### **Choice of Law**

There are several elements to take into consideration when considering the feasibility of the option.

- How much does it cost?

The cost of including a choice of law provision in a contractual agreement or the enactment of choice of law legislation would be minimal. There will be a cost for educating health care

providers to the ramifications of a scenario that requires providers to be familiar with the requirements of another state.

- Are there any foreseeable barriers to administering a “choice of law” provision?
- Is the option politically viable?

Since HIE generally involves bilateral transactions, it is possible that there could potentially be a significant hurdle to overcome in the form of the state’s attitude toward protecting its citizens. For example, if “State A” had a strong consent requirement, and “State B” had a comparatively weak consent requirement, then each time “State B” requested PHI from an HIO in “State A,” the PHI of “State A” citizens would be disclosed under the weaker consent requirement. Having seen a need for a strong consent requirement, “State A” is less likely to agree to let the lower standards apply to disclosures to entities outside the state. This objection would need to be addressed during the legislative process or negotiation process.

Choice of law provisions are generally contractual. In the absence of contractual provisions, courts apply conflict of law principles to determine which forum’s law applies. A state could enact a uniform choice of law statute, as has been done with the UCC, to govern HIE.

### **Interstate Commerce—Pro**

- + Federal participation could add additional revenues.
- + Would create a uniform law for all of the states that join the compact.
- + Cost considerations should not be an issue based upon historical data from the CSG showing modest expenditures, particularly when the federal government provides financial support.<sup>61</sup>
- + *Costs*—Approach 1 would be the least costly approach to use. Providers would not be required to learn new procedures.
- + *Political viability*—An interstate compact is a state-driven mechanism familiar to legislatures. The support by the federal government to encourage adoption of electronic health records (EHRs) by 2013 may encourage state legislatures to act on health IT legislation. Approach 1 is more politically feasible because providers in the responding state are familiar with their own consent laws.
- + *Technically possible*—In the absence of a federal solution, an interstate compact may be one of the best ways to address the barrier caused by different state consent laws.

### **Uniform Law—Pro**

- + Of the 99 uniform laws identified, California enacted or adopted substantially similar laws in 40 instances, or about 50% of the time.
- + NCCUSL costs are picked up by the states that are members, as part of their dues. Each state has to absorb the costs of putting legislation through the process. The

<sup>61</sup> 10 Frequently Asked Questions, Council of State Governments, National Center for Interstate Compacts website. Available at <http://www.csg.org/programs/ncic/resources.aspx>.

group responsible for developing a uniform act would be best able to provide training and potentially reduce overall costs. Approach 1 would be the least costly approach to use. Providers would not be required to learn new procedures.

- + The support by the federal government to encourage adoption of EHRs by 2013 may encourage state legislatures to act on health IT legislation. Approach 1 is more politically feasible because providers in the responding state are familiar with their own consent laws.
- + The NCCUSL website specifically states that an act should be designated as uniform rather than model if:
  - (a) there is a substantial reason to anticipate enactment in a large number of jurisdictions, and
  - (b) “uniformity” of the provisions of the proposed enactment among the various jurisdictions is a principal objective.

Further, the NCCUSL indicates that act shall be designated as a Uniform Law Commissioners’ Model Act if:

- (a) “uniformity” may be a desirable objective, although not a principal objective;
- (b) the act may promote uniformity and minimize diversity, even though a significant number of jurisdictions may not adopt the act in its entirety; or
- (c) the purposes of the act can be substantially achieved, even though it is not adopted in its entirety by every state.

### **Model Law—Pro**

- + Of the model laws proposed by NCCUSL, California has only adopted one that was substantially similar to the proposed law; however, California has adopted many model laws.
- + A model act will provide needed guidance through its example even if states enact it with some modifications. The approach might work best if it is less expansive and does not cover certain special categories of PHI (such as mental health records).
- + *Costs*—NCCUSL costs are picked up by the states that are members, as part of their dues. Each state has to absorb the costs of putting legislation through the process. The group responsible for developing a model act would be best able to provide training and potentially reduce overall costs. Approach 1 would be the least costly approach to use. Providers would not be required to learn new procedures.
- + *Political viability*—This is a step in the right direction and likely to be more helpful than what we have now. The support by the federal government to encourage adoption of EHRs by 2013 may encourage state legislatures to act on health IT legislation. Approach 1 is more politically feasible because providers in the responding state are familiar with their own consent laws.
- + *Technically possible*—Creates a standard for states to follow.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Cost to develop language is more.

- + Ease for parties to dispute, by terms of contract.
- + May be more cost effective to enforce.
- + Not open for public debate.

### **Statutory Provision**

- + Will still incur cost to develop customization to existing statutes, but easier.
- + Statute can spell out enforcement, bring in regulatory oversight.
- + A choice of law provision is an inexpensive solution. A centralized repository may make implementation easier so long as the repository is aware of the requirements and how to apply the choice of law provision.
- + Enacting a uniform statute to standardize the choice of law provision is the subject of separate inquiry. However it is feasible but would require an undetermined amount of time for participating states to enact legislation. Regarding existing practices to address choice of law in contracts, or to resolve matters where contracts fail to address the issue, there is no feasibility issue since the status quo would continue and is well governed by decades of court rulings and probably adoption in every state of the Restatement (Second) of Conflict of Laws.

### **Interstate Compact—Con**

- California has so many laws that cover health information, such as breach notification and mental health protections, that developing a compact to be in accordance with California law could be difficult.
- Federal participation could add additional delays.
- It is difficult to predict how elected officials will respond to an interstate HIE compact. Issues such as the confidentiality of mental health and infectious disease status may challenge feasibility, but the history of adoption of controversial compact legislation such as the recent Great Lakes–St. Lawrence River Basic Water Resources Compact suggests bipartisan support would develop because of the recognized return on investment resulting from HIE between and among the states.<sup>62</sup>
- *Costs*—The cost of implementing an education effort may be difficult to cover due to state budget problems. There is also a cost to providers, yet we do not have a basis to determine what it will be and who will bear those costs. Providers were not given funds to implement HIPAA.

Given the likelihood of significant costs to both develop and implement the interstate compact, states may be discouraged from pursuing this option. Questions will arise as to who should bear the costs for both the development stage and the implementation stage—the government or the stakeholders? Will this become an unfunded mandate on providers by the state? Education costs will be significant. If the compact requires infrastructure to handle administration, this will require on-going operational costs.

Approach 2 could be viewed as the costliest of the three discussed. Providers and HIOs in responding states would need to become familiar with the consent

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<sup>62</sup> Am. H.B. 416, posted at [http://www.legislature.state.oh.us/bills.cfm?ID=127\\_HB\\_416](http://www.legislature.state.oh.us/bills.cfm?ID=127_HB_416).

requirements of multiple requesting states. Approach 3 would be less of a burden on providers and HIOs in that they would be learning one new process.

- *Political Viability*—If we try to adopt an interstate compact that covers all health information, this will make it harder to pass. In addition, the wide variation in state consent laws today makes it likely that it will be difficult to draft an interstate compact that is politically feasible to a high number of states. For instance, responding states in Scenario 2 (the responding state has less stringent consent laws) may object to Approach 2, where the requesting state’s law prevails because it would require them to learn another state’s laws and implement more robust consent requirements before disclosing information.

On the other hand, responding states in Scenario 1 (the responding state has more stringent consent laws) may also object to Approach 2, where the requesting state’s law prevails, but for different reasons. In this case, a requesting state’s less stringent consent requirements would prevail, and this could reduce the level of privacy protection for patient information.

- *Technically Possible*—Approach 3 will force health care providers in all states to adapt to the interstate compact’s consent standards.

### Uniform Law—Con

- Lack of uniformity may make enforcement and use of law difficult in an interstate exchange.
- The cost of implementing an education effort may be difficult to cover due to state budget problems. There is also a cost to providers, yet we do not have a basis to determine what it will be and who will bear those costs. Providers were not given funds to implement HIPAA. Approach 2 could be viewed as the costliest of the three discussed. Providers and HIOs in responding states would need to become familiar with the consent requirements of multiple requesting states. Approach 3 would be less of a burden on providers and HIOs in that they would be learning one new process.
- If we try to implement a law that covers all health information, this will make it harder to pass. The potential that the act could be enacted with significant variation reduces its feasibility as a solution to varying consent laws. In addition, the wide variation in state consent laws today makes it likely that it will be difficult to draft a uniform law that is politically feasible to a high number of states. For instance, responding states in Scenario 2 (the responding state has *less* stringent consent laws) may object to Approach 2, where the requesting state’s law prevails because it would require them to learn another state’s laws and implement more robust consent requirements before disclosing information.
- On the other hand, responding states in Scenario 1 (the responding state has *more* stringent consent laws) may also object to Approach 2, where the requesting state’s law prevails, but for different reasons. In this case, a requesting state’s less stringent consent requirements would prevail, and this could reduce the level of privacy protection for patient information.
- Approach 3 will force health care providers in all states to adapt the interstate compact’s consent standards.

## Model Law—Con

- Lack of uniformity may make enforcement and use of law difficult in an interstate exchange.
- The NCCUSL website specifically states that an act should be designated as uniform rather than model if: (a) there is a substantial reason to anticipate enactment in a large number of jurisdictions, and (b) “uniformity” of the provisions of the proposed enactment among the various jurisdictions is a principal objective. Further, the NCCUSL indicates that an act shall be designated as a Uniform Law Commissioners’ Model Act if: (a) “uniformity” may be a desirable objective, although not a principal objective; (b) the act may promote uniformity and minimize diversity, even though a significant number of jurisdictions may not adopt the act in its entirety; or (c) the purposes of the act can be substantially achieved, even though it is not adopted in its entirety by every state.
- *Costs*—The cost of implementing an education effort may be difficult to cover due to state budget problems. There is also a cost to providers, yet we do not have a basis to determine what it will be and who will bear those costs. Providers were not given funds to implement HIPAA. Approach 2 could be viewed as the costliest of the three discussed. Providers and HIOs in responding states would need to become familiar with the consent requirements of multiple requesting states. Approach 3 would be less of a burden on providers and HIOs in that they would be learning one new process.
- *Political viability*—If we try to implement a law that covers all health information, this will make it harder to pass. The potential that the act could be enacted with significant variation reduces its feasibility as a solution to varying consent laws. In addition, the wide variation in state consent laws today makes it likely that it will be difficult to draft a model act that is politically feasible to a high number of states. For instance, responding states in Scenario 2 (the responding state has *less* stringent consent laws), may object to Approach 2, where the requesting state’s law prevails because it would require them to learn another state’s laws and implement more robust consent requirements before disclosing information.  
  
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- *Technically possible*—Approach 3 will force health care providers in all states to adapt the interstate compact’s consent standards.

## Choice of Law—Con

### ***Contractual Provision***

- Terms not accessible for development of similar contracts.
- State law enforceability may be questionable.

### ***Statutory Provision***

- Legislative process could delay enactment and implementation.

- Could become more political, tied to unrelated issues.
- A contractual choice of law provision may have limited benefit because it does not supersede state consent laws and could lead to conflicts in the states whose laws were not elected. A statutory choice of law provision may have limited benefit if other states adopt inconsistent choice of law provisions.
- If providers will be required to change existing policies and procedures based upon the choice of law, there will be a cost, as well as the need to conduct training of providers and patients. By drafting a consistent but neutral adoption, this could also result in political concerns, since this may mean that another state's laws apply. For example, if your state is very concerned about privacy rights and you are asked to follow the laws of a less stringent state, this may not be politically feasible. Technical feasibility is difficult as providers will not have the time to fully research other states' laws in order to comply with the option. Inconsistent adoption will also hinder success. A choice of law provision that is contractual would not have the force of law behind it. Therefore, it may be seen as an option that is not endorsed by the state, thereby reducing its political feasibility.

## **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 your state. Identify the relative merits of each mechanism in resolving these liability concerns.

### **Interstate Compact**

Health care providers handling PHI in a manner consistent with the terms of the compact should not be in jeopardy of criminal or civil liability.

Since an interstate compact is enacted in statute by states participating in the compact, and assuming the language of the interstate compact statutes is sufficient, all liability concerns should be addressed in a satisfactory fashion. Such compact language must be carefully drafted so it protects HIE parties from civil and criminal liability as well as adverse administrative actions such as those related to provider (e.g., physician, nurse, hospital, nursing home) licensing and regulatory oversight from all pertinent state agencies (e.g., provider licensing boards, pharmacy board, mental health and workers' compensation agencies).

State constitutional issues also must be a consideration in addressing liability concerns. State court application of state constitutional provisions involving such issues as immunity, damage caps, and privacy rights are examples.

Attention must also be given to federal requirements (e.g., HIPAA) that preempt state and therefore interstate compact law. It may be determined that federal recognition through federal legislative enactment or resolution, or perhaps administrative rule promulgation, will be necessary to ensure that liability does not arise from federal quarters.

Finally, cursory review of some interstate compact language suggests that liability has been addressed. Examples include the International Emergency Management Assistance Compact and Northeastern American/Canadian Emergency Management Assistance Compact.<sup>63</sup> The interstate compact has the force of law in the member states. This would supersede any existing conflicting state law. Health care providers handling PHI in a manner consistent with the terms of the compact should not be in jeopardy of criminal or civil liability, because the applicable law within their jurisdiction would be the compact. As long as the disclosures were being made between entities in states that executed the compact, the relative stringency of the other state's consent laws would be immaterial, and the terms of the compact would prevail. However, disclosures to or requests by states that had not executed the compact would still be subject to the laws in effect in the jurisdictions where such disclosures were being made. The interstate compact would not address liability considerations in that case.

### **Uniform Law**

Several factors would affect the ability of the uniform law to adequately address liability concerns.

- The content of the proposal would have the greatest impact. It will need to address how the new law would relate to existing consent requirements.
- How uniformly the states adopt the proposal would be another major factor.
- Another factor would be whether the legislature includes concomitant changes in other consent laws as part of the legislation enacting the uniform law.
- Statutory rules of construction would also be a factor. These rules generally provide that in the case of an irreconcilable conflict between two laws, the language of the most recently enacted would prevail.
- State court interpretation of the uniform law will also affect its success. Certain identical laws, such as provisions of the UCC, are implemented very differently by different state courts. Courts tend to preserve their own state's case law unless the statute clearly demonstrates a break with precedent.

If the uniform law is adopted in every state, the option could address liability concerns. The uniform law content would need to address any concerns relating to existing consents, the need for new consents, etc. Thus as the uniform law is developed, liability concerns should be considered and addressed.

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<sup>63</sup> Voit, W., Vickers, N., & Gavenonis, T. (2003). *Interstate Compacts and Agencies 2003*. Lexington, KY: Council of State Governments, pp. 188, 212.

## Model Law

Each state will have the option of adopting any provisions that the state chooses. This will affect uniformity. Another issue would be whether the legislature in the adopting state changes other laws that might relate to the proposed model law.

Similar to the uniform law, the model act could address liability concerns. The model act content would need to address any concerns relating to existing consents, the need for new consents, etc. Thus, as the model act is developed, liability concerns should be considered and addressed.

A model act becomes the law in adopting states. Several factors would affect the ability of the model act to adequately address liability concerns.

- The content of the proposal would have the greatest impact. It will need to address how the new law would relate to existing consent requirements and supersede them, if necessary, to avoid conflicting obligations.
- How uniformly the states adopt the proposal would be another major factor. Each state must comply with the laws of its jurisdiction. As long as the disclosures were being made between entities in states that adopted the model act, information should be exchanged relatively freely because the model act would address the exchange and access by both the responding and the requesting states. However, disclosures to or requests by states that had not adopted the model act would still be subject to the laws in effect in the jurisdictions where such disclosures were being made. The model act would not address liability considerations in that case.
- Another factor would be whether the legislature includes concomitant changes in other consent laws as part of the legislation enacting the model act.
- Statutory rules of construction would also be a factor. These rules generally provide that in the case of an irreconcilable conflict between two laws, the language of the most recently enacted would prevail.
- State court interpretation of the model act will also affect its success. Certain identical laws, such as provisions of the UCC, are implemented very differently by different state courts. Courts tend to preserve their own state's case law unless the statute clearly demonstrates a break with precedent.

## Choice of Law

Neither method of implementing “choice of law” will address the liability concerns of the parties, unless the state laws of the negotiating partners are similar and do not impose a dominance that conflicts with the other state's laws.

A properly drafted contractual choice of law provision could allocate liability among the parties to the agreement. To further protect the parties, an indemnification provision could be incorporated into a contractual choice of law provision along with the choice of law provisions, such that the requesting party would agree in advance to reimburse fines and

damage awards against the responding state’s provider or HIO for actions taken on the basis of the requesting party’s consent.

With respect to determining which state’s statutes apply to a statutory violation, the determining factor is generally the state in which the violation occurred. State statutes, except for exceptional situations, are not applicable to parties acting outside of the boundaries of the state. A responding state with a prohibition against a certain use of PHI generally cannot apply its statutes to an organization outside of the state. This applies to both uses and disclosures. So, for instance, a request for PHI by a requesting state that is lawful in the requesting state but unlawful in the responding state will not subject the requesting state to liability under the responding state’s laws. Similarly, a disclosure of PHI by a responding state that is lawful in the responding state but unlawful in the requesting state will not subject the responding state to liability under the requesting state’s laws.

Civil liability could also arise from the exchange of PHI if the subject of the PHI or another affected party claimed that he or she suffered damages as a result of the exchange. This type of claim would be brought by a private individual. When determining which state’s laws apply for such a claim, most states either give precedence to the laws of the state in which the wrong occurred, or require the court to examine the facts of the claim to determine the appropriate law to apply. The court might consider facts such as the policies and interests underlying the claim, the dominant contacts among the affected states, the government interests, and other considerations. The choice of law determines the rights of the parties and may limit or preclude recovery for damages.

Choice of law provisions are routinely used in contracts involving parties located in more than one state in order to specify which state’s law applies in the event of contractual dispute. Such clauses are often but not always upheld by judges. For reasons described below, resolution of interstate HIE liability concerns by use of choice of law clauses in contracts or other written instruments cannot be recommended unless state legislatures provide clear guidance through uniform statutory enactments (including participation in a multistate compact).

States have adopted choice of law statutes to provide greater certainty to parties and reviewing courts. For example, R.C. 1304.85 addresses bank fund transfers:

“(A) All of the following apply unless the affected parties otherwise agree or division (C) of this section applies:

(1) The rights and obligations between the sender of a payment order and the receiving bank are governed by the law of the jurisdiction in which the receiving bank is located.

(2) The rights and obligations between the beneficiary’s bank and the beneficiary are governed by the law of the jurisdiction in which the beneficiary’s bank is located.

(3) The issue of when payment is made pursuant to a funds transfer by the originator to the beneficiary is governed by the law of the jurisdiction in which the beneficiary's bank is located.

(B) If the parties described in division (A) of this section have made an agreement selecting the law of a particular jurisdiction to govern rights and obligations between each other, the law of that jurisdiction governs those rights and obligations, whether or not the payment order or the funds transfer bears a reasonable relation to that jurisdiction.

(C)(1) A funds-transfer system rule may select the law of a particular jurisdiction to govern either of the following: (a) The rights and obligations between participating banks regarding payment orders transmitted or processed through the system; (b) The rights and obligations of some or all parties to a funds transfer any part of which is carried out by means of the system.

(2) A choice of law made pursuant to division (C)(1)(a) of this section is binding on participating banks. A choice of law made pursuant to division (C)(1)(b) of this section is binding on the originator, other sender, or a receiving bank having notice that the funds-transfer system might be used in the funds transfer and of the choice of law by the system when the originator, other sender, or receiving bank issued or accepted a payment order. The beneficiary of a funds transfer is bound by the choice of law if, when the funds transfer is initiated, the beneficiary has notice that the funds-transfer system might be used in the funds transfer and of the choice of law by the system. The law of a jurisdiction selected pursuant to division (C)(1) of this section may govern, whether or not that law bears a reasonable relation to the matter in issue.

(D) In the event of inconsistency between an agreement under division (B) of this section and a choice-of-law rule under division (C) of this section, the agreement under division (B) of this section prevails.

(E) If a funds transfer is made by use of more than one funds-transfer system and there is inconsistency between choice-of-law rules of the systems, the matter in issue is governed by the law of the selected jurisdiction that has the most significant relationship to the matter in issue."

Another Ohio example can be found in R.C. 1305.15 regarding choice of law for letters of credit.

### **Interstate Compact—Pro**

- + State law should dominate.
- + If requires consent, then it would alleviate other concerns.
- + Depending on the provisions, could be uniform.
- + Momentum for decades, seemingly accelerating in recent years, has favored uniform state law on matters of regional or national importance. This momentum has been especially visible in the area of data exchange as a result of technological advances (e.g., computers, cell phones, Internet, satellite communication). There appears to be a wide consensus that unimpeded but secure HIE has sufficient societal value to

justify formation of an interstate compact—especially if the federal government is unable to act in a timely and appropriate manner.

- + These general comments are pertinent because they suggest that liability concerns would be appropriately addressed in order to accomplish higher ranked political and social goals.
- + The interstate compact mechanism is neutral and plainly stated, with no increased or decreased risk of liability to providers. The interstate compact could have a provision that directly addresses liability. Any of the approaches would clarify and minimize health care provider liability concerns by providing a clear mandate with regard to consent requirements. Education is the central issue, and as long as the interstate compact is followed, there should not be any different liability concerns.

### **Uniform Law—Pro**

- + NCCUSL drafting committee gets input from experts and is likely to solve liability issues if that is the objective of the uniform law.
- + The additional guidance afforded by the adoption of a uniform law will be beneficial in addressing liability concerns, particularly if the uniform law enjoys widespread adoption. This is a mechanism to address liability, but it will depend on the specifics in the law, which could have less lenient provisions than what is current law in some states.

### **Model Law—Pro**

- + State law concerns should dominate.
- + The additional guidance afforded by the adoption of a model act will be beneficial in addressing liability concerns, particularly if the model act enjoys widespread adoption. This is a mechanism to address liability, but it will depend on the specifics in the law, which could have less lenient provisions than what is current law in some states.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Parties can make liability specific, with indemnity provisions.
- + Choice of law clauses are well understood and allow contracting parties to easily modify the provision as circumstances dictate. Choice of law provisions and considerations are so commonly used that a Google search resulted in more than 6 million hits. As probably is the case with all other states, the Ohio Supreme Court has adopted the Restatement (Second) of Conflict of Laws as the principles governing resolution of choice of law disputes in cases where the parties to a contract have not specified the controlling forum (*Ohayon v. Safetco Ins. Co. of Illinois*, 91 Ohio St.3d 474, 747 N.E.2d 206 [Ohio 2001]).

#### ***Statutory Provision***

- + Can make liability specific.
- + Can provide more protection to the parties with unequal bargaining powers.

- + If a request is made by a requesting state, the responding state will likely lack the jurisdiction to enforce its statutes against the requesting party. As long as the requesting state has complied with the consent requirements of its state, there would be no barrier to the exchange of PHI. Likewise, as long as the responding state has complied with the disclosure requirements of its state, there would be no barrier to the exchange of PHI. This simplifies the exchange process, as each party need only be familiar with, and compliant with, the laws of its own jurisdiction. The statutory approach to determining choice of law might offer some degree of protection from civil liability because the exchange would have been compliant with relevant law.

### **Interstate Compact—Con**

- If not protective of privacy rights, not likely to succeed in California.
- It remains to be seen if there are local or state issues or constituencies that would prevent satisfactory standardized liability protection in multistate compact language. Issues related to HIV, mental health, and substance abuse, or states with unreasonable privacy advocates or self-serving plaintiff attorney associations (without minimizing the legitimacy of mainstream privacy advocates and plaintiff attorney associations) might lead to compact language sufficiently unsatisfactory to defeat successful implementation of HIE.
- An interstate compact may result in more litigation being heard in federal courts. In addition, the adoption of new standards could increase the liability for some health care providers if the interstate compact imposes a level of consent that is more restrictive than some states' current consent requirements. Requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.

### **Uniform Law—Con**

- Lack of uniformity may make liability issues uncertain.
- Will need each legislature to identify conflicting state laws and resolve the predominance of the uniform law.
- Liability concerns are different in the paper versus electronic transfer of information, so any uniform law would need to address special concerns. For instance, concerns regarding errors or security violations are higher with electronic transfer, since, for example, the liability of sending something electronically to the wrong web address and it getting posted online is significantly different from sending paper to a wrong street address.
- The adoption of new standards could increase the liability for some health care providers if the uniform law, as adopted, imposes a level of consent that is more restrictive than some states' current consent requirements. Requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.
- Unless the uniform law is adopted consistently in various states, the law would be unlikely to be able to address liability concerns when a state that has not adopted the uniform law is involved in HIE.

### **Model Law—Con**

- Lack of uniformity may make liability issues uncertain.
- Will need each legislature to identify conflicting state laws and resolve the predominance of the model law.
- Liability concerns are different in the paper versus electronic transfer of information, so any model act would need to address special concerns. For instance, concerns regarding errors or security violations are higher with electronic transfer, since, for example, the liability of sending something electronically to the wrong web address and it getting posted online is significantly different from sending paper to a wrong street address.
- In addition, the adoption of new standards could increase the liability for some health care providers if the model act, as adopted, imposes a level of consent that is more restrictive than some states' current consent requirements. Requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.
- Finally, unless the model act is adopted consistently in various states, the law would be unlikely to be able to address liability concerns when a state that has not adopted the model act is involved in HIE.

### **Choice of Law—Con**

#### ***Contractual Provision***

- Tends to exacerbate the relative unequal bargaining powers of the parties: funding and sophistication.

#### ***Statutory Provision***

- One size may not fit all, not meet all potential liability concerns.
- Of the two approaches to choice of law, the contractual choice of law provision offers less protection against civil liability because the contractual provision only represents a binding agreement between the parties to the contract, not with third parties. A contractual agreement for consenting may be in conflict with state law, which leaves people open to liability. Contractual provisions agreed upon by parties to a contract offer little or no protection from statutory liability. Even with a contractual choice of law provision, the requesting state and responding state would need to ensure that their respective conduct is compliant with the statutory requirements of their respective states. Vendors getting into the HIO business are likely not able to be insured for the consent liability, so having this be the responsibility of a central repository is not feasible at this time. Additionally, providers may be reluctant to participate in an HIO, because their professional liability insurance may not currently cover liability arising from unauthorized disclosure of PHI made electronically. A choice of law provision is unlikely to reduce that barrier. Claims for civil liability for an appropriate use or disclosure of information are more likely to arise between an HIO member and the patient who is the subject of the information, rather than between the parties of the contract. The contractual provisions would likely not help to reduce civil liability.
- Unless legislatures adopt uniform language, relying on choice of law provisions in contracts and agreements (e.g., consent for HIE disclosure) would cause too much

uncertainty and not satisfactorily resolve liability concerns. One can imagine that a party/entity active in HIE would need to know, or be able to determine, the applicable law in each of 50 states.

- Where parties have not specified which state's law controls, the guidance provided by the Restatement (Second) of Conflict of Laws provides too many opportunities to reach different conclusions on the same fact pattern. Section 188 provides that, in the absence of an effective choice of law by the parties, their rights and duties under the contract are determined by the law of the state that, with respect to that issue, has "the most significant relationship to the transaction and the parties" (Restatement at 575, Section 188(1)). Section 188(2)(a) through (d) more specifically provides that courts should consider the place of contracting, the place of negotiation, the place of performance, the location of the subject matter, and the domicile, residence, nationality, place of incorporation, and place of business of the parties.
- When disputes inevitably arise, parties would be able to challenge the validity of the contractual choice of law provision on various grounds (e.g., public policy, unfair bargaining position, *renvoi*) and, even when the challenge is not technically appropriate, history demonstrates that courts would sometimes rule in favor of the challenger. Nonmeritorious challenges, even though unsuccessful, would also cause expense and delay. An example of a party challenging the choice of law—resulting in expenses and delayed resolution—is *Scanlon v. Pfaller*, 2006 WL 1064051 (Ohio App. 12 Dist. 2006).
- These reasons compel a recommendation not to rely on choice of law provisions to facilitate HIE unless legislatures in the affected states have enacted uniform statutes that provide certainty and satisfy liability concerns.

## **7 Ramifications of Acceptance/Rejection**

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

### **Interstate Compact**

#### ***Acceptance***

A number of beneficial ramifications arise from the enactment of an interstate compact. The major one is the establishment of a regulated and standardized system to secure patient consent for electronic exchange of PHI among compact member states regardless of varying consent requirements. Based on this process within the compact, PHI arguably can be exchanged by providers more confidently while protecting patients' privacy rights. This may result in an increase in the authorized interstate exchange of PHI among the member states. A favorable outcome has been realized through another health care related interstate compact. Specifically, an evaluation study of the Nurse Licensure Compact, sponsored by the National Council of State Boards of Nursing, reflected increases in active

licenses based on the benefits offered through the compact<sup>64</sup> There are also several legal ramifications that stem from the utilization of the compact. These ramifications provide added protections for the compact and the compact member states. Of note, the interstate compact becomes statutory law when adopted by each of the member state legislators and has precedence over conflicting statutes of member states (*C.T. Hellmuth & Assoc. v. Wash. Metro. Area Transit Auth.* [D.Md. 1976], 414 F.Supp. 408, 409). Along these same lines, no unilateral action taken by a member state that is in conflict with the compact terms and conditions can be imposed upon the other member states without the approval of the other member states.<sup>65,66</sup> Acceptance of an interstate compact has the potential to create uniformity with respect to how member states require health care entities to obtain a patient’s consent to allow their PHI to be exchanged electronically. It could also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. States will need to have a process for making patients aware of exchanges of PHI and obtaining patients’ permission to share health information.

### **Rejection**

Without the use of the compact or adoption of standardized choice of law statutes, uniform laws, or model acts, there would continue to be discordant requirements for sharing PHI, causing unnecessary burdens for the patient and health care system to determine when sharing of information is legally permitted.

Health information may not be available because providers will not know how to respond to another state’s request. The current barriers will continue:

- The inconsistent, cumbersome, and inefficient processes for requesting patient information between states which currently lack privacy and security standards;
- The inconsistent application of multiple and redundant consent forms for patient confidentiality;
- Misuse, mismanagement, and inappropriate disclosure of patients’ health information by providers, payers, researchers, and emerging HIOs; and
- Inappropriate and inconsistent interpretations of state laws related to consent for release of health information issues, and the potential provider risks or liabilities associated with failure to comply with such laws.

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<sup>64</sup> Multistate Licensure Compact Impact Evaluation. (2003). National Council of State Boards of Nursing website. Available at <http://www.ncsbn.org>.

<sup>65</sup> Buenger, M. & Masters, R. (2003). The Interstate Compact on Adult Offender Supervision: Using Old Tools to Solve New Problems. 9 Roger Williams U.L. Rev. 71, 94.

<sup>66</sup> *Nebraska v. Cent. Interstate Low-Level Radioactive Waste Comm.* [C.A.8, 2000], 207 F.3d 1021, 1026.

## **Uniform Law**

### ***Acceptance***

Acceptance of the NCCSUL Uniform Law has the potential to create uniformity with respect to how adopting states require health care entities to obtain a patient’s consent to allow his or her PHI to be exchanged electronically. It could also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. States will need to have a process for making patients aware of exchanges of PHI and obtaining patients’ permission to share health information.

### ***Rejection***

Health information may not be available because providers will not know how to respond to another state’s request. The current barriers will continue:

- The inconsistent, cumbersome, and inefficient processes for requesting patient information between states which currently lack privacy and security standards; and
- The inconsistent application of multiple and redundant consent forms for patient confidentiality.

## **Model Law**

The ramifications of acceptance and rejection will largely depend on how other states react to the model act and the number of changes that states make to a model act.

## **Choice of Law**

Based on research of pertinent databases for Ohio cases and statutes, no information was found regarding the treatment of PHI for choice of law purposes. As such, noted below are some key questions that it will be necessary to address:

- How is PHI to be characterized?
- Is it to be treated as tangible or intangible?
- Should the choice of law rule for treatment of PHI be the place from where the records are being transferred or the domicile of the patient at the time of the transfer?

## **Interstate Compact—Pro**

- + Potential to resolve conflicts with an agreed-upon mechanism.

## **Uniform Law—Pro**

- + Adoption of the NCCUSL Uniform Law has the potential of creating uniformity with respect to how adopting states require health care entities to obtain a consumer’s consent to allow his or her personal health information to be exchanged electronically. It will also resolve the question of whether or not patient consent is required to enter or share personal health information in an electronic health exchange. States will have a process for making patients aware of exchanges of

personal health information and obtaining patients' permission to share health information.

- + The obvious benefit of adopting a uniform law is that Ohio would have a common legal structure with other states that adopt the uniform law. Having the common legal structure will streamline the information exchange process because states would not need to constantly be analyzing and monitoring other states' laws with respect to consents for the use and disclosure of health information. In addition, adoption of a uniform law would cause Ohio to have a specific and detailed approach to handling consents to the use and disclosure of health information. A uniform law is an opportunity to address issues that may be unclear in the law and (presumably) would allow health care providers to look to a single source to determine the type of consent that may be needed, whether it is a single consent for all health information or separate consents for different types of health information. It should be noted, however, that although the intent is for uniform laws to be adopted without change, in reality the states that adopt a "uniform law" may make modifications.

### **Model Law—Pro**

- + Would clarify statewide exchanges.
- + *Acceptance*—The benefit of adopting a model is that it would create common framework from which states could create a consent law. Having the common legal structure could streamline the information exchange process because states would not need to constantly be analyzing and monitoring other states' laws with respect to consents for the use and disclosure of health information. However, acceptance of a model act will have limited impact if there is a wide variation among the states in the language used to implement the consent law. In addition, adoption of a model act would cause Ohio to have a specific and detailed approach to handling consents to the use and disclosure of health information. A model act is an opportunity to address issues that may be unclear in the law and (presumably) would allow health care providers to look to a single source to determine the type of consent that may be needed—whether it is a single consent for all health information or separate consents for different types of health information.
- + *Adoption*—Adoption of the NCCSUL Model Act has the potential to create uniformity with respect to how adopting states require health care entities to obtain a patient's consent to allow their PHI to be exchanged electronically. It could also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. States will need to have a process for making patients aware of exchanges of PHI and obtaining patients' permission to share health information.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Is occurring right now.
- + Adoption of the choice of law mechanism has the potential to create uniformity with respect to how adopting states require health care entities to obtain a patient's consent to allow his or her PHI to be exchanged electronically. It could also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. States will need to have a process for making patients

aware of exchanges of PHI and obtaining patients' permission to share health information.

- + Typically, the utilization of a formal choice of law provision noted by statute or included in a contract affords predictability, efficiency, and uniformity in the adjudication process by the courts. Of note, contract choice of law provisions also maintain the intent of the parties, regarding contemplated considerations if litigation should arise (e.g., choice of forum, location, nature of information). Courts have rendered added weight for choice of law contract provisions (*Schulke Radio Productions, Ltd. v. Midwestern Broadcasting Co.* [1983], 6 Ohio St.3d 436, 438, 453 N.E.2d 683).
- + Although there are notable benefits with the utilization of formal choice of law provisions, there can be some challenges with them, as well. Specifically, there could be conflicting choice of law provisions among the states involved in a case as to which state's choice of laws should govern the subject matter. The law that would apply would be determined by the court on a case-by-case basis.
- + Uniformity and predictability would be compromised. Also, given the complexities of the exchange of PHI, personal and political sensitivities regarding patient confidentiality and security could be issues. With these potential issues, there arguably is a greater likelihood that patients adversely affected by a choice of law statute will file lawsuits, resulting in an increase in litigation costs (time and expense).
- + Lastly, without a uniform choice of law statute, lack of certainty and predictability will exist. To continue to move forward without any change is not a logical option for Ohio.

### **Interstate Compact—Con**

- The more standards that the compact imposes, the less number of states will join; needs an agreed-upon mechanism to resolve conflicts.
- Overriding state rights is a potential problem with compacts.

### **Uniform Law—Con**

- Health information may not be available because providers will not know how to respond to another state's request. The current barriers will continue.
- The inconsistent, cumbersome, and inefficient processes for requesting patient information between states which currently lack privacy and security standards.
- The inconsistent application of multiple and redundant consent forms for a patient's confidentiality.
- Misuse, mismanagement, and inappropriate disclosure of consumers' health information by providers, payers, researchers, and emerging HIOs.
- Inappropriate and inconsistent interpretations of state laws related to consent for release of health information issues, and the potential provider risks or liabilities associated with failure to comply with such laws.
- The impact of rejection of a uniform law will leave the status quo, which is an inconsistent array of laws that is difficult to manage and interpret. Rejection of a uniform law will have a larger negative impact on Ohio if a uniform law is established

and Ohio does not join other states in the passage of the uniform law. Inconsistencies and inefficiencies will arise for both requests made from other states for health information in Ohio and made by Ohioans for health information in other states. For example, it could lead to patients having to sign multiple consent forms. Inconsistent state laws also increase the probability of misinterpretation or inconsistent interpretation of laws related to the disclosure of health information. These problems could lead to liability for health care providers who improperly disclose health information.

### **Model Law—Con**

- The impact of rejection of a model act will leave the status quo, which is an inconsistent array of laws that is difficult to manage and interpret. Rejection of a model act may have a larger negative impact on Ohio if a model act is established and Ohio does not join other states in the passage of the model act. Inconsistencies and inefficiencies will arise for both requests made from other states for health information in Ohio and made by Ohioans for health information in other states. For example, it could lead to patients having to sign multiple consent forms. Inconsistent state laws also increase the probability of misinterpretation or inconsistent interpretation of laws related to the disclosure of health information. These problems could lead to liability for health care providers who improperly disclose health information. Note, however, that even if a model act is adopted, these same issues will arise if there is not uniformity in how the model act is adopted.
- Health information may not be available because providers will not know how to respond to another state's request. The current barriers will continue:
  - The inconsistent, cumbersome, and inefficient processes for requesting patient information between states which currently lack privacy and security standards;
  - The inconsistent application of multiple and redundant consent forms for a patient's confidentiality;
  - Misuse, mismanagement, and inappropriate disclosure of patients' health information by providers, payers, researchers, and emerging HIOs; and
  - Inappropriate and inconsistent interpretations of state laws related to consent for release of health information issues, and the potential provider risks or liabilities associated with failure to comply with such laws.

### **Choice of Law—Con**

- Health information may not be available because providers will not know how to respond to another state's request. The current barriers will continue:
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  - The inconsistent application of multiple and redundant consent forms for a patient's confidentiality;
  - Misuse, mismanagement, and inappropriate disclosure of patients' health information by providers, payers, researchers, and emerging HIOs; and
  - Inappropriate and inconsistent interpretations of state laws related to consent for release of health information issues, and the potential provider risks or liabilities associated with failure to comply with such laws.

- Absent a formal choice of law mechanism or a mechanism that would offer more certainty and predictability, the courts would be required to determine which of the state's choice of law rules would be applicable based on a common law analysis. This could be a very time-consuming process as it is subject to judicial interpretation. In Ohio, there are several approaches a court could choose in selecting which state's choice of law rules would govern, including identification of the state that has had the most significant relationship to the subject matter (*Bobb Chevrolet, Inc. v. Jack's Used Cars*, L.L.C. [2002] 148 Ohio App.3d 97, 100-101, 772 N.E.2d 171).

## 8 Conflicts With State or Federal Laws

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

### Interstate Compact

It is critical that the interstate compact have the ability to either supersede state consent laws or create a system that designates in which situations whose state law will prevail.

Once a state enters into a compact, the terms of the compact control over the laws of the state, regardless of whether those laws are statutory, regulatory, or common law. In the case of medical records, Ohio has specific and detailed statutes regarding access to certain mental health records, certain records regarding AIDS and HIV tests, and drug and alcohol treatment records (Ohio Rev. Code §5122.3; Ohio Rev. Code §3701.243), regulations pertaining to drug and alcohol treatment records (Oh. Admin. Code §3793:2-01-06), and regulations on the use of Medicaid and other public assistance information (R.C. 5101.27). In addition, by case law, Ohio has recognized a privacy right in general medical records and a cause of action for violation of that privacy right (*Biddle v. Warren General Hospital* [1999], 86 Ohio St.3d 395). The terms of a compact regarding access to medical records would take priority over these laws in any situation in which the compact applies (i.e., if the compact applies only to interstate access to medical records, then Ohio law would continue to apply to intrastate access, while the compact terms would supersede those laws and apply to interstate access).

A compact, however, cannot preempt federal law. Therefore, existing federal law regarding access to medical records, and any future federal laws, would apply rather than the terms of the compact.

Specifically, federal regulations restrict the access to drug and alcohol treatment records from any entity receiving federal assistance. The federal assistance can be in any form, such as funding, reimbursement for services, or federal tax-exempt status (42 C.F.R. Part 2). These federal restrictions will apply regardless of any compact terms. Furthermore, the

federal government could, particularly in connection with Medicare and Medicaid funding, enact or promulgate restrictions pertaining to other types of medical records. Any future laws at the federal level would also apply over the terms of a compact.

Federal law also provides confidentiality protections to certain categories of persons, such as the protection 42 C.F.R. Part 2 provides to individuals in substance abuse treatment programs.

To eliminate the barriers to HIOs caused by conflicting consent laws, it is critical that the option has the ability to supersede at least one state's laws. "A compact is superior in force and effect to both prior and subsequent statutory law. Conflicting statutes in different states, therefore, present no obstacles."<sup>67</sup>

The U.S. Supreme Court has examined interstate compacts and has resolved conflicts among participating states. In the case of *Dyer v. Sims*, 341 U.S. 22, the Supreme Court prevented Virginia from pulling out of an interstate compact when Virginia asserted the compact violated the Virginia Constitution. The Supreme Court stated that interstate compacts cannot be unilaterally nullified or given meaning by an organ of one of the contracting states. To do so would be to allow a state to be its own judge in a conflict with another state. Instead, the Supreme Court asserted that the Supreme Court has the final power to judge the meaning and validity of interstate compacts. The Supreme Court described interstate compacts as analogous to the treaty-making power of sovereign states, an observation it had previously made in *Hinderlider v. LaPlata Co.*, 281 U.S. 176, and in *Rhode Island v. Massachusetts*, 37 U.S. 657.

## Uniform Law

NCCUSL through the study process will work to harmonize the uniform act with existing federal laws and with the input of representatives from the states, and will review and consider critical state laws. Before enacting a uniform act, each state will have to reconcile the proposed act with its laws to determine if any conflicts will exist and whether the uniform act is the preferred law for its state.

HIPAA sets minimum standards regarding the release of PHI. Therefore, no state has consent requirements less stringent than federal law. More stringent state laws would continue to supersede HIPAA. Therefore, to the extent that the uniform law invokes a more stringent requirement than HIPAA, it would continue to apply.

Federal law also provides confidentiality protections to certain categories of persons, such as the protection 42 C.F.R. Part 2 provides to individuals in substance abuse treatment programs.

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<sup>67</sup> What Makes an Interstate Compact? Council of State Governments, National Center for Interstate Compacts website. Available at <http://www.csg.org/programs/ncic/resources.aspx>.

With respect to any possible conflict with state laws, the rules of statutory construction would generally provide that the newly enacted uniform law would prevail. Care should be taken so the uniform law is drafted in a way that is clear whether it is superseding the law.

HIPAA permits providers, insurance companies, and other health care entities to exchange information necessary for treatment, payment, or operations of health care business (TPO). Although HIPAA established strict guidelines for the use and disclosure of PHI by covered entities, those protections must be read in conjunction with the privacy protections for an individual's health information set out in each state. In general, states have more stringent laws regarding certain types of records related to mental health, addiction, HIV, and genetics.

*Conflicts with federal laws:* Under the Supremacy Clause of the U.S. Constitution, no state law can take precedence over federally imposed requirements. However, in enacting HIPAA, Congress did not desire to supersede state laws that are not contrary to and impose more stringent standards with respect to privacy of individually identifiable health information. In other words, this preemption exception furthers the principle that the HIPAA Privacy Rule will defer to any state privacy law that is not contrary to the HIPAA Privacy Rule (meaning that a covered entity can comply with both the state and federal rules) and provides individuals with greater privacy protection (45 C.F.R. 160.202 and 45 C.F.R. 160.203(b)).

*Conflicts with state laws:* Since a uniform law is an "unofficial law proposed as legislation for all the states to adopt as exactly as written."<sup>68</sup> Therefore, if fully adopted by all states, there would be no conflict between states. In reality, however, unless all jurisdictions adopt the uniform law, there will be conflicting laws among the states, which will lead to the problems discussed above in Ramifications of Acceptance/Rejection. The uniform law would need to contain a provision that it supersedes existing state law that conflicts with the uniform law.

Alternatively, steps would need to be taken to harmonize existing state law that may conflict with the uniform law.

### **Model Law**

The drafter of the model law will have to compare the model law provisions to federal law. Also, each adopting state will have to review the laws of its state to determine which portions of the model law to adopt and which portions of its own laws might need to be changed. However, if the entity preparing the model law does not sufficiently review the federal law, any potential conflicts in the model law could be inadvertently adopted by the states. If there is a direct conflict, then the federal preemption may be an issue.

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<sup>68</sup> Garner, B. A. (Ed.). (2004). *Black's Law Dictionary* (8th ed.), p. 1566.

disclosure of PHI by covered entities, those protections must be read in conjunction with the privacy protections for an individual's health information set out in each state. In general, states have more stringent laws regarding certain types of records related to mental health, addiction, HIV, and genetics.

*Conflicts with federal laws:* Under the Supremacy Clause of the U.S. Constitution, no state law can take precedence over federally imposed requirements. However, in enacting HIPAA, Congress did not desire to supersede state laws that are not contrary to and impose more stringent standards with respect to privacy of individually identifiable health information. In other words, this preemption exception furthers the principle that the HIPAA Privacy Rule will defer to any state privacy law that is not contrary to the HIPAA Privacy Rule (meaning that a covered entity can comply with both the state and federal rules) and provides individuals greater privacy protection (45 C.F.R. 160.202 and 45 C.F.R. 160.203(b)).

*Conflicts with state laws:* A model act is "a statute . . . proposed as a guideline legislation for the states to borrow from or adapt to suit their individual needs."<sup>69</sup>

Since a model act permits each state to amend the act, there is potential for conflict between state laws. In order to resolve the conflict between state laws, the choice-of-law principles may apply.

Under the choice of law principles:

- (1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.
- (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include (a) the needs of the interstate and international systems; (b) the relevant policies of the forum; (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue; (d) the protection of justified expectations; (e) the basic policies underlying the particular field of law; (f) certainty, predictability, and uniformity of result; and (g) ease in the determination and application of the law to be applied.

As stated under section (1) of choice of law principles, the statute itself may direct the choice of law. Therefore the model act of each state should provide a provision that directs the process and consent to release of patient information across state lines. The directive should indicate that the requesting state is subject to the laws of the responding state.

*Conflict with existing state laws:* The model act would need to contain a provision that it supersedes existing state law that conflicts with the model act. Alternatively, steps would need to be taken to harmonize existing state law that may conflict with the model act.

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<sup>69</sup> Garner, B.A. (Ed.). (2004). *Black's Law Dictionary* (8th ed.), p. 1025.

HIPAA sets minimum standards regarding the release of PHI. Therefore, no state has consent requirements less stringent than federal law. More stringent state laws would continue to supersede HIPAA. Therefore, to the extent that the model act invokes a more stringent requirement than HIPAA, it would continue to apply.

Federal law also provides confidentiality protections to certain categories of persons, such as the protection 42 C.F.R. Part 2 provides to individuals in substance abuse treatment programs.

With respect to any possible conflict with state laws, the rules of statutory construction would generally provide that the newly enacted model act would prevail. Care should be taken so the model act is drafted in a way such that it is clear whether it is superseding the law. According to Katie Robinson, NCCUSL, relevant federal law is followed as closely as possible in drafting model acts.

### **Choice of Law**

HIPAA sets minimum standards regarding the release of PHI. Therefore, no state has consent requirements less stringent than federal law. More stringent state laws would continue to supersede HIPAA. Therefore, to the extent that the uniform law invokes a more stringent requirement than HIPAA, it would continue to apply.

Federal law also provides confidentiality protections to certain categories of persons, such as the protection 42 C.F.R. Part 2 provides to individuals in substance abuse treatment programs.

A contractual choice of law provision, presumably in an agreement between a health care provider and a patient, may conflict with specific Ohio statutes. For example, by statute, Ohio restricts access to certain mental health records and to certain records regarding AIDS and HIV tests (Ohio Rev. Code §5122.3; Ohio Rev. Code §3701.243). These laws were enacted to protect the privacy of Ohio citizens with regard to information that could be particularly sensitive or damaging. In light of this, if an Ohio patient were to sign an agreement with a provider that the less protective laws of another state apply to the transfer of records, the courts would need to determine if the patient is able to waive the statutory protections and whether, in the particular situation, the patient effectively did waive those protections.

Specifically, under Ohio law, a person may waive rights and privileges conferred by statute, if the waiver does not violate public policy (*Hess v. Akron* [1937], 132 Ohio St. 305).

A statutory choice of law provision, on the other hand, would presumably address the effect it has on specific Ohio medical records protections, thus avoiding the potential conflict with other state laws.

Currently, federal regulations apply regarding access to records pertaining to drug and alcohol treatment from an entity receiving any type of federal assistance (42 C.F.R. Part 2). Because the access restrictions are tied to the entity's continued federal assistance, neither contractual nor state statutory choice of law provisions will supersede the federal restrictions.

### **Interstate Compact—Pro**

- + Has the potential to be the federal law.
- + One of the primary benefits of a compact is the fact that it supersedes the application of contrary state laws. In other words, the benefit is that it makes the rules between the states to the compact uniform, thereby making it easier to access medical information across state lines. This, by nature, means that conflicting state laws must not apply. This results in a collaborative approach among the states to resolving issues created by conflicting state laws and may encourage the federal government to also collaboratively resolve differences with federal law. In addition, the process of entering into a compact may result in individual states reviewing and revising their current privacy laws and statutes.
- + This mechanism provides for consistency in addressing the interstate transfer of health information among member states and removes conflict among differing state laws.

### **Uniform Law—Pro**

- + Although discouraged, it allows states to take those parts of the proposed law that are consistent with existing state law.
- + The process of creating the uniform law could adequately address concerns about conflict with federal law. The study committee will be able to explore any potential conflicts with federal law, or whether the federal government would need to take any additional action regarding electronic transmission of personal health information. As more and more personal health information becomes electronic, states will need universal privacy acts and be looking for models on how to handle interstate transmission. This may naturally occur as part of the combined efforts at the federal and state level to adopt EHRs.
- + The uniform law may impose more stringent laws than the current federal standards, as long as they are not contrary to the current HIPAA laws. Therefore, the uniform law must be no less stringent than HIPAA. The question is whether the uniform law should adopt provisions that include the most stringent state laws, in order to provide the greatest level of privacy to patients.

### **Model Law—Pro**

- + Allows states to take those parts of the proposed law that are consistent with existing state laws.
- + In order to prevent conflict, the model act should include a section that provides that the law of the responding state be applied. This permits the responding entity and/or state to consistently comply with the applicable laws of its state.
- + The group agreed that the process of creating the model act could adequately address concerns about conflict with federal law. The study committee will be able to

explore any potential conflicts with federal law, or whether the federal government would need to take any additional action regarding electronic transmission of personal health information. As more and more personal health information becomes electronic, states will need universal privacy acts and be looking for models on how to handle interstate transmission. This may naturally occur as part of the combined efforts at the federal and state level to adopt EHRs.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Nimble to address concerns.

#### ***Statutory Provision***

- + Best at addressing conflicts in own state law.
- + Ease in complying with HIPAA.

### **Interstate Compact—Con**

- California has so many laws that cover health information, such as breach notification and mental health protections, that developing a compact to be in accordance with California law could be difficult.
- The downside of a compact's preemption of state laws is the fact that it does not permit a state to enact policies that reflect unique cultures or climates that exist in that state.
- The more state laws are in conflict with the interstate compact, the more likely the adoption process will not succeed.

### **Uniform Law—Con**

- Will need each legislature to identify conflicting state laws and resolve the predominance of the uniform law.
- Drafters and those who will implement will have to be diligent in their analysis of federal and state laws for conflicts.
- If too complex to implement, those with less funding may not be able to participate.

### **Model Law—Con**

- Will need each legislature to identify conflicting state laws and resolve the predominance of the model law.
- Drafters and those who will implement will have to be diligent in their analysis of federal and state laws for conflicts.
- If too complex to implement, those with less funding may not be able to participate.
- It may be difficult for the requesting state to obtain the information that it desires, if the responding state prohibits such release. Also, if a state that adopts the model act does not provide a choice of law directive, then in the event of a conflict between states, the courts will have to intervene and conduct an analysis under the seven factors listed above. This can result in costly and time-consuming litigation.

- If the model act is not uniformly adopted across the states, it is uncertain as to whether or not it will conflict with state and federal laws. The more state laws are in conflict with the model act, the more likely the adoption process will not succeed.

### **Choice of Law—Con**

#### ***Contractual Provision***

- Not able to address laws that conflict.
- Interstate access to medical records will continue to be impeded by conflicting requirements. Specifically, two states may each have statutes applying its own laws, rather than the laws of the other state. In these situations, choice of law provisions will make the process for interstate access to medical information less certain, and therefore more difficult.

#### ***Statutory Provision***

- Conflicts with federal laws will not be cured if statute does not conform.
- There will be jurisdictional issues as a contractual agreement for consenting may be in conflict with state laws. Similarly, unless all states enact the same choice of law provision and then the underlying laws of the states are consistent (which is not currently the case), a choice of law provision will not be a practical solution.

## **9 Process for Withdrawal**

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

### **Interstate Compact**

Compacts normally include provisions for a party state to withdraw.

These may include the repeal of the state's ratification law and some notification to other party states.

Withdrawal or modification may be accomplished only in compliance with the terms of the compact or by mutual consent and necessary (usually legislative) action by all members. Usually requires legislative enactment, but compact terms may additionally provide for delay in effective date of withdrawal (i.e., 2 years) and require notice of withdrawal to all other member states. For example, the Interstate Compact on Mental Health, ORC 5119.50, allows for withdrawal by passing legislation repealing the compact and provides that the withdrawal will become effective 1 year after formal notice to all other member states. Additionally, the withdrawal shall not change the status of patients previously transferred between states according to the terms of the compact.

## **Uniform Law**

Withdrawal from a uniform law simply is accomplished by the legislature passing and the governor approving the repeal of the law.

## **Model Law**

A model law would be enacted through the legislative process, and the law would need to be amended, repealed, or declared unenforceable for it not to bind Californians.

In Ohio and Illinois, withdrawal from a model act is accomplished by the legislature passing the law and the governor approving the repeal of the law.

## **Choice of Law**

A statutory “choice of law” would govern until it was repealed or declared unenforceable.

Depending on the terms of their agreement, the parties should be able to terminate the exchange. The agreement should make provisions as to the data already transmitted.

Contractual provisions can be withdrawn or modified by amendment to the contract. Statutes can be superseded or modified by the passage of another statute. If choice of law is specified by parties to a transaction or claim, withdrawal would need to be in accordance with the rules relating to the transaction or claim, either as specified in agreement or by common law. This element is not applicable to nonparty/state law determinants about choice of law other than withdrawal from statute with regard to: choice of law would be by legislative enactment.

## **Interstate Compact—Pro**

- + Not easily renounced by other members.
- + It is essential to adapt to changes in circumstance over time. Interstate compacts do permit states to withdraw if needed, which is an important clause in order to increase buy-in by stakeholders.

## **Uniform Law—Pro**

- + The ability to repeal or modify a uniform law gives states control over consent policies.
- + Promotes the ability to get the law passed initially, as states are not definitely locked in, they can later change their minds. There is some limitation on withdrawal in that the executive branch in the state may veto legislative attempts at later change.

## **Model Law—Pro**

- + Promotes the ability to get the law passed initially, as states are not definitely locked in, they can later change their minds. There is some limitation on withdrawal in that the executive branch in the state may veto legislative attempts at later change. Might be more attractive for quick acceptance if states could modify the terms of the act (which, of course, would have the problem of destroying uniformity).

- + The ability to repeal or modify a model act gives states control over consent policies.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Ease, pursuant to terms of contract.
- + A contractual provision is easier to withdraw from than a statute because it requires no legislative action.

### **Interstate Compact—Con**

- Will need to cover the impact on exchanges that occurred previous to the withdrawal.
- Complex and potentially lengthy process to modify terms or withdraw.
- The withdrawal from the interstate compact would create uncertainty over the handling of PHI and create problems for health care providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the interstate compact. Keeping track of which states have adopted or withdrawn from the uniform law will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.

### **Uniform Law—Con**

- Difficult to repeal a law, and until repealed, the law would be binding.
- Urgency bills require two-thirds vote to amend, to fix unintended consequences.
- The repeal of the uniform law would create uncertainty over the handling of PHI and create problems for health care providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the uniform law. Keeping track of which states have adopted or withdrawn from the uniform law will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.
- Allows for the possibility that the whole uniform system can fall apart at any time. Uniformity is dependent on 50 state legislators and governors.

### **Model Law—Con**

- Difficult to repeal a law, and until repealed, the law would be binding.
- Urgency bills require two-thirds vote to amend, to fix unintended consequences.
- Allows for the possibility that the whole system can fall apart at any time. Consistency is dependent on 50 state legislators and governors. Withdrawal could destroy commonality.
- The repeal of the model act would create uncertainty over the handling of PHI and create problems for health care providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the model act. Keeping track of which states have adopted or withdrawn

from the model act will be difficult. Questions may arise as to what prevails if a state has withdrawn.

### **Choice of Law—Con**

#### ***Contractual Provision***

- The ease with which it is possible to withdraw from a contractual choice of law provision may not provide the parties with much of a mandate for robust HIE.

#### ***Statutory Provision***

- Difficult to repeal a law.
- Urgency bills require two-thirds vote to amend, to fix unintended consequences.

## **10 State Responsibilities**

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

### **Interstate Compact**

Responsible for educating stakeholders regarding the consent requirements that would apply under the interstate compact.

If the compact envisions a governing or administrative body, the member states may incur a fiscal responsibility to support the administrative body.

State government officials and policy makers would have to promote the compact and enact legislation authorizing the state to join the compact. In the same legislation, the state legislature will have to designate a lead governmental agency. The lead governmental agency and any subsequent statutes and administrative regulations will have to serve both to promote and educate potential users and other governmental entities as to the expectations created by the compact.

### **Uniform Law**

States would be responsible for enacting the uniform law or one substantially similar. During and after enactment, states would need to educate stakeholders regarding the new consent requirements.

States would be responsible for educating stakeholders regarding the consent requirements that would apply after the adoption of the uniform law.

State government would have to enact the uniform law without change. To the extent any uniform law was consistent with current status of consent law in a state, there should not be significant obstacles to adoption. If the uniform law were significantly different from current state law, passage might be more difficult.

## **Model Law**

Each state is responsible for comparing its current law to the model law. Each state would then have to decide which portions of the model law to adopt and whether that state has any laws that need to be changed. Then that state would have to pass all or only portions of the model law through the legislative process. Finally, the state may need to create regulations to implement the statute.

State government would have to enact model act legislation, either “as is” or with changes. To the extent any model act was consistent with current status of consent law in a state, there should not be significant obstacles to adoption “as is.” If a model act were significantly different from current state law, passage with changes would be more likely.

States would be responsible for educating stakeholders regarding the consent requirements that would apply after the adoption of the model act.

## **Choice of Law**

The adoption of agreements that are consistent with a state law that specifies California law as the prevailing law would predominately be undertaken by private entities, and only in a dispute, through the court system, would the state undertake any responsibilities.

State responsibilities include the enforcement of the applicable statutes, within the discretion of the enforcement authority. The state may assist with implementation efforts concerning new statutes and will sometimes publish compliance guidance and other materials such as Frequently Asked Questions databases. The state also enforces contractual provisions when raised by litigation.

Generally, states have only the responsibility to enforce their own laws. For this reason, courts will often go to great length to avoid applying or interpreting foreign laws. Conversely, courts will, on occasion, make significant efforts to apply the laws of their jurisdiction. These inclinations are motivated by preferences and familiarity rather than formal legal theories. Nevertheless, the expression of this preference is effectively a choice of law.

## **Interstate Compact—Pro**

- + Will need to ensure transparency on the decision-making process.
- + By serving as the primary driver of a compact, state government injects a higher level of stability and predictability into the expectations of HIE. This stability and predictability can be bolstered by the force of law as each member state insures compliance with the processes and mechanisms established through the compact.
- + The education of stakeholders regarding the consent requirements will result in buy-in.

### **Uniform Law—Pro**

- + Potential for regulatory oversight and regulations to ensure uniformity and ease of implementation.
- + Providers prefer a mandate rather than a discretionary or permissive approach to consent.
- + A uniform law would potentially offer greater consistency among states and greater ease of information transfer across states than a model act.

### **Model Law—Pro**

- + State has responsibility in deciding which portions of the law to enact.
- + Potential for regulatory oversight and regulations to ensure uniformity and ease of implementation.
- + Potentially easier acceptance by states of model act over a uniform law, due to ability to make changes, or to adopt part but not all of model act.
- + Providers prefer a mandate rather than a discretionary or permissive approach to consent.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Minimal state responsibility.
- + The ambiguities created by the current state of affairs do allow for some flexibility to address unexpected circumstances without having to formally amend fixed or codified terms.

#### ***Statutory Provision***

- + Potential for regulatory oversight and regulations.

### **Interstate Compact—Con**

- Lack of resources may impact implementation.
- Education will be needed.
- As with all governmental programs or involvement, there will be a certain amount of bureaucracy accompanying compact-sanctioned transactions. Additionally, due to variations in governmental structures from state to state, there will be some inconsistencies as to the specific governmental entity managing compact issues or concerns; however, the impact of these variations should be minimal.
- An interstate compact may be pursued without providing adequate funding and content analysis to support an initiative to educate stakeholders on the compact's consent procedures. The group estimated that it might cost providers \$120,000 to educate their staff and patients. Funding support by the state will be a critical component for increasing buy-in by providers.

### **Uniform Law—Con**

- Lack of resources may impact implementation.
- Education will be needed.
- If there are variations in the law, it could lead to conflicting interpretations and differences in implementation.
- This will impose additional mandates on providers, which will have a cost. If the uniform law is only an overlay to the laws concerning paper, then providers will have to figure out if they need two processes in place to handle the difference between EHR transfer versus paper transfer. The drafters should consider cost to providers when creating the legislation. In addition, the drafters should consider cost to patients when creating the legislation.
- A uniform law offers much less flexibility; there is a greater likelihood that states would refuse to enact uniform law than a model act.

### **Model Law—Con**

- Lack of resources may impact implementation.
- Education will be needed.
- If there are variations in the law, it could lead to conflicting interpretations and differences in implementation.
- Greater likelihood of inconsistency among states due to potential multiple variations of model act being adopted.
- This will impose additional mandates on providers, which will have a cost. If the model act is only an overlay to the laws concerning paper, then providers will have to determine if they need two processes in place to handle the difference between EHR transfer versus paper transfer. The drafters should consider cost to providers when creating the legislation. In addition, the drafters should consider cost to patients when creating the legislation.

### **Choice of Law**

#### ***Contractual Provision***

- No oversight currently being performed; may need to develop.
- This being the present state of affairs, choosing this option continues the present uncertainty.

#### ***Statutory Provision***

- Integration of other state regulators.
- Choice of law will not be helpful unless we have consistent adoption and application. There is a possibility that the choice of law could be in conflict with both state and federal laws, as well as result in a contract dispute if there is a violation.

## 11 State's Rights

How does the proposal impact issues related to importance of maintaining state sovereignty and adhering to state constitutional limitations?

### Interstate Compact

A state can retain as much of its primary sovereignty as the terms of the compact will allow.

A compact is used in matters affecting the interests of multiple states or, in the case of access to medical records, the individual citizens of multiple states. As such, it permits states to work together to address the mutual practical and policy issues. This reinforces the rights of the state to address such issues. Nevertheless, because the compact supersedes the application of an individual state's laws, it also limits the ability of a state to unilaterally establish policy in the area covered by the compact.

As noted by CSG, "compact language is usually drafted with state constitutional requirements common to most state constitutions such as separation of powers, delegation of power, and debt limitations in mind. The validity of the state authority to enter into compacts and potentially delegate authority to an interstate agency has been specifically recognized and unanimously upheld by the U.S. Supreme Court in *West Virginia v. Sims*, 341 U.S. 22 (1951)."<sup>70</sup>

States join the interstate compact only after going through the legislative process. Once a member, the state has the rights stated in the terms of the compact. Under the approaches considered in this document, there is not an administrative or arbitration process that would affect a state's rights. One right states would be expected to retain is the right to withdraw from the compact.

### Uniform Law

The uniform act, having been developed through the NCCUSL process, will have had experts and state representatives provide input in the drafting of the act. States retain the ability to establish requirements that are more responsive to their needs, but if the changes are substantially dissimilar, the benefit of uniformity maybe lost.

The uniform law mechanism sets forth a state solution to the issue of the interstate exchange of PHI, instead of a federal mandated approach. States retain the ability to establish requirements that are more responsive to their needs.

State government has little to no control over text of a uniform law to be adopted; "take it or leave it" is only option to exercise state sovereignty.

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<sup>70</sup> Frequently Asked Questions: Compacts Generally, Council of State Governments—National Center for Interstate Compacts. Available at [http://online.nwf.org/site/DocServer/Compact\\_FAQs.pdf?docID=701](http://online.nwf.org/site/DocServer/Compact_FAQs.pdf?docID=701).

## **Model Law**

Each state will have the authority to adopt whatever portions of the model law it chooses to adopt and can adopt alternative language to the model law. Therefore, each state retains the complete right to enact the law as it decides it should be. In this manner, a state's rights are not implicated.

However, as stated above, if federal law does control and a provision is somehow adopted that does not comply with federal law, then federal preemption questions could arise.

State government has greater control over text of model act to be adopted.

The model act mechanism sets forth a state solution to the issue of the interstate exchange of PHI, instead of a federal mandated approach. States retain the ability to establish requirements that are more responsive to their needs.

## **Choice of Law**

If California were to enact a "choice of law" that made its rules concerning privacy rights dominant over all health information covered under California law, such a law would be the ultimate exercise of sovereignty; however, there may be concerns over the impact of the Commerce Clause.

States generally are sovereign within their jurisdiction (except for certain defined claims that are reserved to the federal government) and have an interest in applying their own law and protecting their own citizens. The state may agree to permit the law of the requesting state to be the choice of law in matters of consent, but by so doing, the state is removing the protections of its own laws from its citizens' PHI, given that HIO members located in a given state probably have a preponderance of PHI from residents of that state. A state may not wish to have a choice of law provision that applies the law of another state.

States are also likely to resist preemption of their state laws in favor of a federal statute that governs choice of law in consent matters.

## **Interstate Compact—Pro**

- + Need a strong presence in the drafting.
- + The establishment of a compact makes it less likely that the federal government will enact or promulgate preemptive laws or regulations. In other words, an effective compact will lessen or eliminate the need for federal government intervention. Thus, a compact will assist in preserving the rights of the states to have control over the policies governing access to medical records.
- + An interstate compact is a reasonable, state-directed solution to the problem of conflicting state laws.

## **Uniform Law—Pro**

- + Need a strong presence in the drafting.

- + States retain the ability to establish requirements that are more responsive to their needs.
- + A uniform law would potentially offer greater consistency among states and greater ease of information transfer across states than a model act.

### **Model Law—Pro**

- + States maintain their ability to choose or not to choose which provisions to adopt.
- + Offers greater deference to individual states and state sovereignty, due to ability to make changes, or to adopt part but not all of model act.
- + States retain the ability to establish requirements that are more responsive to their needs.

### **Choice of Law—Pro**

#### ***Statutory Provision***

- + State can preserve as much sovereignty as it wants, can preserve its police powers.
- + Drafting will be very important.

### **Interstate Compact—Con**

- Need to ensure retention of jurisdiction for disputes involving state laws.
- A compact will limit the rights of the individual compact states to alter the policies or procedures to access medical records. In other words, a state may enact new laws pertaining to privacy or access to specific health records, but the compact provisions will supersede those laws in any situation in which the compact applies. Thus a state cannot unilaterally alter the process for access to medical records in any situation in which the compact applies.
- An interstate compact does not ensure a solution for every state. This would require a federal standard. An interstate compact will also require another layer of legal analysis for providers.

### **Uniform Law—Con**

- If all states do not adopt the act with similar language, it might work well for only those states whose acts are in alignment. This may detract from the consistency of the overall impact of the uniform law.
- A uniform law offers less deference to individual states and state sovereignty.

### **Model Law—Con**

- Less likely to reach objective of facilitating exchange of information across states; end result could be similar to current situation (status quo).
- If all states do not adopt the act with similar language, it might work well for only those states whose acts are in alignment. This may detract from the consistency of the overall impact of the model act.

## Choice of Law—Con

### ***Contractual Provision***

- A generic law may result in the state giving up some of its rights (e.g., “the disclosing state’s laws apply”).

### ***Statutory Provision***

- Businesses would not like different laws for each state.

## 12 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?

### **Interstate Compact**

Since compacts are agreements between states, the U.S. Supreme Court is the usual forum for the resolution of disputes between member states.

Compacts frequently include provisions to resolve disputes through arbitration or other means.

As an interstate compact is essentially a congressionally approved contract among the member states, with its remedies best set forth within the terms of compact. The enforceability compact is directly tied to congressional approval; without such approval, the compact is nonbinding and legally unenforceable upon the members. Thus, disputes within an approved compact are matters between the states and within federal subject-matter jurisdiction. However, federal courts are often reluctant to apply certain contract remedies as the parties and the compact are atypical (*Waterfront Com’n of New York Harbor v. Construction and Marine Equipment Co., Inc.*, 928 F.Supp. 1388 [D.N.J. 1996]). For example, federal courts will refrain from the equitable remedy of reforming the compact even in the face of unforeseen circumstances (*Texas v. New Mexico*, 462 U.S. 554, 103 S.Ct. 2558, 77 L.Ed.2d 1 [1983]; *New Jersey v. New York*, 118 S.Ct. 1726 [1998]). While the remedy of monetary damages is complicated by the Tenth Amendment, specific performance is a reasonable alternative (*Texas v. New Mexico*, 462 U.S. 554). However, when the terms of the compact set forth a dispute resolution mechanism, the courts generally prefer deference to that mechanism even when the mechanism is not efficient or necessarily effective (see *Texas v. New Mexico*, 462 U.S. 554; *Waterfront Com’n of New York Harbor*, 928 F.Supp. 1388). A compact, in and of itself, does not directly alter the intrastate legal expectations. That is, a potential interstate compact on HIE across state

boundaries can be limited only to the management of that exchange setting. It is only when the compact terms address the specific issue addressed by the compact that the effect of joining the compact serves to create a cognizable exception to the standard or usual expectations. However, even a well-crafted compact term cannot create an exception to a constitutional expectation if the state legislature does have specific authority to create the exception. Nevertheless, the pressure that standardized interstate exchange expectations create on intrastate exchanges to match those expectations will be proportional to the amount or reutilization of the interstate exchange through the established interstate compact protocols. In other words, the more the health care system uses the interstate compact mechanisms, the more likely the health care system will look to those mechanisms as the generalized standards for all exchange. For these reasons, the compact should carefully set out the enforcement mechanisms that arbitrate concerns and divergent understanding in a timely fashion (e.g., governing bodies, mediation board, dispute board, etc.). Additionally, given the potential pressure to standardize intrastate HIE by the standardization of interstate HIE, it is potentially advisable for the compact to specifically address the matter in its construction and terms.

Enforcement in the context of interstate compacts is normally viewed from the prospective of ensuring compliance with their provisions. In addressing this issue, CSG states:

A violation of compact terms, like a breach of contract, is subject to judicial remedy. Since compacts are agreements between states, the U.S. Supreme Court is the usual forum for the resolution of disputes between member states. However, compacts can, and frequently do, include provisions to resolve disputes through arbitration or other means.<sup>71</sup>

In the context of crafting an interstate compact that addresses consent issues for the release of PHI, enforcement of unauthorized releases of information can lead to criminal or civil sanctions. State consent laws typically include some form of penalty for the unauthorized release of information. For example, violation of Illinois’s Mental Health and Developmental Disabilities Confidentiality Act is a Class A misdemeanor. The act also authorizes a person “aggrieved by a violation” to sue for “damages, an injunction, or other appropriate relief.”

With respect to Approaches 1 and 2, the statutory authority for the criminal or civil sanctions in the requesting or responding state will presumably still exist under the auspices of the interstate compact.

The ramifications of sanctioning persons for violating the consensus consent requirements developed by compact members under Approach 3 would have to be addressed in the drafting process. One option would be the creation of an arbitration process.

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<sup>71</sup> Council of State Governments, p. 2. Available at <http://ssl.csg.org/compactlaws/Introoverview.doc>.

## **Uniform Law**

Under the terms of the uniform act, enforcement will probably be based on state laws, incorporating the terms of the act.

Under the uniform law mechanism, enforcement issues fall within the purview of the adopting states.

States generally are sovereign within their jurisdiction (except for certain defined claims that are reserved to the federal government) and have an interest in applying their own law and protecting their own citizens. Each state approves and enforces its own statutes, which are only applicable within the jurisdiction of that state. States develop statutes that they believe protect the interests of their residents, but state statutes are not enforceable beyond the proponent state's jurisdiction. A state with a restrictive consent requirement has no authority in most situations to enforce its statute against an HIO or provider that operates outside of the state's boundaries, even if the violation involved the PHI of a resident of that state. In the scenario of an HIO that is exchanging PHI, the actions affecting the PHI are being performed in two or more states. The responding state will have jurisdiction over the initial collection of the PHI, while the requesting state will have jurisdiction over the subsequent use of that PHI. The issue of where the disclosure occurred will likely decide which state's law is applicable to the disclosure, and may even involve a third state where the data is physically stored or where the HIO operates. The use of a uniform law could help to standardize the statutes, while allowing each state to maintain its own statutes and to use its existing enforcement agencies and processes.

## **Model Law**

Under the terms of the model law, enforcement will probably be based on state laws, incorporating the terms of the law.

Under a model act, the enforcement mechanism could defer these decisions to the states, or it could specify a uniform enforcement mechanism, determining which state's law would apply, and providing remedies.

Under the model act mechanism, enforcement issues fall within the purview of the adopting states. States generally are sovereign within their jurisdiction (except for certain defined claims that are reserved to the federal government) and have an interest in applying their own law and protecting their own citizens. Each state approves and enforces its own statutes, which are only applicable within the jurisdiction of that state. States develop statutes that they believe protect the interests of their residents, but state statutes are not enforceable beyond the proponent state's jurisdiction. A state with a restrictive consent requirement has no authority in most situations to enforce its statute against an HIO or provider that operates outside of the state's boundaries, even if the violation involved the PHI of a resident of that state. In the scenario of an HIO that is exchanging PHI, the actions

affecting the PHI are being performed in two or more states. The responding state will have jurisdiction over the initial collection of the PHI, while the requesting state will have jurisdiction over the subsequent use of that PHI. The issue of where the disclosure occurred will likely decide which state's law is applicable to the disclosure, and may even involve a third state where the data is physically stored or where the HIO operates. The use of a model act could help to standardize the statutes, while allowing each state to maintain its own statutes and to use its existing enforcement agencies and processes.

### **Choice of Law**

Enforcement could be problematic under "choice of law" for the consumer. If the choice of law agreement is between providers, without real knowledge and participation by the consumer, the consumer may not be aware of which law is controlling and may not be bound by any third-party agreement.

Under the choice of law approach, enforcement issues fall within the purview of the adopting states.

States generally are sovereign within their jurisdiction (except for certain defined claims that are reserved to the federal government) and have an interest in applying their own law and protecting their own citizens. Each state approves and enforces its own statutes, which are only applicable within the jurisdiction of that state. States develop statutes that they believe protect the interests of their residents, but state statutes are not enforceable beyond the proponent state's jurisdiction. A state with a restrictive consent requirement has no authority in most situations to enforce its statute against an HIO or provider that operates outside of the state's boundaries, even if the violation involved the PHI of a resident of that state. In the scenario of an HIO that is exchanging PHI, the actions affecting the PHI are being performed in two or more states. The responding state will have jurisdiction over the initial collection of the PHI, while the requesting state will have jurisdiction over the subsequent use of that PHI. The issue of where the disclosure occurred will likely decide which state's law is applicable to the disclosure, and may even involve a third state where the data is physically stored or where the HIO operates. The use of a choice of law provision could help to clarify which statute to apply, while allowing each state to maintain its own statutes and to use its existing enforcement agencies and processes. The requesting and responding states are obligated to comply with the statutes of the state in which they reside. If a state passes a choice of law statute that requires compliance with the requesting state's law, the state would still be enforcing its own statute, although it may have to interpret and apply the requesting state's applicable law. The states would likely use the existing enforcement agencies and methods that they currently apply.

### **Interstate Compact—Pro**

- + Can design flexibility with enforcement.

- + Possible to create a certification process to ease implementation.
- + Uniformity will ease enforcement.
- + By addressing enforcement, the compact remains the master of its own fate.
- + Enforcement is necessary to achieve compliance and gives the compact a sense of importance.

### **Uniform Law—Pro**

- + Can be specifically addressed in the provisions of the uniform law.
- + Each state retains the ability to decide enforcement issues, and may set up a mechanism as it sees fit, unless directed by the uniform law. The formation of a quick, deliberative advisory body to enforce the law will circumvent time delays, as well as define parameters to avoid having tort litigation define the law.
- + If there is no enforcement mechanism specified, then it would probably make passage by the states easier and faster since states will not be locked into a mechanism they may not like.

### **Model Law—Pro**

- + Can be specifically addressed in the provisions of the model law.
- + If there is no enforcement mechanism specified, then it would probably make passage by the states easier and faster since states will not be locked into a mechanism they may not like.
- + Each state retains the ability to decide enforcement issues, and may set up a mechanism as it sees fit, unless directed by the model act. The formation of a quick, deliberative advisory body to enforce the law will circumvent time delays, as well as define parameters to avoid having tort litigation define the law.

### **Choice of Law—Pro**

#### ***Contractual Provision***

- + Ease for parties to dispute, by terms of contract.
- + May be more cost effective to enforce.

#### ***Statutory Provision***

- + Statute can spell out enforcement, bring in regulatory oversight.
- + A consistent choice of law provision could result in the state enforcing its own choice of law provision, rather than enforcing another state's law.

### **Interstate Compact—Con**

- Cannot depend on the Office of Inspector General (OIG)-Civil Rights for enforcement; will need each state's enforcement to be on top of it.
- If the standards are permissive, may lack enforceability.
- Failing to address enforcement within the terms of the compact fosters litigation and ambiguity within the compact processes.

- Without a clearly defined enforcement provision, federal courts are confounded as to the appropriate remedies. However, it is important to note that Ohio cannot, under current law, agree to arbitration clauses.
- States will be required to coordinate their state law with what the compact dictates. There will be additional costs if an arbitration process is created. This may also create third-party rights where none previously existed.

### **Uniform Law—Con**

- Lack of uniformity can cause major problems with a uniform enforcement program.
- If not drafted appropriately, the uniform law could create additional confusion over enforcement issues and lead to competing legal jurisdictions ruling on consent policies. A judicial remedy for enforcement might arise which would take a longer time period. Providers requiring quick action may be delayed in getting needed information. Uniform laws could help to standardize the requirements and simplify compliance. However, uniform laws are not required to be implemented verbatim, so some variation will remain. Additionally, jurisdiction will determine which state's statute will be applied. The applicable state statute will likely change during the life cycle of the PHI. One state's statute will apply while the PHI is initially collected and added to the HIO. A second state's statute will apply to the request for disclosure and to the subsequent uses of the PHI. Possibly, a third state's statute will apply to the disclosure, depending on the actual mechanism of disclosure and where the disclosure is deemed to have taken place.

### **Model Law—Con**

- Lack of uniformity can cause major problems with a uniform enforcement program.
- If there is no enforcement mechanism specified, then there may be widely varying enforcement mechanisms from state to state. Unless there is some resolution on which state's law applies with regard to enforcement (i.e., the receiving or the responding state's laws) then there may be forum shopping, conflicting state decisions, and varying remedies.
- If not drafted appropriately, the model act could create additional confusion over enforcement issues and lead to competing legal jurisdictions ruling on consent policies. A judicial remedy for enforcement might arise which would take a longer time period. Providers requiring quick action may be delayed in getting needed information. Model acts could help to standardize the requirements and simplify compliance. However, model acts are not required to be implemented verbatim, so some variation will remain. Additionally, jurisdiction will determine which state's statute will be applied. The applicable state statute will likely change during the life cycle of the PHI. One state's statute will apply while the PHI is initially collected and added to the HIO. A second state's statute will apply to the request for disclosure and to the subsequent uses of the PHI. Possibly, a third state's statute will apply to the disclosure, depending on the actual mechanism of disclosure and where the disclosure is deemed to have taken place.

### **Choice of Law—Con**

#### ***Contractual Provision***

- State law enforceability may be questionable.

### **Statutory Provision**

- Choice of law provisions are not required to be implemented verbatim, so some variation may remain. The applicable state statute will likely change during the life cycle of the PHI. One state’s statute will apply while the PHI is initially collected and added to the HIO. A second state’s statute will apply to the request for disclosure and to the subsequent uses of the PHI. Possibly, a third state’s statute will apply to the disclosure, depending on the actual mechanism of disclosure and where the disclosure is deemed to have taken place.

## **13 Other Considerations**

### **Interstate Compact**

Must consider need for congressional approval of compact and effect thereof—affects whether compact will be considered federal law, and aspects of jurisdiction and enforcement; should consider careful design of compact administration to be effective and efficient.

One of the overarching issues to be resolved for an interstate compact attempting to address the conflict of varying consent laws on the interstate transfer of health information 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, in *Virginia v. Tennessee*, 148 U.S. 503, 13 S.Ct. 728, 37 L.Ed. 537 (1893), the U.S. Supreme Court held that only those agreements which affect the power of the national government or the “political balance” within the federal government require the consent of Congress. Under the *Virginia v. Tennessee* rule, just because an agreement by two or more states is called a “compact,” that does not automatically mean that it must obtain congressional consent.

If an interstate compact does affect a federal interest, the absence of congressional consent renders it void as between the states. Generally, if an interstate compact merely accomplishes what the states are otherwise empowered to do unilaterally, then no federal interest arises. 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 necessary. The Illinois and Iowa Quad Cities Interstate Metropolitan Authority Compact is an example of that approach. It contains the following provision that addresses the issue of congressional consent:

Article 19. Consent of Congress. The Attorneys General of the states of Iowa and Illinois shall jointly seek the consent of the Congress of the United States

to enter into or implement this compact if either of them believes the consent of the Congress of the United States is necessary.<sup>72</sup>

Furthermore, the compact terms provided that it was “binding on the states of Illinois and Iowa to the full extent allowed without the consent of Congress.”<sup>73</sup>

An interstate compact concerning consent requirements for the release of PHI does not appear to affect federal interests. The interstate compact does not shift power between the states and federal government; in fact, the intent is to remain compliant with federal consent law, such as HIPAA. The interstate compact does not encroach on a power reserved to Congress; instead, it seeks to rationalize laws that individual states currently enforce. Certainly, the states are already empowered to pass laws concerning privacy protections for their citizens and persons within their jurisdiction. It appears likely that the contemplated interstate compact to standardize the application of state law to PHI requests would not require congressional consent. In the event that congressional consent is deemed appropriate, such consent has been implied after the fact and explicitly given after the fact. The drafting and legislation of the interstate compact could proceed, and consent could be sought, if needed, after a final version of the interstate compact has been adopted. Alternatively, congressional consent could be obtained preemptively, such as by passing an act, but seeking such an advance consent is likely outside the scope of this project.

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 the requesting state’s consent laws.

### **Uniform Law**

The Illinois General Assembly will likely try to improve a uniform law that is introduced.

### **Model Law**

Federal action is currently underway with respect to consent management in the context of electronic prescribing systems and EHRs. The American Health Information Community, an advisory group to the U.S. Department of Health and Human Services on HIE, has published a Use Case for Consent Management, which can be expected, over the next several years, to generate criteria for the Interoperability Certification performed by the Certification Commission for Health Information Technology, a nonprofit organization established to certify health care IT products. Such certification is a means by which e-prescribing and EHR systems can be certified as interoperable, and therefore eligible for Stark Exceptions and

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<sup>72</sup> Interstate Compacts (45 ILCS 30/), Quad Cities Interstate Metropolitan Authority Compact Act, Illinois General Assembly website. Available at <http://www.ilga.gov/LEGISLATION/ILCS/ilcs3.asp?ActID=647&ChapAct=45%26nbsp%3BILCS%26nbsp%3B30%2F&ChapterID=10&ChapterName=INTERSTATE+COMPACTS&ActName=Quad+Cities+Interstate+Metropolitan+Authority+Compact+Act>.

<sup>73</sup> Ibid.

Anti-Kickback Safe Harbors if used in a health IT donation program. At a minimum, the model act should at least consider maintaining consistency or at least compatibility with the Consent Management Use Case.

### **Choice of Law**

HISPC-Illinois determined that the choice of law mechanism is a very cumbersome approach and legally complicated. 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.

States may be reluctant to give up protections they have established for their residents' PHI and to rely on other states' statutes with, potentially, varying degrees of protection. Additionally, the interest groups within each state that advocated adoption of the protections will probably work to convince state lawmakers that there should be one standard of protection for PHI, and adhering to their own state statute, rather than selecting law based on circumstances of the request, best provides that uniformity.

Finally, the ability of a choice of law provision to work depends on its consistent adoption by numerous states (such as a "model" or "uniform" choice of law provision). This is unlikely to occur. Even if it were adopted uniformly, the underlying laws are inconsistent. Therefore, a choice of law provision that states that the laws of the "requesting" state or the "responding" state will apply will continue to provide an inconsistent approach to HIE since the current scheme of laws is already inconsistent.

### **Pro**

None.

### **Con**

None.

## PROCESS FOR DEVELOPING THE OPTION:

### Discussion

The IL and CA analyses discuss the development of two variations of Choice of Law COL – contractual and statutory.

### PROs

#### IL

- Contractual COL is easily executed by including a provision into an agreement specifying which state's law prevails
- A statutory choice of has the force of the law behind it

#### CA

- Contractual
  - Ease of negotiating terms
  - Many entities already doing it
  - Can customize it to fit unique situations
- Statutory
  - Uniform for state
  - More buy-in and open to the consumer and community
  - Easily understood process

#### OH

- Protects the justified expectations of the parties and clarifies what their rights and liabilities are in a given situation
- State laws have already been interpreted by the courts, thereby allowing a greater degree of certainty about what those laws mean

### CONs

#### IL

- Doesn't alter the legal framework of the states where the private parties exist
- States are likely to continue to want their laws to apply, notwithstanding a COL provision
- Passing a COL statute could be difficult and time-consuming, and could include undesired modifications and amendments during the legislative process

#### CA

- Contractual
  - May not resolve legal liability issues
- Statutory
  - Complexity of legislative process and non-uniformity in adoption by other states

- Less nimble than contracts
- If too California centric, may hinder exchange

OH

- Increased time for negotiation and development of an appropriate COLs provision

## **LENGTH OF TIME REQUIRED TO FORMULATE:**

### Discussion

The CA analysis references HISPC collaborative efforts as a factor that might speed formulation. OH talks about a lengthy negotiations process, while IL notes that contractual would be quicker than a statutory approach.

### PROs

IL

- A contractual COL provision could be negotiated rather quickly if the parties coming together have similar interests and positions.

CA

- Contractual provision less time consuming than legislation

OH

- Spending additional time on the “front end” establishing the applicable COLs will likely lead to less time on the “back end” deciding which laws apply to a given dispute

### CONs

IL

- Negotiations for a contractual provision could be lengthy if parties to the agreement differ on which state law should prevail
- Legislatures may not be willing to move quickly to implement a statutory COL provision

CA

- Time consuming and will probably require additional regulations to implement

OH

- Writing a COLs provision might raise additional issues that the drafting committee or participating states may prefer to keep closed for the sake of getting the compact, model act, or uniform law finished

## IMPLEMENTATION REQUIREMENTS:

### Discussion

The OH analysis highlights the need for research to help drafters creating the COL provision, unless it simply establishes that the law of the requesting state (or responding state) applies in all circumstances. CA noted possible conflicts with statutorily mandated COL provisions among different states. IL discussed how the COL provision would be operationalized by stakeholders.

### PROs

#### IL

- Implementation via a central repository that was responsible for operationalizing the disclosure would be the easiest method if the technology would allow for the determination of whether the consent laws are met prior to disclosure.
- Providers will have less uncertainty about which form to use and what rules to apply once it is settled which state law applies.

#### CA

- Contractual
  - Easy to customize to situation
- Statutory
  - Uniformity through out state; unclear for interstate unless similar laws
  - More accessible, terms are available for research and adoption by other states, in contracts

#### OH

- With a properly defined COLs provision, future disputes can be resolved more expeditiously by the courts, or through a defined dispute resolution process.

### CONS

#### IL

- To the extent a COL provision indicates that another state's law applies, the process to repeatedly update providers (or a central repository) on existing laws in other states will be cumbersome. Given that health care laws change frequently, providers don't necessarily have the time to research any updated consent law changes in order to transfer the information in a timely manner. This could lead to confusion.

#### CA

- Statutory
  - May require regulations to implement

- Need to be consistent with other state’s COL so business practices can be uniform

OH

- Increased negotiation or drafting time, as this may be a major point of discussion while attempting to reach consensus among the stakeholder communities as to the appropriate guidelines for the HIE transaction.

**LEGAL FRAMEWORK/RULES OF ENGAGEMENT:**

Discussion

In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a compact may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;”* and, *Approach 2 – the laws of the “Requesting State Prevails.”* IL also set up two sub groupings – scenarios defining how strict the consent laws of the responding or requesting state were – with Scenario 1 analyzing situations where the responding state’s laws were more stringent, and Scenario 2 discussing the reverse.

PROs

IL

- Examples of workable COL options:
  - Generically drafted provision adopted by each state, i.e. “requestors follow the consent laws of the responding states and responders follow the consent laws of the responding state”
  - A multi-state RHIO contractually agreeing to a more stringent disclosure, with providers in the less stringent states not violating their own law, just being overly compliant
- *Approaches*
  - Approach 1 easiest to implement because it is closest to the status quo
  - Scenario 1 likely to provide freer flow of needed health information
  - Scenario 2 privacy concerns are best protected

OH

- Status quo/current state of the law is known; allows parties to choose forum/gives parties more flexibility

CONs

IL

- Benefits not realized if the COL provision is not adopted consistently by all relevant states
- This complicates things exponentially given that there are currently 50 state consent laws which will then have an overlay of 50 COL provisions

- Contractual COL cannot overrule a statutory provision.

#### OH

- No guarantee that the parties' choice will be implemented/followed by courts
- Courts and attorneys applying laws of a different state may lack expertise in interpretation and application of that state's laws

### **IMPACT ON STAKEHOLDER COMMUNITIES:**

#### Discussion

The IL analysis discussed stakeholder involvement in the negotiation process. Stakeholders will also be involved in the legislative process. CA noted the burden of to implement a COL provision in accordance with the variances in the state laws. OH notes that the COL option may not eliminate barriers.

#### Positive Impact

##### IL

- A clearly drafted COL provision that is adopted by all parties can simplify things and result in the expedited exchange of health information.
- May help with stakeholder liability issues.

##### CA

- Contractual
  - Ease to create for Provider/payors
- Statutory
  - More transparent for everyone

##### OH

- Some Recognition of COL by Courts
- Reduced Litigation

#### Negative Impact

##### IL

- Conflict if different states adopt different COL provisions
- Privacy concerns may not be adequately addressed if the COL provision results in a less stringent environment
- Conversely a more stringent environment could inhibit the free flow of information need to care for patients

##### CA

- Contractual

- Not transparent for consumers, regulators or otherwise affected entities/persons
- Not helpful public health or research, unless contract provides
- Statutory
  - May make it harder to customize for unique situations; less influence over the results

#### OH

- Inconsistent Judicial Interpretation, Remaining Fear of Liability and Deterred Uptake
- Disparate Burden and Professional Ethics
- Consumers might be even less able to represent themselves adequately should a conflict arise
- Many consumers would be less informed in negotiating such terms - increases the risk that contractual COL provisions would be overturned

### **FEASIBILITY:**

#### Discussion

IL and CA overtly discussed feasibility in terms of “cost” and “political viability.” IL also raised the question as to whether the option was “technically possible.” CA added criteria for: foreseeable barriers to administering a COL provision; ease of enforceability; and uniformity with other states.

#### PROs

##### IL

- A COL is an inexpensive solution. A centralized repository may make implementation easier so long as the repository is aware of the requirements and how to apply the COL provision.

##### CA

- Contractual
  - Cost to develop language is more
  - Ease for parties to dispute, by terms of contract
  - Maybe more cost effective to enforce
  - Not open for public debate
- Statutory
  - Will still incur cost to develop customization to existing statutes, but easier
  - Statute can spell out enforcement, bring in regulatory oversight

##### OH

- Enacting a uniform statute to standardize the COL is the subject of separate inquiry. However it is feasible but would require an undetermined amount of

time for participating states to enact legislation. Regarding existing practices to address COL in contracts, or to resolve matters where contracts fail to address the issue, there is no feasibility issue since the status quo would continue and is well governed by decades of court rulings and probably adoption in every state of the Restatement (Second) of Conflict of Laws.

### CONs

#### IL

- Limited effectiveness of contractual COL provision because it does not supersede state consent laws
- Statutory COL may have limited benefit if other states adopt inconsistent provisions
- There will be a cost, as well as the need to conduct training of providers and patients
- Political concerns may arise over the application of other state laws
- Technical feasibility is difficult as providers will not have the time to fully research other states' laws in order to comply with the option

#### CA

- Contractual
  - Terms not accessible for development of similar contracts
  - State law enforceability may be questionable
- Statutory
  - Legislative process could delay enactment and implementation
  - Could become more political, tied to unrelated issues

#### OH

- COL would require an undetermined but probably lengthy amount of time for participating states to enact legislation
- Cost, delay and uncertainty of Ohio's COL practices
- In cases of disputes between or among parties, existing case law permits a party to litigate the issue and sometimes prevail for reasons more related to the forum in which the litigation is initiated than the strict application of COL principles or contractual language to the matter at hand.

### **DOES THE OPTION ADDRESS LIABILITY CONCERNS:**

#### Discussion

CA – “Neither method of implementing ‘choice of law’ will address the liability concerns of the parties, unless the state laws of the negotiating partners are similar and do not impose a dominance that conflicts with the other state’s laws.”

OH – “Choice of law provisions are routinely used in contracts involving parties located in more than one state in order to specify which state’s law applies in the event of

contractual dispute. Such clauses are often but not always upheld by judges. For reasons described below, resolution of interstate health information exchange liability concerns by use of choice of law clauses in contracts or other written instruments cannot be recommended unless state legislatures provide clear guidance through uniform statutory enactments (including participation in a multi-state compact).”

### PROs

#### IL

- A COL provision enacted as a state statute offers greater protection to the requesting and responding states as there would be no violation
- Compliance with a state statute might help avoid or reduce civil liability if compliance to the statute is considered fulfillment of the duty owed to the plaintiff
- If the state takes action, it increases the ability for others to get insurance for risks involved in the process.
- If a request is made by a requesting state, the responding state will likely lack the jurisdiction to enforce its statutes against the requesting party. As long as the requesting state has complied with the consent requirements of its state, there would be no barrier to the exchange of PHI
- Likewise, as long as the responding state has complied with the disclosure requirements of its state, there would be no barrier to the exchange of PHI. This simplifies the exchange process, as each party need only be familiar with, and compliant with, the laws of its own jurisdiction. The statutory approach to determining COL might offer some degree of protection from civil liability because the exchange would have been compliant with relevant law.

#### CA

- Contractual
  - Parties can make liability specific, with indemnity provisions
- Statutory
  - Can make liability specific
  - Can provide more protection to the parties with unequal bargaining powers

#### OH

- COL clauses are well understood and allow contracting parties to easily modify the provision as circumstances dictate

### CONs

#### IL

- Of the two approaches to COL, the contractual COL provision offers less protection against civil liability because the contractual provision only represents a binding agreement between the parties to the contract, not with

third parties. A contractual agreement for consenting may be in conflict with state law, which leaves people open to liability. Contractual provisions agreed upon by parties to a contract offer little or no protection from statutory liability. Even with a contractual COL provision, the requesting state and responding state would need to ensure that their respective conduct is compliant with the statutory requirements of their respective states. Vendors getting into the HIO business are likely not able to be insured for the consent liability, so having this be the responsibility of a central repository is not feasible at this time. Additionally, providers may be reluctant to participate in an HIO, because their professional liability insurance may not currently cover liability arising from unauthorized disclosure of protected health information made electronically. A COL provision is unlikely to reduce that barrier.

- Claims for civil liability for an appropriate use or disclosure of information are more likely to arise between an HIO member and the patient that is the subject of the information, rather than between the parties of the contract. The contractual provisions would likely not help to reduce civil liability.

#### CA

- Contractual
  - Tends to exacerbate the relative unequal bargaining powers of the parties: funding and sophistication
- Statutory
  - One size may not fit all, not meet all potential liability concerns

#### OH

- Unless legislatures adopt uniform language, relying on COL provisions in contracts and agreements (e.g., consent for HIE disclosure) would cause too much uncertainty and not satisfactorily resolve liability concerns. One can imagine that a party/entity active in health information exchange would need to know, or be able to determine, the applicable law in each of 50 states.
- Where parties have not specified which state's law controls, the guidance provided by the Restatement (Second) of Conflict of Laws provides too many opportunities to reach different conclusions on the same fact pattern
- When disputes inevitably arise, parties would be able to challenge the validity of the contractual COL provision on various grounds (e.g., public policy, unfair bargaining position, renvoi) and, even when the challenge is not technically appropriate, history demonstrates that courts would sometimes rule in favor of the challenger
- These reasons compel a recommendation not to rely on COL provisions to facilitate HIE unless legislatures in the affected states have enacted uniform statutes that provide certainty and satisfy liability concerns.

### **RAMIFICATIONS OF ACCEPTANCE/REJECTION:**

The state analyses identified the benefit of acceptance as an elimination or some mitigation of the barriers to HIE. Rejection will leave those barriers intact.

## **CONFLICTS WITH STATE OR FEDERAL LAWS:**

### Discussion

The state analyses highlighted the problem that contractually executed COL provisions have with respect to conflicts since state law would supersede the contract. Statutorily enacted approaches would be better able to address conflicts.

### PROs

#### CA

- Contractual
  - Nimble to address concerns
- Statutory
  - Best at addressing conflicts in own state law
  - Ease in complying with HIPAA

### CONs

#### IL

- There will be jurisdictional issues as a contractual agreement for consenting may be in conflict with state laws
- Similarly, unless all states enact the same COL provision and then the underlying laws of the states are consistent (which is not currently the case), a COL provision will not be a practical solution

#### CA

- Contractual
  - Not able to address laws that conflict
- Statutory
  - Conflicts with federal laws will not be cured if statute does not conform

#### OH

- Interstate access to medical records will continue to be impeded by conflicting requirements. Specifically, two states may each have statutes applying its own laws, rather than the laws of the other state. In these situations, COL provisions will make the process for interstate access to medical information less certain, and therefore more difficult

## **PROCESS FOR WITHDRAWAL:**

### Discussion

The analyses from the states noted the need for statutory COL provisions to be repealed while contractual provisions would subject to modification procedures set out in the agreement.

### PROs

IL

- A contractual provision is easier to withdraw from than a statute because it requires no legislative action.

CA

- Contractual
  - Ease, pursuant to terms of contract

OH

- To extent specified by parties, within parties' control

### CONs

IL

- The ease of which it is possible to withdraw from a contractual COL provision may not provide the parties with much of a mandate for robust health information exchange.

CA

- Statutory
  - Difficult to repeal a law
  - Urgency bills require 2/3 vote to amend, unintended consequences

OH

- Length of time; uncertainty

## **STATE RESPONSIBILITIES:**

### Discussion

CA and OH pointed to the state responsibilities with respect to enforcement of COL provisions. IL noted the need for state assistance in implementing COL efforts to remove barriers to HIE.

### PROs

CA

- Contractual
  - Minimal state responsibility
- Statutory

- Potential for regulatory oversight & regulations

OH

- Ambiguities created by the current state of affairs does allow for some flexibility to address unexpected circumstances without having to formally amend fixed or codified terms

### CONs

IL

- COL will not be helpful unless we have consistent adoption and application
- COL could be in conflict with both state and federal laws, as well as result in a contract dispute if there is a violation

CA

- Contractual
  - No oversight currently being performed; may need to develop
- Statutory
  - Integration of other state regulators

OH

- This being the present state of affairs, choosing this option continues the present uncertainty.

## **STATE'S RIGHTS:**

### Discussion

The state analyses noted that states are sovereign within their jurisdiction (except for certain defined claims that are reserved to the federal government) and have an interest in applying their own law and to protect their own citizens. The state may agree to permit the law of the requesting state to be the choice of law in matters of consent, but by so doing, the state is removing the protections of its own laws from its citizens. A state may not wish to have a choice of law provision that applies the law of another state. States are also likely to resist pre-emption of their state laws in favor of a federal statute that governs choice of law in consent matters.

### PROs

CA

- Statutory
  - State can preserve as much sovereignty as it wants, can preserve its police powers
  - Drafting will be very important

OH

- Statutory COL provisions or preferences preserve the rights of the state to govern the policies affecting the medical privacy of its citizens.

### CONs

#### IL

- A generic law may result in the state giving up some of its rights (e.g. “the disclosing state’s laws apply”).

#### CA

- Statutory
  - Business would not like different laws for each state

#### OH

- By preserving each state’s right to implement its own policies regarding access to medical records, COL mechanisms do not effectively address the barriers to interstate access created by differing laws.

## **ENFORCEMENT:**

### Discussion

The IL analysis indicated that “each state approves and enforces its own statutes, which are only applicable within the jurisdiction of that state. States develop statutes that they believe protect the interests of their residents, but state statutes are not enforceable beyond the proponent state’s jurisdiction.” OH noted that “enforcement is often a predetermined matter set forth in the terms of the agreement or transaction. Unless otherwise prohibited by law or judicially determined to be inequitable, courts will enforce the predetermined choice.

### PROs

#### IL

- A consistent COL provision could result in the state enforcing its own COL provision, rather than enforcing another state’s law.

#### CA

- Contractual
  - Ease for parties to dispute, by terms of contract
  - Maybe more cost effective to enforce
- Statutory
  - Statute can spell out enforcement, bring in regulatory oversight

#### OH

- Establishing which state’s laws will govern the agreement or transaction adds predictability to the Parties’ relationship.

## CONs

### IL

- An inconsistent COL provision could result in confusing enforcement. A COL provision could help to standardize the requirements and simplify compliance

### CA

- Contractual
  - State law enforceability may be questionable

### OH

- The failure to clearly establish a COL often leads to additional litigation prior to reaching the merits of the underlying dispute

## **OTHER CONSIDERATIONS:**

## **CONCLUSION:**

### IL

HISPC - Illinois determined that the COL mechanism is a very cumbersome approach and legally complicated. Specifying a COL 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. States may be reluctant to give up protections they have established for their residents' PHI, and to rely on other states' statutes with, potentially, varying degrees protection. Additionally, the interest groups within each state that advocated adoption of the protections will probably work to convince state lawmakers that there should be one standard of protection for PHI, and adhering to their own state statute, rather than selecting law based on circumstances of the request, best provides that uniformity.

Finally, the ability of a COL provision to work depends on its consistent adoption by numerous states (such as a "model" or "uniform" COL provision). This is unlikely to occur. Even if it were adopted uniformly, the underlying laws are inconsistent. Therefore, a COL provision that states that the laws of the "requesting" state or the "responding" state will apply will continue to provide an inconsistent approach to HIE since the current scheme of laws is already inconsistent.

### OH

COL is a legal concept that underlies all interstate transactions regardless of what is being transacted. As such, "COL" is not, in and of itself, an option for HIE. Instead, COL is a necessary discussion point for the remaining true options. The

failure to conceptually address COL would only serve to perpetuate the current ambiguities in interstate HIE; thereby, seriously undermining any attempt to standard interstate HIE. Accordingly, the Legal Working Group formally concludes that regardless of the option ultimately pursued (Model Law, Uniform Law, or Interstate Compact), “COL” must be a specific discussion point on any agenda and the concept must be specifically addressed within the text of the Model Law, Uniform Law, or Interstate Compact.

## PROCESS FOR DEVELOPING THE OPTION:

### Discussion

CA quoted an ABA publication describing the 5 Keys to success in summary:

1. Inclusive process
2. A good “sales pitch”
3. Well-planned marketing strategy
4. Develop a network of champions
5. Develop a proactive transition plan

IL quoted the Council of State Governments National Center for Interstate Compacts on 5 steps for developing compact: *Advisory Group; Drafting Team; Education; Enactment; and, Transition.*

OH outlined common characteristics of a compact that would have to be negotiated: (a) the creation of an independent joint regulatory organization or body; (b) uniform guidelines, standards, or procedures conditioned on action by the other states involved; (c) the states are not free to modify or repeal their laws unilaterally; and (d) statutes requiring reciprocation.

OH also addressed the issue of Congressional approval. The OH analysis indicates that it appears “approval would be necessary...”

Furthermore, OH indicates - “Congressional consent may have the effect of transforming the compact into federal law. In *Cuyler v. Adams*, 449 U.S. 433, 440 (1981), the U.S. Supreme Court concluded that ‘where Congress has authorized the States to enter into a cooperative agreement, and where the subject matter of that agreement is an appropriate subject for congressional legislation, the consent of Congress transforms the State’s agreement into federal law under the Compact Clause.’”

IL discussed Congressional approval in the **OTHER CONSIDERATIONS** section. CA raised the issue in the **LENGTH OF TIME REQUIRED TO FORMULATE** section.

OH also raised the issue of continued monitoring of technological advances.

### PROs

IL

- Adoption by multiple states standardizes the process and is more effective in addressing the barrier to HIE
- Issues can be examined in depth

CA

- Informal and legislative approved development will foster sponsors

OH

- Allows states to draw the parameters

CONs

IL

- Long negotiation process in dealing with issues such as privacy
- Lot of work for little results if not adopted by majority of states leaving the barrier to HIE largely in place

CA

- CA would need strong presence to ensure consistency with CA ideals

OH

- Congressional approval may lead to federal interference by fed govt. and courts

**LENGTH OF TIME REQUIRED TO FORMULATE:**

Discussion

OH indicated that it could take years.

CA and IL cited CSG study discussing around 5 years

PROs

IL

- Process provides enough time to examine issues

CA

- The more that policy makers are interested, the quicker it will get done

OH

- Length of process could offset later problems with compact terms

CONs

IL

- Process could get bogged down
- Removal of HIE barrier delayed

OH

- Removal of HIE barrier delayed

**IMPLEMENTATION REQUIREMENTS:**

### Discussion

CA discussed the CSG developmental process. IL and OH indicated legislative approval for admission or delegation of authority for admission to Executive.

### PROs

IL

- Process familiar with legislatures

OH

- Participating states should be able to reach some consensus in advance as to the most effective way to get state participation as early as possible.

### CONs

IL

- Ratification process could delay implementation of HIE
- During compact transition period, providers need to be educated raising cost issues

OH

- Delay

## **LEGAL FRAMEWORK/RULES OF ENGAGEMENT:**

### Discussion

In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a compact may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;” Approach 2 – the laws of the “Requesting State Prevails;” and, Approach 3 – the compact defines the procedures in what was labeled “Compact Defined Consent.”* IL also set up two sub groupings – scenarios defining how strict the consent laws of the responding or requesting state were – with Scenario 1 analyzing situations where the responding state’s laws were more stringent, and Scenario 2 discussing the reverse.

OH addressed the issue of Congressional approval again and noted that a compact acts like a contract.

### PROs

IL

- A1 – easiest to implement.

- A1 – information could flow quickly once the requesting state submits a request that meets the responding state’s requirements
- A1S1 – If the consent was obtained at the time of collection of the data, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- A1S1 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A1S2 – Information could flow easily and quickly if the requesting state complies with its own, more stringent, laws
- A2S2 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A2S1 – Information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure
- A2 – Requesting states need only to be familiar with their own state’s laws
- A3 – A uniform process easier to understand in the context of interstate exchange of PHI
- A3 – A consistent set of documentation to permit access and disclosure of information.

#### OH

- Superior in force and effect to prior and subsequent state statutes

#### CONs

#### IL

- A1S2 – There is a lesser focus on privacy concerns which could be objectionable to privacy advocates
- A1S1 – May delay the release of PHI if the requesting state submits a consent that does not meet the higher standards of the responding state
- A2S2 – Access to PHI in the requesting state will be delayed while healthcare providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards
- A2 – Healthcare providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- A2S1 – May raise objections from responding states that do not wish to release PHI under less demanding consent requirements
- A2 – No advance planning because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information

- A3 – Difficult to find consensus, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approaches 1 or 2.
- If the compact-defined consent requirements are not implemented properly, the failure to provide adequate education would result in confusion by healthcare providers
- States with lenient consent requirements, compact-defined consent could be objectionable if the imposes new, more stringent requirements
- States with robust consent requirements may object to less stringent compact-defined requirements

OH

- Drafters must satisfy all potential adopters - consistent terms; effective administration defined; timeframe for legislative action; potential need for Congressional approval

## **IMPACT ON STAKEHOLDER COMMUNITIES:**

### Discussion

IL and CA discussed how the ratification process would give stakeholders an opportunity to provide input.

OH indicates that stakeholder impact appears to be mixed at best

### Positive Impact

IL

- Impose the same rules on member states resulting in great connectivity
- Providers get better understanding of complying with laws
- Assist in protecting providers from inappropriate disclosures/help with evidentiary documentation if required to defend the disclosure
- Improve the quality of healthcare for patients and assist in more efficient delivery of health care
- Gives stakeholders a voice
- Increase buy-in
- Eliminate ambiguity.

CA

- Depends on the scope of the compact

### Negative Impact

IL

- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Some groups may organize against the compact
- Providers need to adapt to compact requirement
- A compact that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A compact with a more stringent environment could inhibit the free flow of information
- Compacts with extensive differences would mean that providers and patients may not initially be familiar with the requirements for HIE

#### OH Pros and Cons by Stakeholders

- Consumer Interests
  - Consumers which experience diminished protections and rights may forgo treatment or seek it in different jurisdictions
- Health Care Providers
  - Provides added certainty about what law to apply reducing disputes among providers, concerns surrounding liability and professional hesitation due to patient confidentiality obligations
  - More immediate remedy than would a national solution
  - Larger health care providers could realize more exponential gains by consistency in law
  - Uncertainty that state courts would interpret compact terms consistently, may still deter interstate exchange
  - Time, expense and potential confusion in complying with compact would also be an obstacle to interstate health information exchange
  - Smaller health care providers may be experience more problems with resources, compliance programs and liability concerns
- Health Plans and Other 3rd Party Payers
  - Added certainty may be especially beneficial to larger multi-state health plans
- State Government
  - Some traditional sovereignty would necessarily be reduced in reaching the collective's objectives
  - Political problems –
    - State's lost ability to pass new and dissimilar laws
    - Executive branch appointments to the interstate council or advisory board may be contended
    - Distribution of funding requirements may be problematic and especially for those states with limited health care budgets
- Employers
  - Similar concerns to health plans

#### **FEASIBILITY:**

## Discussion

IL and CA overtly discussed feasibility in terms of “cost” and “political viability.” IL also raised the question as to whether the option was “technically possible.” OH touched on costs in its analysis as well.

With respect to cost, \$1.2 million in support provided for the “Adult Compact” versus the approximate \$100,000 cost of the “Interstate Compact for the Placement of Children. IL also referenced discussed the higher costs embodied in its “Approach 3.”

Regarding political viability, IL noted that compacts afford states the opportunity to address the problem without federal interference. CA noted a compact’s responsiveness to local needs. The analysis also identified the need for flexibility in the compact to address future developments.

## PROs

### IL

- Costs – Approach 1 would be least costly
- Political Viability – A compact would be a state-driven solution with Approach 1 possibly more viable because of the minimum of disruption to health care providers
- Technically Possible – Compact may be one of the best ways to address the barrier

### CA

- Federal participation could add revenue

## CONs

### IL

- Costs
  - Educating providers on the compact will be costly
    - Providers will resist higher costs
    - State governments are experiencing financial problems
  - Approach 2 would be an expensive option for providers and HIO who want to be able to effectively exchange health data because they would have to understand other state laws
  - Approach 3 could be viewed as less costly than Approach 2 because it would entail learning one new system, although it would still be a costly burden on providers
- Political Viability
  - There will be political difficulty in getting states with a history of more stringent consent requirements to adopt a compact viewed as loosening standards

- Conversely, states with less stringent requirements may balk at a more stringent compact
- Technically Possible – Approach 3 will require healthcare providers in all states to adapt to the compact’s requirements

CA

- CA has so many health information laws, developing a compact in accordance with CA law may be difficult
- Federal participation could add delays

**DOES THE OPTION ADDRESS LIABILITY CONCERNS:**

Discussion

All states indicated that a compact should address liability concerns.

PROs

IL

- Properly drafted the compact would clarify and minimize provider liability concerns
- Education is the central issue in ensuring providers follow the compact and benefit from the liability protections

CA

- State law should dominate
- If the compact requires consent, then it would alleviate other concerns

OH

- Liability concerns would be appropriately addressed in order to accomplish higher ranked political and social goals

CONs

IL

- An interstate compact may result in more litigation being heard in federal courts
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion

CA

- If not protective of privacy rights, not likely to succeed

OH

- It remains to be seen if there are local or state issues or constituencies that would prevent satisfactory standardized liability protection in multi-state compact language.

#### **RAMIFICATIONS OF ACCEPTANCE/REJECTION:**

The state analyses identified the benefit of acceptance as an elimination of barriers to HIE. Rejection will leave those barriers intact.

#### **CONFLICTS WITH STATE OR FEDERAL LAWS:**

##### Discussion

The states noted that the compact would supersede conflicting state laws, but not federal law.

##### PROs

IL

- This mechanism provides for consistency and removes conflict among differing state laws.

OH

- This results in a collaborative approach among the states to resolving issues created by conflicting state laws, and may encourage the federal government to also collaborative resolve differences with federal law
- The process of entering into a compact may result in individual states review and revising their current privacy laws and statutes

##### CONs

IL

- The more state laws are in conflict with the interstate compact, the more likely the adoption process will not succeed

CA

- California has so many laws that cover health information that, such as breach notification and mental health protections, developing a compact to be in accordance with California law could be difficult

OH

- The downside of a compact's pre-emption of state laws is the fact that it does not permit a state to enact policies that reflect unique cultures or climates that exist in that state

## **PROCESS FOR WITHDRAWAL:**

### Discussion

The state analyses noted that withdrawal basically involves the repeal of the ratification statute. However, the compact terms may contain notification or transition processes impacting on the withdrawal.

### PROs

IL

- It is essential to adapt to changes in circumstance over time

OH

- Not easily renounced by other members

### CONS

IL

- Withdrawal would create uncertainty over the handling of PHI and create problems for healthcare providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the interstate compact
- Keeping track of which states have adopted or withdrawn from the compact will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.

CA

- Will need to cover the impact on exchanges that occurred previous to the withdrawal

OH

- Complex and potentially lengthy process to modify terms or withdraw

## **STATE RESPONSIBILITIES:**

### Discussion

The states highlighted the need to educate stakeholders regarding compact requirements. CA also noted the possible costs if an administrative body were created as part of the compact. OH discussed the promotion of the compact and ratification legislation.

### PROs

IL

- The education of stakeholders regarding the consent requirements will result in buy-in

CA

- Will need to ensure transparency on decision making process
- Strong advocacy to ensure state rights

OH

- As the primary driver of a compact, state government injects a higher level of stability and predictability into the expectations of HIE
- Stability and predictability can be bolstered by the force of law as each member state insures compliance with the processes and mechanisms established through the compact
- These efforts and any subsequent educational campaigns should have minimal fiscal impact in the long-term.

CONs

IL

- A compact may be pursued without providing adequate funding and content analysis to support an initiative to educate stakeholders - estimated to cost providers \$120,000
- Funding support by the state will be a critical component for increasing buy-in by providers

OH

- Bureaucracy
- Variations in governmental structures from state-to-state, will cause some inconsistencies as to the entity managing compact issues or concerns

**STATE'S RIGHTS:**

Discussion

The states referenced the rights of a state to enter and withdraw from a compact.

PROs

IL

- An interstate compact is a reasonable, state-directed solution to the problem of conflicting state laws

CA

- Need a strong presence in the drafting

OH

- An effective compact will lessen or eliminate the need for federal government intervention – thus assist in preserving the rights of the states to have control over the policies governing access to medical records

### CONs

#### IL

- An interstate compact does not ensure a solution for every state – this would require a federal standard
- A compact will also require another layer of legal analysis for providers.

#### CA

- Need to ensure retain jurisdiction for disputes involving state laws

#### OH

- A compact will limit the rights of the member states to alter the policies or procedures to access medical records

## **ENFORCEMENT:**

### Discussion

IL and CA analyses discussed the issue of enforceability in relation to enforcing the terms of the compact and in terms of enforcing consent requirements. The structure of the compact affects the enforcement of the consent requirements. For example, IL’s Approaches 1 and 2 envisioned the acceptance of one of the party states standards and presumably enforcement. Approach 3, the creation of a compact standard would clearly indicate a need for a more detailed enforcement mechanism to be spelled out.

OH focused some of its discussion on the tie between enforceability and Congressional approval. The OH analysis noted that “without such approval, the compact is nonbinding and legally unenforceable upon the members.” The analysis also points out that “a compact, in and of itself, does not directly alter the intrastate legal expectations.”

### PROs

#### IL

- Enforcement is necessary to achieve compliance and gives the compact a sense of importance

#### CA

- Possible to create a certification process to ease implementation
- Can design flexibility with enforcement; maybe medication or ADR

#### OH

- Enforcement needs to be spelled out in the compact

### CONs

#### IL

- States will be required to coordinate their state law with what the compact dictates
- There will be additional costs if an arbitration process is created
- This may also create third-party rights where none previously existed.

#### CA

- Can not depend on OIG-Civil Rights for enforcement, will need additional state enforcement
- Permissive standards may lack enforceability.

#### OH

- Failing to address enforcement in the compact fosters litigation and ambiguity
- Without a clearly defined enforcement provision, federal courts are confounded as to the appropriate remedies

### **OTHER CONSIDERATIONS:**

#### IL

- One of the overarching issues to be resolved for an interstate compact is whether Congressional consent is required.
- An interstate compact concerning consent requirements for the release of PHI does not appear to affect federal interests. The interstate compact does not shift power between the states and federal government; in fact, the intent is to remain compliant with federal consent law, such as HIPAA. The interstate compact does not encroach on a power reserved to Congress; instead, it seeks to rationalize laws that individual states currently enforce. Certainly, the states are already empowered to pass laws concerning privacy protections for their citizens and persons within their jurisdiction. It appears likely that the contemplated interstate compact to standardize the application of state law to PHI requests would not require Congressional consent. In the event that Congressional consent is deemed appropriate, such consent has been implied after the fact and explicitly given after the fact. The drafting and legislation of the interstate compact could proceed, and consent could be sought, if needed, after a final version of the interstate compact has been adopted. Alternatively, Congressional consent could be obtained preemptively, such as by passing an Act, but seeking such an advance consent is likely outside the scope of this project.
- 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 the requesting state's consent laws.

OH

- Must consider need for Congressional approval of compact and effect thereof – affects whether compact will be considered federal law, and aspects of jurisdiction and enforcement; should consider careful design of compact administration to be effective and efficient
- A question for discussion is how will the standardized system to secure patient consent under the compact be effected when exchanging PHI with non-compact states?

## CONCLUSION:

IL

- HISPC – Illinois determined that the process for developing interstate compacts, described by the Council of State Governments, was a reasonable and appropriate process. Being able to work through a number of state legislatures will allow for the main relevant issues to surface during the drafting process. The outcome of enacting the compact will allow for the efficient exchange of needed personal health information, as states will have a process for making patients aware of exchanges of personal health information and obtaining patients' permission to share health information. The overarching concern with this mechanism remains the length of time required to trigger enactment as well as the burden on providers to adopt the new privacy standards. Enactment could be hindered if state legislatures are slow to adopt the compact. Illinois providers report a current consent process this is working for them, and are leery to take on the cost of implementing new standards that seem unneeded.

OH

- An interstate compact is, by its very nature, a contract among the states. Typically, the compacts are narrowly drawn to a specific purpose but often have far reaching implications. A compact on HIE will be no exception. The scope of such a compact could be unprecedented; however, the limits of its scope are not yet clear. While an interstate compact has both advantages and disadvantages, the most significant difference appears to be related to the forum in which the details of HIE would be addressed.

**PROCESS FOR DEVELOPING THE OPTION:**

Discussion

IL: National Conference of Commissioners on Uniform State Laws (NCCUSL) has a process to develop legislation with a wide group of stakeholders, including state commissioners. The process entails a Study Committee, Drafting Committee, and approval by an Executive Committee and at least 20 state representatives at an annual meeting of the Commissioners. The Study Committee recommends whether to draft an act and whether to designate it as “Uniform” or “Model”.

Additionally, other associations and interest groups may draft Model Acts. These acts are then submitted to the state legislatures for approval. Unlike a Uniform Law, Model Acts are not expected to be adopted verbatim, but provide guidance on language for state approval. NCCUSL Commissioners are obligated to promote adoption to achieve necessary and desirable uniformity. Even if state legislatures incorporate a Uniform or Model Act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently. IL describes in this section a number of examples of Model Acts that have been passed.

OH: Also described the NCCUSL process, as well as examples of other groups that develop Model Acts. Provided a description of the existing Study Committee on Health Care Information Interoperability that waiting for the results of the HISPC Collaborative prior to moving forward on interstate consent issues.

CA: Also described the NCCUSL process as well as examples of other groups that develop Model Acts. Described the CA process for approving legislation.

PROs

IL: NCCUSL is a respected organization with a sound process, which allows for in-depth examination as well as sufficient review by a significant number of states. Successful completion of the process is likely to lead to a consistent principle by a large number of states.

OH: Similar to IL. Noted that the flexibility in adoption of the language may make it easy to pass the various state legislatures.

CA: None noted.

CONs

IL: States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. May be a lengthy process will no requirement that states ultimately adopt the drafted legislation in a consistent manner. The lack of emphasis on verbatim adoption of the Model Act may result in confusion.

## Model Act

OH: Similar to IL.

CA: None noted

### **LENGTH OF TIME REQUIRED TO FORMULATE:**

#### Discussion

IL: Five to seven years. Noted the Study Committee on Health Care Information Interoperability at NCCUSL, suggesting that this may help speed up the process. Gave an example of the Turning Point Collaborative, whose Model Act took 3 years to be released for approval by states.

OH: Several years.

CA: Years. Gave two examples.

#### PROs

IL: Process provides enough time to examine issues by multiple reviewers and stakeholders.

OH: Length of process makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Described an expedited process, which would reduce the timeline for development to one year, after which it would be released to the states for approval.

CA: None listed.

#### CONs

IL: Process is lengthy and has the potential for limited success. Involvement of multiple interest groups may slow down the process, particularly those with a high concern for patient privacy.

OH: Other approaches may be quicker.

CA: None listed.

### **IMPLEMENTATION REQUIREMENTS:**

#### Discussion

IL: Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the Governor, or an override by the

## Model Act

legislature if Governor would veto the bill. Illinois has enacted over 95 Uniform and Model Acts according to NCCUSL.

OH: Described the process for legislative passage in OH, as well as named the stakeholder groups that could participate. Suggests that a government agency be empowered and funded to appropriately implement the legislation.

CA: Implementation will require the review of existing consent laws.

### PROs

IL: If the Model Act is simple, the state will simply repeal the old language and replace it with the new act, limiting the amount of additional work.

OH: A model act would allow any Ohio nuances to be taken into account to the extent not accounted for in a uniform law.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

### CONs

IL: If the Model Act is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time-consuming. There is no guarantee that courts in various jurisdictions will interpret a Model Act consistently, thereby reducing its effectiveness as a solution for inconsistent laws. Significant time may have been spent to create a good Model Act, yet it can be rejected or changed by the states' legislatures.

OH: The implementation of a model act may allow for state variation that defeats the stated objective of uniformity. Diverse stakeholder groups may make consensus difficult.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

## **LEGAL FRAMEWORK/RULES OF ENGAGEMENT:**

### Discussion

IL: In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a Model Act may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;” Approach 2 – the laws of the “Requesting State Prevails;” and, Approach 3 – Uniform Consent.* For this analysis, there are two scenarios: (1) Scenario 1, in which the responding state has more stringent consent

## Model Act

requirements for the release of PHI than that of the requesting state; and, (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state.

OH: In all likelihood, the move to a Model Act will include the adoption of a uniform consent form.

CA: Did not include this section in their document.

### PROs

#### IL

- A1 – easiest to implement.
- A1 – information could flow quickly once the requesting state submits a request that meets the responding state’s requirements
- A1S1 – If the consent was obtained at the time of collection of the data, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- A1S1 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A1S2 – Information could flow easily and quickly if the requesting state complies with its own, more stringent, laws
- A2S2 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A2S1 – Information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure
- A2 – Requesting states need only to be familiar with their own state’s laws
- A3 – A uniform process easier to understand in the context of interstate exchange of PHI
- A3 – A consistent set of documentation to permit access and disclosure of information.

#### OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

### CONs

#### IL

- A1S2 – There is a lesser focus on privacy concerns which could be objectionable to privacy advocates
- A1S1 – May delay the release of PHI if the requesting state submits a consent that does not meet the higher standards of the responding state

## Model Act

- A2S2 – Access to PHI in the requesting state will be delayed while healthcare providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards
- A2 – Healthcare providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- A2S1 – May raise objections from responding states that do not wish to release PHI under less demanding consent requirements
- A2 – No advance planning because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information
- A3 – Difficult to find consensus, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approaches 1 or 2.
- If the compact-defined consent requirements are not implemented properly, the failure to provide adequate education would result in confusion by healthcare providers
- States with lenient consent requirements, compact-defined consent could be objectionable if the imposes new, more stringent requirements
- States with robust consent requirements may object to less stringent compact-defined requirements

OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

### **IMPACT ON STAKEHOLDER COMMUNITIES:**

#### Discussion

IL: Stakeholders involved significantly. Impact depends on the approach selected. Less stringent states will need to change their procedures. Stakeholders who advocate for privacy will want more stringent requirements, while those advocating free flowing information will advocate less stringent requirement.

OH: Described the wide variety of stakeholder groups that will need to be included.

CA: Similar to IL. Noted the involvement of stakeholders in the process leads to ample opportunities to provide education.

#### Positive Impact

IL

- Impose the same rules on member states resulting in great connectivity

## Model Act

- Providers get better understanding of complying with laws
- Assist in protecting providers from inappropriate disclosures/help with evidentiary documentation if required to defend the disclosure
- Improve the quality of healthcare for patients and assist in more efficient delivery of health care
- Gives stakeholders a voice
- Increase buy-in
- Eliminate ambiguity.

OH: To the extent Ohio presents any nuances not accounted for in a uniform law, a model act will allow for more stakeholder input.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

### Negative Impact

#### IL

- Length of time for adoption may result in longer period of uncertainty for healthcare providers
- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Providers need to adapt to the new requirements of the Model Act
- A Model Act that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A Model Act with a more stringent environment could inhibit the free flow of information
- Special interest group promulgation of the Model Act may result in narrow issues being addressed that do not meet the needs of all stakeholders

OH: Again, a model act's allowance of this input may perpetuate state variances that a uniform law is better designed to address.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

### **FEASIBILITY:**

#### Discussion

IL: Discussed feasibility in terms of "cost" and "political viability" and whether the option was "technically possible." OH touched on costs in its analysis as well.

## Model Act

With respect to cost, \$100,000 is typical for a one-year study and two-year drafting process. Additional process expenses are covered by NCCUSL. There may be considerable costs for both the stakeholders and the public for implementation.

Regarding political viability, NCCUSL reports that need rather than complexity often dictates the successful adoption by states. Privacy advocates vs. free-flow advocates will also weigh in politically.

The Model Act is technically possible mainly if it is adopted by all states with few modifications. Flexibility can be useful for implementation.

OH: In a model act, there is often variability in the final product which may result in some of the same road blocks to sharing of information that the states face now.

CA: Raised similar discussions questions that were addressed in the IL version, but did not answer those questions.

### PROs

IL: The Model Act will provide needed guidance even if the states enact it with some variation. The approach will work best if it is less expansive and does not cover certain special categories of protected health information.

- Costs – Approach 1 would be least costly
- Political Viability – A Model Act would be a state-driven solution with Approach 1 possibly more viable because of the minimum of disruption to health care providers
- Technically Possible – Creates a standard for all states to follow

OH: None listed.

CA: None listed.

### CONs

IL

- Costs
  - Educating providers on the uniform law will be costly
    - Providers will resist higher costs
    - State governments are experiencing financial problems
  - Approach 2 would be an expensive option for providers and HIO who want to be able to effectively exchange health data because they would have to understand other state laws
  - Approach 3 could be viewed as less costly than Approach 2 because it would entail learning one new system, although it would still be a costly burden on providers
- Political Viability

## Model Act

- The potential that the act could be enacted with significant variation reduces its feasibility as a solution to varying consent laws.
  - There will be political difficulty in getting states with a history of more stringent consent requirements to adopt a compact viewed as loosening standards
  - Conversely, states with less stringent requirements may balk at a more stringent compact
- Technically Possible – Approach 3 will require healthcare providers in all states to adapt to the compact's requirements

OH: Provided the description by NCCUSL on the criteria for creating a Model Act vs. a Uniform Law.

CA: None listed.

### **DOES THE OPTION ADDRESS LIABILITY CONCERNS:**

#### Discussion

IL: Liability is based upon the content adopted, the amount of uniformity between states, the concomitant changes to other state law, statutory construction and court interpretation.

OH: The option could address liability concerns.

CA: Similar to IL

#### PROs

IL: Additional guidance in the uniform law will be beneficial.

OH: None listed.

CA: None listed.

#### CONs

##### IL

- Liability concerns in the paper vs. electronic transfer are different so the uniform law will have to address special concerns.
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially

## Model Act

lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.

- Unless the Model Act is adopted consistently in various states, the law would be unlikely to be able to address liability concerns when a state that has not adopted the Model Act is involved in HIE.

OH: None listed.

CA: None listed.

### **RAMIFICATIONS OF ACCEPTANCE/REJECTION:**

IL and OH identified the benefit of acceptance as an elimination of barriers to HIE. Rejection will leave those barriers intact. OH noted that variation in how the Model Act is adopted may also result in additional confusion going forward. CA did not comment in this section.

### **CONFLICTS WITH STATE OR FEDERAL LAWS:**

#### Discussion

IL: Federal law sets a minimum standard with HIPAA requirements, as well as confidentiality protections to certain categories of persons. The rules of statutory construction would generally provide that the newly enacted uniform law would prevail.

OH: Notes that states may have more stringent requirements than HIPAA. If not uniformly adopted, conflicts with state laws may still occur. Listed the choice-of-law principles as a method to resolve conflict between states with inconsistent language in their Model Act.

CA: The drafter of the Model Act will research conflict with federal law. Individual states will research conflicts with their existing laws during the legislative approval process. If there is a direct conflict, then the federal preemption may be an issue.

#### PROs

IL: This mechanism provides for consistency and removes conflict among differing state laws. Potential conflict with federal law would be reviewed and resolved by the study committee.

OH: In order to prevent conflict, the model act should include a section that provides that the law of the responding state be applied. This permits the responding entity and/or state to consistently comply with the applicable laws of their state.

CA: None listed.

## Model Act

### CONs

IL: If the Model Act is not uniformly adopted across the states, it is uncertain as to whether or not it will conflict with state and federal laws. The more state laws are in conflict with the Model Act, the more likely the adoption process will not succeed.

OH: It may be difficult for the requesting state to obtain the information that they desire, if the responding state prohibits such release. Also, if a state that adopts the model act does not provide a choice of law directive, then in the event of a conflict between states the courts will have to intervene and conduct an analysis under the seven factors listed above. This can result in costly and time consuming litigation.

CA: None listed.

### **PROCESS FOR WITHDRAWAL:**

#### Discussion

The state analyses noted that withdrawal basically involves the repeal of the ratification statute.

#### PROs

IL

- Provides states with control

OH

- Promotes passage

CA: None noted.

#### CONs

IL

- Withdrawal would create uncertainty over the handling of PHI and create problems for healthcare providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the Model Act.
- Keeping track of which states have adopted or withdrawn the Model Act will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.

OH

- Allows for the possibility that the system will fall apart at any time.

CA: None noted.

**STATE RESPONSIBILITIES:**

Discussion

IL highlighted the need to educate stakeholders regarding consent requirements. OH and CA noted the need by states to review whether or not the Model Act was significantly different from existing laws.

PROs

IL

- Provider prefers a mandate.

OH

- Flexibility to adopting the language may make it easier for states to adopt, in comparison with Uniform Law.

CA: None noted

CONs

IL

- Cost will be a burden for providers and patients. If the Model Act is only an overlay to the laws concerning paper, then providers will have to determine if they need two processes in place to handle the difference between EHR transfer vs. paper transfer.

OH

- Greater likelihood of inconsistency among states, given the potential for multiple variations.

CA: None noted

**STATE'S RIGHTS:**

Discussion

The states referenced the rights of a state to establish requirements as they see fit.

PROs

IL

- States still have the option to establish requirements that are more responsive to their needs

## Model Act

OH

- Similar to IL

CA: None noted

### CONs

IL

- If states do not adopt it uniformly, the current problems may continue. It may only work well for those states whose acts are similar. This may detract from the overall impact of the Model Act.

OH

- Flexibility may inhibit ability to ensure free exchange, leaving the situation similar to the current state.

CA: None noted

## **ENFORCEMENT:**

### Discussion

All states noted that enforcement issues fall within the purview of the adopting states. The use of a Model Act could help standardize the individual state statutes.

### PROs

IL: Each state retains the ability to decide enforcement issues. The formation of a quick, deliberative advisory body to enforce the law will circumvent time delays, as well as define parameters to avoid having tort litigation define the law.

OH: If enforcement is not specified, passage is easier so that states can retain their right to establish their enforcement mechanism

CA: None noted

### CONs

IL: If not drafted appropriately, the Model Act could create additional confusion over enforcement issues and lead to competing legal jurisdictions ruling on consent policies. A judicial remedy for enforcement might arise which would take a longer time period. Additionally, jurisdiction will determine which state's statute will be applied. The applicable state statute will likely change during the life cycle of the PHI.

## Model Act

OH: Similar to IL

CA: None noted

### **OTHER CONSIDERATIONS:**

IL: Noted a variety of groups working on health IT at the federal level, and suggest a need for the Model Act to take these activities into consideration during the drafting period.

OH: None noted

CA: None noted

### **CONCLUSION:**

HISPC – Illinois determined that there are a number of difficulties with the Model Act mechanism. Significant work and time may have been spent to create a good Model Act, yet it can be rejected or changed by the states' legislatures. While the process for drafting and adoption is credible, the lack of emphasis on verbatim adoption may result in confusing and conflicting state laws that hinder efficient interstate transfer of personal health information. Costs to draft, adopt, educate and implement will be considerable, yet the risk of a lack of uniform adoption is fairly high. The best outcome for this legal mechanism may be as an example for states that are looking for models on how to handle interstate transmission.

OH: While a model act may be a step in the right direction, it is not a solution to the existing problem – that is, inconsistency among the states regarding necessary consent for the use and disclosure of health information. If each state tweaks the model act to meet the needs of its constituents, we will be in the same place that we are today – with a “crazy quilt” of inconsistent state laws. The model act may lessen the differences among the states, but it will not bring the uniformity that is necessary to provide the consistency and certainty that is needed. Another potential problem with the model act is the time for creation and implementation. It can take years for the process to run its course, which leads to a conclusion that other options (e.g., federal legislation) may be more viable.

CA: None noted.

**PROCESS FOR DEVELOPING THE OPTION:**

Discussion

IL: National Conference of Commissioners on Uniform State Laws (NCCUSL) has a process to develop legislation with a wide group of stakeholders, including state commissioners. The process entails a Study Committee, Drafting Committee, and approval by an Executive Committee and at least 20 state representatives at an annual meeting of the Commissioners. It is then submitted to the states. Approval of an act as a Uniform Act obligates Commissioners from each state to promote verbatim adoption by their respective legislatures. Even if state legislatures incorporate a Uniform or Model Act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently.

OH: Also described the NCCUSL process. Provided a description of the existing Study Committee on Health Care Information Interoperability that waiting for the results of the HISPC Collaborative prior to moving forward on interstate consent issues.

CA: Also described the NCCUSL process. Included information about a California State Commission on Uniform State Laws.

PROs

IL: NCCUSL is a respected organization with a sound process, which allows for in-depth examination as well as sufficient review by a significant number of states. Successful completion of the process is likely to lead to a national standard.

OH: Similar to IL.

CA: Similar to IL. Noted that NCCUSL would likely receive support by external groups like the National Governor Association, which will help create a sound process.

CONs

IL: States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. May be a lengthy process will no requirement that states ultimately adopt the drafted legislation.

OH: Similar to IL. Additionally noted that the large number of states required to participate may cause a lengthy drafting process.

CA: None noted

**LENGTH OF TIME REQUIRED TO FORMULATE:**

## Uniform Law

### Discussion

IL: Five to seven years. Noted the Study Committee on Health Care Information Interoperability at NCCUSL, suggesting that this may help speed up the process. Also provided a comparison chart of other Uniform Laws, length of time and number of adopting states.

OH: Several years.

CA: Gave detailed description of the Study Committee on Health Care Information Interoperability at NCCUSL. Also described the legislative process of the state of California in detail.

### PROs

IL: Process provides enough time to examine issues, by multiple reviewers and stakeholders.

OH: Length of process makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Noted that Ohio is generally accepting of Uniform Laws.

CA: Identified the NCCUSL process as successful.

### CONs

IL: Process is lengthy and has the potential for limited success. Involvement of multiple interest groups may slow down the process, particularly those with a high concern for patient privacy.

OH: Other approaches may be quicker.

CA: None listed.

## **IMPLEMENTATION REQUIREMENTS:**

### Discussion

IL: Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the Governor, or an override by the legislature if Governor would veto the bill. Illinois has enacted over 95 Uniform and Model Acts according to NCCUSL.

OH: Described the process for legislative passage in OH, as well as named the stakeholder groups that could participate. Suggests that a government agency be empowered and funded to appropriately implement the legislation.

## Uniform Law

CA: Implementation will require the review of existing consent laws.

### PROs

IL: If the Uniform Law is simple, the state will simply repeal the old language and replace it with the new act, limiting the amount of additional work.

OH: The network of stakeholders will support implementation.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

### CONs

IL: If the Uniform Law is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time-consuming. There is no guarantee that courts in various jurisdictions will interpret a Uniform Law consistently, thereby reducing its effectiveness as a solution for inconsistent laws.

OH: Diverse stakeholder groups may make consensus difficult.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

## **LEGAL FRAMEWORK/RULES OF ENGAGEMENT:**

### Discussion

IL: In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a Uniform Law may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;”* *Approach 2 – the laws of the “Requesting State Prevails;”* and, *Approach 3 – Uniform Consent.* For this analysis, there are two scenarios: (1) Scenario 1, in which the responding state has more stringent consent requirements for the release of PHI than that of the requesting state; and, (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state.

OH: In all likelihood, the move to a Uniform Law will include the adoption of a uniform consent form.

CA: Did not include this section in their document.

### PROs

IL

## Uniform Law

- A1 – easiest to implement.
- A1 – information could flow quickly once the requesting state submits a request that meets the responding state’s requirements
- A1S1 – If the consent was obtained at the time of collection of the data, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- A1S1 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A1S2 – Information could flow easily and quickly if the requesting state complies with its own, more stringent, laws
- A2S2 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A2S1 – Information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure
- A2 – Requesting states need only to be familiar with their own state’s laws
- A3 – A uniform process easier to understand in the context of interstate exchange of PHI
- A3 – A consistent set of documentation to permit access and disclosure of information.

### OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

### CONs

### IL

- A1S2 – There is a lesser focus on privacy concerns which could be objectionable to privacy advocates
- A1S1 – May delay the release of PHI if the requesting state submits a consent that does not meet the higher standards of the responding state
- A2S2 – Access to PHI in the requesting state will be delayed while healthcare providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards
- A2 – Healthcare providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- A2S1 – May raise objections from responding states that do not wish to release PHI under less demanding consent requirements
- A2 – No advance planning because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information

## Uniform Law

- A3 – Difficult to find consensus, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approaches 1 or 2.
- If the compact-defined consent requirements are not implemented properly, the failure to provide adequate education would result in confusion by healthcare providers
- States with lenient consent requirements, compact-defined consent could be objectionable if the imposes new, more stringent requirements
- States with robust consent requirements may object to less stringent compact-defined requirements

OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

### **IMPACT ON STAKEHOLDER COMMUNITIES:**

#### Discussion

IL: Stakeholders involved significantly. Impact depends on the approach selected. Less stringent states will need to change their procedures. Stakeholders who advocate for privacy will want more stringent requirements, while those advocating free flowing information will advocate less stringent requirement.

OH: Described the wide variety of stakeholder groups that will need to be included.

CA: Similar to IL

#### Positive Impact

IL

- Impose the same rules on member states resulting in great connectivity
- Providers get better understanding of complying with laws
- Assist in protecting providers from inappropriate disclosures/help with evidentiary documentation if required to defend the disclosure
- Improve the quality of healthcare for patients and assist in more efficient delivery of health care
- Gives stakeholders a voice
- Increase buy-in
- Eliminate ambiguity.

OH: Need to identify stakeholder groups and get their input

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

Negative Impact

IL

- Length of time for adoption may result in longer period of uncertainty for healthcare providers
- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Providers need to adapt to the new requirements of the Uniform Law
- A Uniform Law that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A Uniform Law with a more stringent environment could inhibit the free flow of information

OH: It will take sufficient time to engage and satisfy the concerns of all the stakeholders groups. There is no guarantee of majority buy-in.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

**FEASIBILITY:**

Discussion

IL: Discussed feasibility in terms of “cost” and “political viability” and whether the option was “technically possible.” OH touched on costs in its analysis as well.

With respect to cost, \$100,000 is typical for a one-year study and two-year drafting process. Additional process expenses are covered by NCCUSL. There may be considerable costs for both the stakeholders and the public for implementation.

Regarding political viability, NCCUSL reports that need rather than complexity often dictates the successful adoption by states. Privacy advocates vs. free-flow advocates will also weigh in politically.

The Uniform Law is technically possible mainly if it is adopted by all states in uniform way, rather than with modifications.

OH: A Uniform Law is more likely to minimize diversity of content.

CA: Provided a discussion similar to IL. Noted that CA has a strong interest in patient privacy rights. CA has enacted Uniform Laws 50% of the time. Reported the same information as IL on “technically possible.”

## Uniform Law

### PROs

IL: The approach will work best if it is less expansive and does not cover certain special categories of protected health information.

- Costs – Approach 1 would be least costly
- Political Viability – A Uniform Law would be a state-driven solution with Approach 1 possibly more viable because of the minimum of disruption to health care providers
- Technically Possible – Creates a standard for all states to follow

OH: Provided the definition by NCCUSL of when to designate an act as uniform vs. model.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

### CONs

IL

- Costs
  - Educating providers on the Uniform Law will be costly
    - Providers will resist higher costs
    - State governments are experiencing financial problems
  - Approach 2 would be an expensive option for providers and HIO who want to be able to effectively exchange health data because they would have to understand other state laws
  - Approach 3 could be viewed as less costly than Approach 2 because it would entail learning one new system, although it would still be a costly burden on providers
- Political Viability
  - There will be political difficulty in getting states with a history of more stringent consent requirements to adopt a compact viewed as loosening standards
  - Conversely, states with less stringent requirements may balk at a more stringent compact
- Technically Possible – Approach 3 will require healthcare providers in all states to adapt to the compact's requirements

OH: Time, expense and no guarantee of success

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

**DOES THE OPTION ADDRESS LIABILITY CONCERNS:**

Discussion

IL: Liability is based upon the content adopted, the amount of uniformity between states, the concomitant changes to other state law, statutory construction and court interpretation.

OH: The option could address liability concerns.

CA: Similar to IL

PROs

IL: Additional guidance in the Uniform Law will be beneficial.

OH: None listed, but discussion section had statements that could be interpreted as pros and cons.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

CONs

IL

- Liability concerns in the paper vs. electronic transfer are different so the Uniform Law will have to address special concerns.
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.
- If the law is not adopted uniformly, this could cause more liability.

OH: None listed, but discussion section had statements that could be interpreted as pros and cons.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

**RAMIFICATIONS OF ACCEPTANCE/REJECTION:**

The state analyses identified the benefit of acceptance as an elimination of barriers to HIE. Rejection will leave those barriers intact.

**CONFLICTS WITH STATE OR FEDERAL LAWS:**

## Uniform Law

### Discussion

IL: Federal law sets a minimum standard with HIPAA requirements, as well as confidentiality protections to certain categories of persons. The rules of statutory construction would generally provide that the newly enacted Uniform Law would prevail.

OH: Notes that states may have more stringent requirements than HIPAA. If not uniformly adopted, conflicts with state laws may still occur.

CA: The study committee will research conflict with federal law. Individual states will research conflicts with their existing laws during the legislative approval process.

### PROs

IL

- This mechanism provides for consistency and removes conflict among differing state laws. Potential conflict with federal law would be reviewed and resolved by the study committee.

OH

- HIPAA creates a minimum standard and the Uniform Law should consider the most stringent standard, in order to provide the greatest privacy protection.

CA: None listed.

### CONs

IL

- The more state laws are in conflict with the Uniform Law, the more likely the adoption process will not succeed

OH

- It may be difficult to obtain consensus across states.

CA: None listed.

## **PROCESS FOR WITHDRAWAL:**

### Discussion

The state analyses noted that withdrawal basically involves the repeal of the ratification statute.

### PROs

## Uniform Law

IL

- Provides states with control

OH

- Promotes passage

CA: None noted.

### CONS

IL

- Withdrawal would create uncertainty over the handling of PHI and create problems for healthcare providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the Uniform Law.
- Keeping track of which states have adopted or withdrawn the Uniform Law will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.

OH

- Allows for the possibility that the system will fall apart at any time.

CA: None noted.

## **STATE RESPONSIBILITIES:**

### Discussion

The states highlighted the need to educate stakeholders regarding consent requirements.

### PROs

IL

- Providers prefer a mandate.

OH

- Greater consistency and ease than a model act

CA: None noted

### CONS

IL

- Cost will be a burden for providers and patients

## Uniform Law

OH

- Offers less flexibility and more states might refuse to participate

CA: None noted

### **STATE'S RIGHTS:**

#### Discussion

The states referenced the rights of a state to establish requirements as they see fit.

#### PROs

IL

- States still have the option to establish requirements that are more responsive to their needs

OH

- Could result in greater uniformity and ease of exchange

CA: None noted

#### CONs

IL

- If states do not adopt it uniformly, the current problems may continue

OH

- Offers less deference to individual states

CA: None noted

### **ENFORCEMENT:**

#### Discussion

Enforcement issues fall within the purview of the adopting states. OH noted that the Uniform Law could adopt a uniform enforcement procedure.

#### PROs

IL

- Each state retains the ability to decide enforcement issues

OH

## Uniform Law

- If enforcement is not specified, passage is easier so that states can retain their right to establish their enforcement mechanism

CA: None noted

### CONS

IL

- If not adopted uniformly, it could create additional confusion over enforcement

OH

- Similar to IL

CA: None noted

### **OTHER CONSIDERATIONS:**

IL: General Assembly is likely to try and improve upon the Uniform Law introduced

OH: None noted

CA: None noted

### **CONCLUSION:**

HISPC - Illinois determined that the process for developing Uniform Law, described by the National Conference of Commissioners on Uniform Laws, was a reasonable and appropriate process. Adoption of the NCCUSL Uniform Law has the potential of creating uniformity with respect to how adopting states require health care entities to obtain a patient's consent to allow their PHI to be exchanged electronically. It may also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. The NCCUSL has representation from every state, and the process allows for the necessary issues to be raised and resolved. Yet the length of time required to develop and adopt a Uniform Law would mean a longer period of uncertainty for healthcare providers, and the end result may not be adoption by the majority of states. In addition, the potential for inconsistent application and interpretation of the Uniform Law by different states could result in inconsistent consent requirements. If not adopted, a Uniform Law may provide needed guidance through its example even if states enact it with some modifications. The approach might work best if it is less expansive, yet if the Uniform Law is only an overlay to the laws concerning paper, then providers will have to figure out if they need two processes in place to handle the difference between the electronic transfer vs. paper transfer. The drafters should also consider cost to providers for implementation when creating the legislation.

## Uniform Law

OH: A Uniform Law approach has the benefit of providing a common, consistent legal structure among jurisdictions. This approach will lessen administrative burdens because all states would be working under the same set of rules and expectations. It would also offer the opportunity to have a nationally recognized and utilized consent form that would be common among all health care providers. Public education could be consistent and, thus, consumers' understanding of the impact of providing consent would be enhanced. That said, it would be challenging to establish a Uniform Law that meets with a broad enough consensus to get buy in from the states. Also, simply establishing a Uniform Law does not mean that all 50 states will adopt it. Unless all 50 states adopt it, we will be in a situation similar to where we are today – that is, having inconsistencies among states. As noted above, it is not uncommon for states to modify a Uniform Law – so even if a Uniform Law is promulgated by the NCCUSL, it is possible that state legislatures may pass a medical consent law in a manner that destroys the uniformity. Another potential problem with the Uniform Law is the time for creation and implementation. It can take years for the process to run its course, which leads to a conclusion that other options (e.g., federal legislation) may be more viable.

CA: None noted.