July 31, 2009

Health Information Security and Privacy Collaboration

Intrastate and Interstate Consent Policy Options Collaborative—Final Report

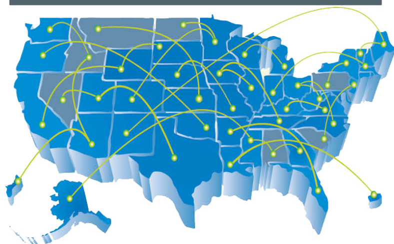
Prepared for

RTI International
230 W Monroe, Suite 2100
Chicago, IL 60606

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

Prepared by

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



Contract Number HHSP 233-200804100EC
RTI Project Number 0211557.000.007.100

Contract Number HHSP 233-200804100EC
RTI Project Number 0211557.000.007.100

July 31, 2009

Health Information Security and Privacy Collaboration

Intrastate and Interstate Consent Policy Options Collaborative—Final Report

Prepared for

RTI International
230 W Monroe, Suite 2100
Chicago, IL 60606

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

Prepared by

Jeff Johnson, Illinois
Laura McAlpine, Illinois
Holt Anderson, North Carolina
Linda Attarian, North Carolina
Trish Markus, North Carolina
Andrew Weniger, North Carolina
Bill Mitchin, Ohio
Stephanie Jursek, Ohio

Identifiable information in this report or presentation is protected by federal law, section 924(c) of the Public Health Service Act, 42 USC. § 299c-3(c). Any confidential identifiable information in this report or presentation that is knowingly disclosed is disclosed solely for the purpose for which it was provided.

Contents

Section Page

1. Introduction 1-1

2. Components and Areas for Consideration 2-1

2.1 Process for Development 2-1

2.1.1 Interstate Compacts—A Historical Context 2-1

2.1.2 Goal 2-1

2.1.3 Process 2-1

2.1.4 References 2-11

2.2 Governance Structure, Uses and Disclosures 2-12

2.2.1 Purpose and Description of Governing Body (North Carolina Perspective) 2-12

2.2.2 Two Potential Approaches to Governance Structure of an Interstate Compact on Consent (North Carolina Perspective) 2-15

2.2.3 Implications (Pros/Cons, Risks/Benefits) of Each Governance Structure Approach (North Carolina Perspective) 2-18

2.2.4 Feasibility and Potential Challenges of Each Approach (North Carolina Perspective) 2-22

2.2.5 Comments (North Carolina Perspective) 2-24

2.2.6 References (North Carolina Perspective) 2-25

2.2.7 Purpose and Description of Governing Body of an Interstate Compact (Illinois/Ohio Perspective) 2-26

2.2.8 Summary of Purpose of Governing Body for Two Potential Approaches to the Use of an Interstate Compact to Facilitate HIE Between States with Varying Consent Laws (Illinois/Ohio Perspective) 2-28

2.2.9 Implications of Each Approach With Respect To the Governance Structure (Pros/Cons, Risks and Benefits) (Illinois/Ohio Perspective) 2-30

2.2.10 Conclusions (Illinois/Ohio Perspective) 2-31

2.2.11 References (Illinois/Ohio Perspective) 2-31

2.3 Certification for Data Privacy and Security to Support Interoperable Health Information Systems 2-31

2.3.1 Purpose 2-31

2.3.2 Summary of Various Approaches 2-31

2.3.3 Implications, Pros/Cons, Benefits/Risks of Each Approach 2-32

2.3.4 Potential Challenges and Analysis of Feasibility of Each Approach 2-34

2.3.5 Comments 2-35

2.3.6 References 2-35

2.4 Enforcement 2-35

2.4.1 Purpose 2-35

2.4.2 Summary of Various Approaches 2-36

2.4.3 Implications, Pros/Cons, Benefits/Risks of Each Approach 2-36

2.4.4 Potential Challenges and Analysis of Feasibility of Each Approach 2-37

2.4.5 Reference 2-38

2.5 Liabilities 2-38

2.5.1 Purpose 2-38

2.5.2 Summary of Approaches 2-38

2.5.3 Implications, Pros/Cons, Benefits/Risks of Each Approach 2-39

2.5.4 Potential Challenges and Analysis of Feasibility of Each Approach 2-40

2.5.5 Comments 2-41

2.5.6 References 2-41

2.6 Parties to the Agreement 2-42

2.6.1 Purpose 2-42

2.6.2 Summary of Approaches 2-43

2.6.3 Implications, Pros/Cons, Benefits/Risks of Each Approach: 2-45

2.6.4 Potential Challenges and Analysis of Feasibility of Each Approach 2-45

2.6.5 Comments 2-45

2.6.6 References 2-46

2.7 Outreach to External Parties 2-46

2.7.1 Goal 2-46

2.7.2 Desired Outcome Objectives: 2-46

2.7.3 Target Audience: 2-46

2.7.4 Funding Partners 2-48

2.7.5 Membership Outreach for the Advisory, Drafting and Steering Committees 2-49

2.7.6 Education 2-50

2.7.7 Timeline 2-52

2.7.8 References 2-52

3. Next Steps, Future Research 3-1

3.1 Illinois' and Ohio's Perspective 3-1

3.2 North Carolina's Perspective 3-1

1. INTRODUCTION

In Phase 1 of the Health Information Security and Privacy Collaboration (HISPC), 34 states and territories identified variations in state laws and organization-level business policies that appeared to impede health information exchange (HIE) within and between states and then identified and proposed practical solutions for overcoming those barriers while simultaneously preserving privacy and security protections for health information. States participating in HISPC Phase 2 implemented some of the solutions identified in Phase 1 as well as identified and reviewed high priority areas on which multi-state collaboratives could focus to develop common, replicable multistate solutions to the previously-identified barriers to health information exchange within and between states. In HISPC Phase 3, participating states and territories were asked to further develop and implement the common, replicable multistate solutions with a view to reducing the variation in states' privacy and security policies, practices, and laws.

The Intrastate and Interstate Consent Policy Options Collaborative was formed to identify the different approaches to consumer consent for health information exchange within and between states, and to propose policy approaches for consent that facilitate interstate electronic health information exchange. In HISPC Phase 3, the Collaborative determined that there is a significant difference of opinion among health care stakeholders nationwide regarding the optimal process for capturing meaningful consent to use or disclose personal health information for specified purposes, and that this difference of opinion is one underlying reason for the wide variance in state laws, regulations, and policies about such consent. The Collaborative also determined that an interstate compact was one of two legal mechanisms that could afford a consistent, potentially nationwide approach for addressing what consent law or policy applies to the interstate exchange of health information.

During the HISPC Challenge and Innovation Extension phase, the Collaborative was charged with further exploring whether an interstate compact may serve as a mechanism to eliminate barriers to interstate exchange of health information when state consent laws and requirements conflict. Those barriers, identified in HIPSC Phase 1, include variation among state laws and policies regarding what consent is required for release of consumers' protected health information (PHI) and the resultant confusion about what consent laws or policies apply to a given situation involving health information exchange. This confusion results in health care stakeholders' fear of civil or criminal liability for accessing, using or disclosing PHI in violation of another state's—or their own state's—consent laws. Such fear of liability delays health information exchange while stakeholders seek legal advice about, or administrative permission to complete, the exchange. Such delay in or failure to exchange health information, in turn, results in delays in the provision of health care, duplicate testing and treatment, increased health care costs, and reduced quality of health care in general.

Given the short duration of the HISPC Challenge and Innovation Extension phase and the substantial complexity of the consent issue, the Collaborative did not set out during this phase to draft an interstate compact. Instead, the Collaborative's goal was to establish a foundational body of knowledge about the significant concepts that should be included, or considered for inclusion, in an interstate compact addressing consumer consent in the context of electronic health information exchange.

In pursuit of this goal, the Collaborative determined to identify and define potential components, or areas for consideration, of an interstate compact addressing barriers to interstate HIE posed by differing state consent laws, and to note the purpose of each component or area. The Collaborative also agreed to identify differing approaches to each component or area for consideration, including the implications and pros and cons, or benefits and risks, of each approach. Finally, the Collaborative agreed to identify potential challenges posed by the approaches to each component, and to evaluate the feasibility of each proposed approach.

As the Collaborative discussed the different components it sought to define and the potential approaches to those components, it became evident that there was a split among the participating states regarding the structure of the compact. Although it was agreed that the purpose of the compact would be to eliminate the barriers to health information exchange created by differing state consumer consent laws and policies, and it was further agreed that the intent of the compact would be to provide states an approach to consumer consent that would preempt inconsistent state laws and therefore not require states participating in the compact to amend their existing consent laws, the groups disagreed as to how this purpose should be achieved. One group supported what the Collaborative termed the "reciprocity" or "choice of law" approach. That group believed that the compact should operate in one of the following ways: (1) the interstate compact would provide that the consent laws of the state requesting health information would prevail when PHI is exchanged between member states; or (2) the consent laws of the state sending health information would be applied to these transactions. Another group supported what the Collaborative termed the "harmonization" approach. That group believed that one of the key functions of the interstate compact would be to set forth agreed-upon consumer consent rules or laws that would apply to each state joining the compact and that would supersede existing, contradictory consent laws or rules in those states. The third group believed that the structure of the compact needs to be determined by the policy leaders and stakeholders developing the compact.

The Collaborative ultimately agreed that the harmonization and reciprocity approaches should be presented in its final report for further consideration. Accordingly, this report sets forth the different components that were identified as essential to an interstate compact; various approaches to each component and a discussion of the implications of each approach; and the potential challenges and feasibility of each approach. The report also

includes a discussion of whether and how the reciprocity approach and the harmonization approach to an interstate compact may affect the challenges and feasibility of the components of the compact.

2. COMPONENTS AND AREAS FOR CONSIDERATION

2.1 Process for Development

2.1.1 Interstate Compacts—A Historical Context

From colonies to states, interstate compacts have a long history in the United States. Even the writers of the Constitution debated interstate relations and what formal mechanisms would be required to manage those relations. From the full faith and credit clause to the interstate commerce clause to interstate compacts, acceptance and enforcement of other states' laws and regulations vary significantly. "Compacts are fundamentally negotiated agreements among member states that have the status of both contract and statutory law."[1] Interstate compacts are the only mechanism in the Constitution that states themselves can use to negotiate directly with other states without violating federal law. Therefore, interstate compacts are essential since they are the only way a state can create a state-based solution to a regional problem while retaining policy control.[2]

Although interstate compacts have existed in the United States since its inception, fewer than 40 were developed in the first 140 years of the United States. Typically, compacts addressed boundary disputes, and states would commission representatives to settle the multi-jurisdictional issues. This approach was particularly effective for permanent, bi-state issues. However, as other needs developed for interstate agreements, a more complicated process emerged. Beginning in the twentieth century, interstate compacts were developed as multilateral administrative schemes. Today, compacts typically involve more than two states, and subjects vary from transportation to health to energy to education.[3] An interstate compact addressing consent to release health information for electronic health information exchange falls in the category of a "regulatory" or "administrative" compact, allowing the member states to provide coordinated regulation.[4]

2.1.2 Goal

To present options on the process for developing an interstate compact addressing consent to release health information in the context of electronic health information exchange (HIE).

2.1.3 Process

The development of any interstate compact should be a state-driven and state-championed solution to a policy issue. Outlined below are key steps to the development process of a

[1] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association, 2.
[2] Ibid, 2.
[3] Ibid, 178.
[4] Ibid, 15.

regulatory compact, as experienced by the Council on State Government. These steps include: Advisory Group, Drafting Team, Education, Enactment and Transition.[5]

According to The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide, there are five keys to success[6] in the development of an interstate compact. These essentials have been incorporated into the process described further in this document:

1. An Inclusive Process—"The importance of including as many key stakeholders as possible early on in the development of an interstate compact simply cannot be overstated."[7]
2. An Effective "Sales Pitch"—A compact must compete for attention with a multitude of other issues, legislation and events; therefore, Broun et.al. recommend that the sales pitch include three essential elements:
   - The need to be addressed or the issues to be resolved; this should also include the consequences of inaction;
   - An explanation of the compact mechanism itself; and
   - An explanation of the process by which the proposal was developed.
3. A Broad-Based Marketing Strategy—While the message behind the compact is important, so is the plan for dissemination to legislatures and the public.
4. A Network of Champions—Support is essential for passage and acceptance of an interstate compact, therefore identifying key stakeholders and addressing their concerns early (ensuring concerns are addressed early on in the process) is essential.
5. A Proactive Transition Plan—Even though the compact may not take effect until a certain number of states approve the agreement, the transition phase begins when the first state passes a proposed agreement. It is essential to sustain the momentum to secure approval in other states.

The following is an estimated timeline for the process of developing an interstate compact which addresses consent to release health information in the context of HIE:

? Year 1: Pre-Advisory Group—In the first 6 months, interested stakeholders will identify a convener, secure funding and recruit members to participate in the Advisory Group, Drafting Committee and Steering Committee.

? Years 1–2: Advisory Group—In the second 6 months, the Advisory Group and the Steering Committee will be established, which can take up to 9 months.

? Years 2–3: Drafting Committee is formed and begins work, which takes approximately 10–14 months.

---

[5] National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from, http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.

[6] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association, 88–94.

[7] Ibid, 89.

- ? Year 3: Education—Once the compact is drafted, it is available for legislative approval. Technical assistance, education and outreach are key for successful adoption and implementation of the compact.
- ? Year 4: Enactment—The number of years for enactment varies significantly depending on the number of states required to sign before the compact may be implemented.
- ? Year 5: Transition—This final part of the process, which can take 12–18 months, is dominated by the formation and implementation of the bylaws, rules and a Commission.

Pre-Advisory Group

Purpose. The start of a successful process for the development of an interstate compact includes the formation of a pre-advisory group to organize the framework and secure the funding. Pre-advisory groups have been formed both formally and informally—in some cases through legislation by concerned states that appointed commissioners to begin the process of drafting the compact, and in others by interested stakeholders acting without official charge who bring their concerns to a lead organization that facilitates the drafting process.[8]

In the case of addressing consent in the context of electronic health information exchange, the Health Information Security and Privacy Collaboration (HISPC) teams in the states of Ohio, North Carolina and Illinois have organized a multistate collaborative, the "Intrastate and Interstate Consent Policy Options Collaborative." This collaborative, which initially looked at four distinct legal mechanisms, and subsequently chose to further develop an interstate compact, has established a foundational body of knowledge on the concepts that should be included as well as outlined a process for the development of the interstate compact. Additional states expressing interest in participation include: West Virginia, Arkansas, New Jersey, Oklahoma, New Mexico, Kentucky, Minnesota and Iowa.

The work products of the Collaborative can serve as a resource to organizations which may assume the lead role, as convener, in starting a formal process to develop a compact and secure funding. The Collaborative has identified potential conveners in the Outreach to External Parties section. Briefly, these include: the National Governor's Association; the Nationwide Health Information Network (NHIN); the National Conference of State Legislatures (NCSL); the Council on State Government (CSG)/National Center on Interstate Compacts (NCIC); the State-level Health Information Exchange (SLHIE) Leadership Forum; and, the eHealth Initiative and the Foundation for eHealth Initiative.

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to the use of a pre-Advisory Group for development of an interstate compact.

---

8 Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association, 83–84.

1. Interstate Compact for Adult Supervision of Sex Offenders[9]

   This compact was specifically designed to replace an existing compact, "The Interstate Compact for the Supervision of Parolees and Probationers." As the offender population grew and mobility issues became paramount, stakeholders identified a need to revise the compact. In the 1990s, practitioners approached the National Institute of Corrections (NIC) concerned about managing the movement of parolees and probationers in states other than where they were sentenced. The NIC Board then conducted a public hearing and convened an ad-hoc committee to consider issues related to interstate movement by parolees and probationers. The ad-hoc committee recommended a revision of the existing compact, which was pursued in 1998.

2. Interstate Compact on the Placement of Children[10]

   The compact was initiated by a group of interested stakeholders in the early 1950s, with numerous states signing on by the 1960s. Over time, problems with the existing language, including overly broad language and inadequate procedures for addressing the needs of children in the 21st century, resulted in stakeholders initiating a process of review. In 2004, the American Public Human Services Association (APHSA) adopted a policy resolution to rewrite the compact and simultaneously took on the role of convener.

3. Interstate Compact on the Educational Opportunity for Military Children[11]

   Prior to the development of the compact, the Department of Defense worked with school districts that served large populations to ease transition of military children as they moved from state to state. As the population of these children grew, the Department of Defense concluded that either an interstate compact must be developed or it would pursue Congressional action. The Department chose this method because education is typically a state issue, and the interstate compact process allots the state a prominent role in development and implementation of the compact.

Advisory Group

Purpose. Comprised 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. An Advisory Group including the right stakeholders is invaluable. Typically, an Advisory Group is comprised of approximately 20 individuals, each of whom is representative of various groups and states. Examples of possible members to address consumer consent issues in interstate HIE include

[9] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

[10] Oppenheim, Liz. (2005). Reforming the Interstate Compact on the Placement of Children. National Center for Interstate Compacts. Retrieved from http://www.csg.org/programs/ncic/documents/ConnectionsWinter2005.pdf.

[11] Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military Children. National Center for Interstate Compacts. Retrieved from, http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.

the following (see Outreach to External Parties document for suggested organizational representatives):

- Issue experts from academia, business, government
- Health information experts familiar with consent issues
- Health care practitioners and providers
- Consumer groups

An Advisory Group usually meets once or twice over a period of two to three months, with its work culminating in a set of recommendations as to what the final compact product should look like.[12]

> First, the process must be inclusive. The importance of including as many key stakeholders as possibly early on in the development cannot be overstated...at a minimum, this means providing all interested parties with notice of the proposed initiative and a chance to present comments and suggestions at a point in the process when input can still be received and incorporated into any final proposal...But even if key stakeholders are afforded opportunities to review and comment on draft proposals, agreements developed without the direct participation of interested parties remain vulnerable to criticism, whether well founded or not, from those who are excluded from the process. This can result in additional obstacles for compact proponents when forced to defend their development strategy during the legislative consideration of a proposed compact....in an effort to preempt such opposition, some of the most successful compact development efforts in recent years have included multiple opportunities for stakeholder input from the beginning.[13]

An additional issue to be addressed by the Advisory Group includes identifying the need for the creation of an interstate administrative agency vested with authority from states with the flexibility to react to future changes in federal law, as well as to identify additional funding streams for addressing HIE.

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to the use of an Advisory Group for development of an interstate compact.

[12] Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military Children. National Center for Interstate Compacts. Retrieved from, http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.

[13] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association. 89

1. Interstate Compact for Adult Supervision of Sex Offenders[14]

   In 1998, an Advisory Group was formed to learn about interstate compacts in general, and to explore options for the development of an interstate compact to address current problems. Options first addressed included to:

   – Do away with the interstate compact completely.
   – Support improvements through the existing governing structure.
   – Explore possible changes in the membership of Probation and Parole Compact Administrators Association (PPCAA) by contacting the state appointing authorities.
   – Add to the existing structure some form of national board that would represent key external stakeholders.
   – Replace the existing compact with an entirely new compact.

   The Advisory Group decided to replace the existing compact. In so doing, it determined that NIC needed to acquire expertise regarding interstate compacts in general and in how legislation is drafted and enacted, and that the drafters of a replacement compact would require a broader range of expertise than the current Advisory Group. In 1999, NIC formed a cooperative agreement with National Center for Interstate Compacts (NCIC), a program of the Council of State Governments (CSG) to co-facilitate the process.

2. Interstate Compact on the Placement of Children[15]

   APHSA developed and facilitated an Advisory Group, reflecting a diverse group of state human service administrators, child welfare experts and compact administrators. The purpose of the group was to provide recommendations for the issues in the compact and its implementation.

3. Interstate Compact on Educational Opportunity for Military Children

   An Advisory Group met twice in 2006 and included school superintendents from military communities, education associations, legislators and executive branch officials. The group's purpose was to broadly address challenges of military moves in proposing the compact. [16] The group then offered recommendations on what the final compact should include.[17]

Drafting Team

Purpose. While an Advisory Group enjoys thinking about the issue from a macro-level, it works in conjunction with a Drafting Team that documents the thoughts, ideas and suggestions of the Advisory Group in a draft compact. The Drafting Team is typically

[14] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.
[15] http://www.csg.org/programs/ncic/documents/ConnectionsWinter2005.pdf
[16] Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military Children. National Center for Interstate Compacts. Retrieved from, http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.
[17] Council of State Governments. (2008, January). Interstate Compact on Educational Opportunity for Military Children: Legislative Resource Kit, pg. 55. Retrieved from, http://www.csg.org/programs/ncic/documents/RESOURCEKIT-January2008final.pdf.

comprised of five to eight compact and issue experts. Members typically also include lawyers, as well as subject matter, legislative drafting, and compact drafting experts.

The Drafting Team combines the recommendations, along with its own thoughts and expertise, into a draft compact that is then circulated to state officials for comment. The document also is made open for comments from a wide spectrum of stakeholders and the public. Following these comment periods, the compact is revised as needed and finally released back to the Advisory Group for final review to ensure that it meets the original spirit of the group's recommendations. A Drafting Team often meets three to four times over a period of 10 to 14 months, with significant staff work and support between sessions.[18]

> As development of the new Interstate Compact for Adult Offender Supervision continued during the next two years, stakeholder participation was built into every step of the process. The drafting team that drew up the proposed agreement was as representative of the varied interests at stake as was the advisory group that oversaw the effort.[19]

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to the use of a Drafting Team for development of an interstate compact.

1. Interstate Compact for Adult Supervision of Sex Offenders[20]

   From January to September 1999, a 17-member Drafting Team developed the compact proposal, conducted broad-based field review (290 individuals, agencies and associations), and sought and received critique. After all responses were compiled and analyzed, the team made adjustments and approved the final language. It took six months to compile the Advisory Committee suggestions and draft the language used for the compact.[21]

2. Interstate Compact on the Placement of Children[22]

   APHSA convened the Drafting Team with numerous meetings across the states. From December 2004 through September 2005, two drafts of the rewritten compact were

[18] National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from, http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.

[19] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association. 90.

[20] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

[21] Interstate Compact for Adult Sex Offenders. (2002, July). State Officials Guide. Retrieved from, http://www.csg.org/programs/ncic/documents/SOG.pdf.

[22] Oppenheim, Liz. (2005). Reforming the Interstate Compact on the Placement of Children. National Center for Interstate Compacts. Retrieved from, http://www.csg.org/programs/ncic/documents/ConnectionsWinter2005.pdf.

disseminated for review and comment. A third draft was then prepared and sent to each state for final approval in November 2005.[23]

3. Interstate Compact on Educational Opportunity for Military Children

   CSG convened a Drafting Team in 2006 and, by the end of 2007, a draft bill was completed and presented to State legislators.[24] The drafting team focused on implementing the "thoughts, ideas and suggestions" of the advisory group. The drafting team included five compact and issue experts.[25]

Education

Purpose. Once completed, the interstate compact is made available to states for legislative approval. During this phase of the initiative, state-by-state technical assistance and on-site education about the need for the interstate compact and its provisions are keys to rapid success. A majority of state legislators have limited knowledge about interstate compacts and, in cases where the compact addresses a significant issue, leg work 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.[26]

> Like any other piece of legislation, a proposed interstate compact must compete with numerous issues and initiatives for the attention of lawmakers as it winds its way through the legislative process, and even a well-conceived proposal will languish along the way if unassisted by an effective sales pitch.[27]

Three components for an effective sales pitch include: (1) a compelling case on the merits; (2) an explanation of the compact mechanism itself; and (3) an explanation of the process by which the proposal was developed[28]

A broad-based marketing strategy also is essential. "Getting the word out, not only to key stakeholders but also to the public at large, can be an important part of any effort to win passage of an interstate compact."[29]

Finally, using a Network of Champions is key to a successful educational effort. "Given the challenge of winning support from legislators and key stakeholders in multiple states, the

[23] http://www.aphsa.org/Policy/ICPC-REWRITE/Resource%20Materials/HISTORY%20OF%20THE%20ICPC.pdf
[24] Council of State Governments. (n.d.). Kansas, Kentucky Enact Compact on Education Transition for Military Children. Retrieved from, http://www.csg.org/about/MilitaryCompactPressRelease.aspx.
[25] Council of State Governments. (2008, January). Interstate Compact on Educational Opportunity for Military Children: Legislative Resource Kit, 55. Retrieved from, http://www.csg.org/programs/ncic/documents/RESOURCEKIT-January2008final.pdf.
[26] National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from, http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.
[27] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association. 90.
[28] Ibid. 90-91.
[29] Ibid. 90-91.

developers of any interstate compact must also work to build and mobilize a network of advocates on its behalf."[30]

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to education for development of an interstate compact.

1. Interstate Compact for Adult Supervision of Sex Offenders[31]

   In 1999, the education component was implemented in the form of marketing. The stakeholders, coordinated by NCIC, dispersed video, developed web pages, and held five conferences and a legislative briefing. The goal was to educate those who make law and their constituencies.

2. Interstate Compact on the Placement of Children[32]

   APHSA began the education process in March 2006, working to support states in getting the compact adopted, through the development of legislative information materials.

3. Interstate Compact on Educational Opportunity for Military Children[33]

   In July 2007, after the drafting team completed its work, the document was opened for comment to stakeholders and the general public.

Enactment

Purpose. A majority of interstate compacts do not become active right away. Rather, interstate compacts typically become activated when a pre-set number of states join 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 thereby created, because the first 35 jurisdictions to join would meet soon thereafter to fashion the operating rules of the compact.

Most interstate compacts take up to seven years to reach critical mass. However, the most recent effort managed by CSG, the Adult Compact, reached critical mass in just 30 months

---

[30] Ibid. 92.

[31] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

[32] Oppenheim, Liz. (2005). Reforming the Interstate Compact on the Placement of Children. National Center for Interstate Compacts. Retrieved from, http://www.csg.org/programs/ncic/documents/ConnectionsWinter2005.pdf.

[33] Council of State Governments. (2008, January). Interstate Compact on Educational Opportunity for Military Children: Legislative Resource Kit, pg. 55. Retrieved from, http://www.csg.org/programs/ncic/documents/RESOURCEKIT-January2008final.pdf.

from its first introduction in 2000.[34] This was most likely due to the sensitive nature of the subject matter, as well as a highly motivated base of support.

"The trick is to sustain momentum generated in those states that first approve a compact while continuing to work its passage elsewhere."[35]

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to enactment of an interstate compact.

1. Interstate Compact for Adult Supervision of Sex Offenders[36]

   In 2000, Colorado became the first state to enact the Adult Compact; nine states went on to enact the compact during the first year, and an additional 16 did so in the second. However, the compact required 35 states to become effective, and this milestone was not achieved until 2002. The sensitive subject matter, coupled with several high-profile compact cases that resulted in violence, motivated a strong response from government, organizations, and individuals alike. This led to all 50 states, the District of Columbia, the U.S. Virgin Islands and Puerto Rico signing the compact.

2. Interstate Compact on the Placement of Children

   The compact was released for consideration in March 2006. According to the bylaws, the compact must be adopted by 35 states to be activated. [37] As of June 2009, seven states have enacted the compact, with pending legislation in three other states.[38] It is important to note that the original compact remains in effect until 35 states ratify the revision. APHSA continues to work toward full implementation of the revised compact.

3. Interstate Compact on Educational Opportunity for Military Children[39]

   Ten states are required to approve the compact legislation before enactment may begin.

---

[34] National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from, http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.

[35] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association, 93.

[36] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

[37] The Council of State Governments National Center for Interstate Compacts. (2007, January). Interstate Compact for the Placement of Children: Model Legislative Testimony. Retrieved from, http://www.csg.org/programs/ncic/documents/ICPC-Boiler-PlateLegislativeTestimony.pdf.

[38] Council of State Governments. (2009, June). Interstate Compact for the Placement of Children: 2009 State Legislative Activity. Retrieved from, http://www.csg.org/programs/ncic/InterstateCompactforthePlacementofChildren.aspx.

[39] Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military *Children.* National Center for Interstate Compacts. Retrieved from, http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.

Transition

Purpose. Following enactment by the required minimum number of states, the new compact becomes operational and, depending upon the administrative structure set forth in the compact, begins 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 operate. Typically, transition activities run for between 12 and 18 months before the compact body is independently running.[40]

"Successful compact making also requires an effective and proactive plan for the transition period that begins when the first state passes a proposed agreement."[41]

Summary of Various Approaches. The following examples, drawn from existing compacts, illustrate approaches to the transition period of an interstate compact.

1. Interstate Compact for Adult Supervision of Sex Offenders[42]

   In 2002, a planning session for the first Commission meeting was held to provide guidance to NIC and CSG staff regarding the future of the compact.

2. Interstate Compact on the Placement of Children[43]

   By signing the compact, member states established the Interstate Commission for the Placement of Children. The Commission consists of one member from each state who has the legal authority to vote on binding policy matters. The Commission also includes individuals from organizations identified in the bylaws.

3. Interstate Compact on Educational Opportunity for Military Children[44]

   Once 10 states approve the compact language, an interstate commission will be formed to act as a liaison between the state and the interstate commission.

2.1.4 References

Adoption.com. (n.d.). Interstate Compact on the Placement of Children. Retrieved from http://glossary.adoption.com/interstate-compact-on-the-placement-of-children-(icpc).html.

---

[40] National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from, http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.

[41] Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association, pg 93.

[42] Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from, http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

[43] Council of State Governments. Interstate Compact for the Placement of Children, 16. Retrieved from, http://ssl.csg.org/dockets/27cycle/2007B/27Bbills/1827b02childrencompact.pdf.

[44] Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military Children. National Center for Interstate Compacts. Retrieved from, http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.

Broun, Caroline, Buenger, Michael, McCabe, Michael & Masters, Richard. (2007). The Evolving Use and the Changing Role of Interstate Compacts: A Practitioner's Guide. American Bar Association.

Council of State Governments. (n.d.). Kansas, Kentucky Enact Compact on Education Transition for Military Children. Retrieved from http://www.csg.org/about/MilitaryCompactPressRelease.aspx.

Council of State Governments. (n.d.). Interstate Compact for the Placement of Children. Retrieved from http://ssl.csg.org/dockets/27cycle/2007B/27Bbills/1827b02childrencompact.pdf.

Council of State Governments. (2002). Interstate Compact for Adult Supervision: How did We Arrive at this Point? Retrieved from http://www.csg.org/programs/ncic/documents/AdultCompactHistory.pdf.

Council of State Governments. (2008, January). Interstate Compact on Educational Opportunity for Military Children: Legislative Resource Kit. Retrieved from http://www.csg.org/programs/ncic/documents/RESOURCEKIT-January2008final.pdf.

Council of State Governments. (2008, February). Military Moves: New Compact Aims to Ease Education Challenges Faced by Military Children After Parent's Transfer. Retrieved from http://www.csg.org/pubs/Documents/SN0802.pdf.

Council of State Governments. (2009, June). Interstate Compact for the Placement of Children: 2009 State Legislative Activity. Retrieved from http://www.csg.org/programs/ncic/InterstateCompactforthePlacementofChildren.aspx.

Dusenberry, Mary Branham. (2008). New Compact Aims to Ease Education Challenges Faced by Military Children. Retrieved from National Center for Interstate Compacts: http://csg-web.csg.org/programs/ncic/documents/CONNECTIONS_Spring2008final_screen.pdf.

Interstate Compact for Adult Sex Offenders. (2002, July). State Officials Guide. Retrieved from http://www.csg.org/programs/ncic/documents/SOG.pdf.

National Center for Interstate Compacts. 10 Frequently Asked Questions. Retrieved from http://www.csg.org/programs/ncic/documents/CompactFAQ.pdf.

Oppenheim, Liz. (2005). Reforming the Interstate Compact on the Placement of Children. Retrieved from the National Center for Interstate Compacts: http://www.csg.org/programs/ncic/documents/ConnectionsWinter2005.pdf.

2.2 Governance Structure, Uses and Disclosures

2.2.1 Purpose and Description of Governing Body (North Carolina Perspective)

As noted above, an interstate compact is a formal, legally binding agreement between two or more states on matters that affect the interests of multiple states or their citizens. The language of the compact incorporates the terms of the agreement and prevents a signatory

state from unilaterally establishing policy on matters addressed by the terms of the compact.

When an interstate compact is established to address matters beyond simple multilateral agreements, such as regulatory issues that transcend the interests of individual states, or to facilitate a uniform solution to emerging regional issues, the interstate compact needs a strong governing body and administrative structures to achieve its purpose. In this regard, the Council of State Governments has noted:

> Traditional interstate compacts offer few details as to the issues of governance and administration. This is not surprising given the spirit and reciprocal nature in which they were intended to operate. However, as the administrative nature of state government has evolved over the last half-century, it has become necessary to develop structures and organization procedures that transcend one state's internal operation and apply uniformly to all member jurisdictions of interstate agreements.[45]

As noted above, an interstate compact addressing individual or consumer consent to release health information for HIE falls in the category of a "regulatory" or "administrative" compact. The governing body of such a compact can serve to ensure accountability, training, compliance, enforcement, rulemaking, information gathering and sharing, and overall staffing in order to achieve the terms of the agreement adopted under the compact.[46] The governing body should have enumerated powers and duties to achieve the purpose of the agreement, and the terms of the compact should authorize the governing body to adopt rules to address the specifics of state interaction and to make adjustments as needed throughout the life of the compact.[47]

According to the Council of State Governments, the governing body of a regulatory compact should be "an unambiguous third-party organization"[48] and should be clearly described in the compact language, including specific details about:

? Creation

? Name

? Membership

? Ex-officio membership (if any)

? Voting rights

? Voting majority

---

[45] Council of State Governments, "Developing the Right Structure for Success: Compact Governance," available at http://www.csg.org/programs/ncic/documents/Success.pdf, p. 1.
[46] Id.
[47] Id.
[48] Id at p. 2.

? Meeting frequency

? Structure

? Committees (e.g., executive, compliance, IT, finance, rules, etc.)

? Records maintenance

? Public access

? Meeting notice requirements

? Manner of acting

? Closed meetings (if permitted)

? Information sharing system[49]

Specific powers and duties of the governing body also should be described in the compact, including the following:

? Dispute resolution

? Rulemaking

? Oversight, supervision, and coordination between states

? Enforce compliance with compact rules

? Establish/maintain offices

? Buy/maintain insurance

? Hire personnel

? Establish committees

? Elect/appoint officers/employees

? Establish budget

? Borrow/raise money/spend money

? Initiate legal action

? Adopt bylaws

? Annual reports to member states

? Coordinate training and education

? Establish standards for collecting/exchanging data, including privacy principles[50]

Finally, the governing body must develop and maintain bylaws pursuant to which it will conduct compact business. Compact bylaws must:

[49] Id.
[50] Id.

- Address the requirement to adopt bylaws
- Establish a fiscal year
- Establish an executive committee and other appropriate committees
- Establish titles and responsibilities of officers and staff
- Establish the manner of conducting business
- Provide transition rules
- Establish standards and procedures for compliance and technical assistance and training[51]

There are numerous governance models for interstate compacts. Some of these include:

- Compact Administrators and Associations. Under this model, an individual is responsible for coordinating a state's participation in the compact; the compact administrator may act individually or in concert with counterparts in other states, in which case the governing body would be comprised of a multi-state association of administrators. The Council of State Governments notes that this type of governance structure is often chosen by those compacts requiring a great degree of interstate communication and cooperation.[52] Compacts employing an association of compact administrators include the (Interstate) Wildlife Violator Compact, the Interstate Compact on Juveniles, and the New England Compact on Involuntary Detention for Tuberculosis Control.[53]
- Intergovernmental Commission. Under this model, a commission governs the agreement and activities between the participating states. This governance model is commonly used for compacts which require significant coordination, rulemaking, and interstate communications. Compacts employing an intergovernmental commission include the Adult Compact, the Interstate Compact on the Placement of Children, and the Delaware River Basin Compact.
- Existing Agency. Under this model, an existing state agency, whose duties already include administration of the subject matter of the compact, administers the compact. An example of such a compact is the Colorado River Compact.

2.2.2 Two Potential Approaches to Governance Structure of an Interstate Compact on Consent (North Carolina Perspective)

As noted in the introduction, the Collaborative determined that there were two ways in which an interstate compact could address the challenge that the difference in state consent laws and regulations pose to HIE. Under the "choice of law" or "reciprocity" approach, the compact could provide either that the consent laws of the state in which the entity requesting and receiving the health information is located (the "requesting state") should be

[51] Id at p. 3.
[52] Council of State Governments, "A Guide to Development, Content, and Format Interstate Compacts," available at http://www.csg.org/programs/ncic/documents/Format.pdf.
[53] Voit, William Kevin, Council of State Governments; Nitting, Gary, University of Kentucky (1998). "Interstate Compacts and Agencies," available at http://www.csg.org/programs/ncic/documents/CompactsAgencies98.pdf.

applied to and govern HIE, or that the consent laws of the state in which the entity responding to the request and sending the health information is located (the "responding state") should be applied to and govern HIE. Under the "harmonization" approach, the compact could establish agreed-upon consent laws and rules which would apply to and govern HIE. Under either approach, states joining the compact would not have to amend their existing laws on consent because the provisions of the compact regarding consent would supersede existing, contradictory consent laws or rules in those states.

Because these two approaches affect how the compact is operated, the Collaborative determined to evaluate each approach in the context of the compact's governance structure and functions. In this section we evaluate the possible implications of each approach on HIE, along with the potential challenges and feasibility of each approach, based upon the Collaborative's research and findings regarding consent policy in Phase 3 of HISPC.

Reciprocity Approach

A significant purpose of this approach to compact governance would be to minimize the amount of bureaucracy and administrative duties involved in operating the compact. Under this approach, the governing body would establish rules governing which state's consumer consent laws apply when health information is exchanged between states that adopt the compact. Such a governing body would be expected to be more ministerial than regulatory. For this reason, participating states might agree to remain responsible for monitoring and enforcing compliance with their own laws pertaining to consent. Alternatively, the compact might provide for a dispute resolution role for the governing body in order to address any conflicts that may arise. The governing body likely would not be authorized to establish rules that conflict with or supersede existing laws of participating states related to consumer consent to release health information through HIE.

Under this approach, the governing body could be authorized to:

1. Adopt bylaws and perform administrative duties as necessary;
2. Establish and appoint committees as necessary to address issues that member states or their stakeholders identify;
3. Develop a database or other mechanism for tracking consent laws and rules of all participating states, noting how those laws are interpreted by each state in the event of a dispute;
4. Assist states, public health authorities, providers, regional health information organizations (RHIOs), payers, and consumer groups in becoming familiar with the relevant consumer consent laws of the participating states;
5. Establish uniform definitions that apply to only interstate HIE;
6. Coordinate training and education of providers, entities, state governments, etc.; and
7. Perform other functions as necessary to execute the provisions of the compact.

Harmonization Approach

A significant purpose of this approach to compact governance would be to encourage broad stakeholder participation and consensus on consent policy for HIE. Under this approach, the governing body would undertake more of a regulatory role in order to establish agreed-upon consent rules, policies, and guidance governing consumer consent applicable to HIE between participating states. Consent rules established by the compact would supersede conflicting state laws regarding the specific information exchanges addressed by the compact. This approach could provide some flexibility in terms of what HIE situations are addressed by the compact. For example, the compact could be drafted to address all instances of HIE (including exchange of sensitive information) or a more limited group of exchanges, depending upon the goals and positions of the participating states. The governing body, with participating state feedback, could determine which information exchanges the compact would propose to govern.

Under this approach, the governing body could be authorized to:

1. Adopt bylaws and perform administrative duties;
2. Establish and appoint committees as necessary to address issues that member states or their stakeholders identify;
3. Oversee, supervise and coordinate operational issues between states;
4. Establish uniform definitions applicable to those information exchanges addressed by the compact;
5. Adopt rules pertaining to the uses and disclosures for which consent is required;
6. Adopt rules pertaining to when disclosure without consent is permitted;
7. Adopt rules pertaining to when disclosure without consent is required;
8. Adopt rules pertaining to the minimum administrative procedures necessary to obtain consent;
9. Establish the minimum necessary data elements of consent (perhaps for each type or category of information exchange governed by the compact);[54]
10. Develop a model consent form;
11. Adopt rules pertaining to who must obtain consent, how consent is documented and maintained, and who can rely on consent once it is documented and made available to other entities;

[54] See Foundation of Research and Education of AHIMA, State-Level Health Information Exchange Consensus Project, "HIE Policies and Practices: Developing Options and Implementation Guidance to Foster Consistency," Interim Report, August 15, 2008, available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043512.pdf, p. 8 (hereinafter referred to as "HIE Policies and Practices") ("[l]ack of harmonization at the [data] attribute level may be enough to trigger the provider in one state to reject another state's consent/authorization").

12. Develop model privacy practices based on consensus building around HIE privacy principles;
13. Develop minimum standards for consumer awareness of and education about the compact's privacy practices and consent;
14. Develop minimum standards for provider education on how to implement the compact's privacy principles/practices;
15. Adopt rules pertaining to consumers' rights and responsibilities to revoke consent and the durability of consent absent revocation;
16. Adopt rules or guidance regarding related privacy and security safeguards;
17. Adopt rules to enforce compact policies and procedures;
18. Adopt dispute resolution and/or appeal procedures; and
19. Perform other functions as necessary to execute the provisions of the compact.

2.2.3 Implications (Pros/Cons, Risks/Benefits) of Each Governance Structure Approach (North Carolina Perspective)

Reciprocity Approach

Administrative Framework. This approach might require a smaller or less robust governing body—meaning that the governing body might have less overall authority—because the compact would appear to be largely self-administering once it is determined which state's consent laws apply.

It appears that the authority of the governing body would not include enforcement—meaning that each participating state would enforce its own laws. For example, if a provider in North Carolina violates North Carolina consent laws when disclosing health information at the request of a provider in South Carolina, then North Carolina, not the governing body of the compact, would have jurisdiction to enforce its laws against the provider who has disclosed information in violation of the applicable consent law. The governing body would, however, be responsible for ensuring that all participating states are in compliance with the bylaws and any other guiding principles of the compact.

The costs to the governing body could include (but not be limited to) those costs associated with compiling, monitoring, and maintaining a database of participating states' consent laws, regulations, and rules, or with creating or purchasing and implementing another mechanism for tracking different states' consent laws and rules.

In general, the costs for this approach would appear to be lower than those for the harmonization approach.

Challenge to Maintain Current State Law Database or Other Mechanism for Tracking Other States' Consent Requirements. Under this approach, the governing body might not have the authority to react on behalf of the compact to changes in federal

law involving the changing health information privacy and security environment. The governing body instead might need to implement a self-executing framework that would update the database or tracking mechanism to reflect any changes in a participating state's consumer consent laws or rules. Alternatively, the governing body might have to rely on each state to notify the governing body (or update the database or tracking mechanism) of any such changes in a timely and accurate fashion.

Challenge to Instill Confidence in the Value and Credibility of HIE. Inconsistencies among participating states' laws, regulations, and policies on consent may create confusion and increase the likelihood of disputes about which is the applicable law or policy and accordingly add to stakeholders' reluctance to exchange information.[55] Such inconsistencies could both hinder HIE and raise questions among providers (about the completeness, accuracy and reliability of the PHI) and consumers (about the privacy and security that will be afforded their information), and among both groups regarding the value of HIE.[56]

Impact on RHIOs and Other Entities with Cross-Jurisdictional Presence. Under this approach, it is possible that more than one state's laws would apply to a single exchange of health information among a series of related providers who reside in more than one state but who participate in the same RHIO or who are employed by the same health care organization. To afford the opportunity for informed consent, consumers would need to be informed that the RHIO or the health care organization has multiple release of information practices and that these practices may vary depending on the state in which their treating or consulting providers work. Additional potential ramifications for cross-jurisdictional entities under this approach include:

? Provider training and consumer awareness education may be more costly (because the lack of standardization may create confusion)

? Maintaining the status quo regarding state consent laws is likely to receive the approval of providers (who will not have to learn new processes for obtaining consumer consent)

? However, the lack of standardized consent practices may result in less consumer approval

? This approach may result in greater liability concerns (again due to confusion that may result from the fact that differing consent standards will be applied depending upon the location in which health care services are provided)[57]

---

[55] See Association of State and Territorial Health Officials, "Privacy Issues in Public Health Information Exchange Across State Lines," February 27, 2007, available at http://www.astho.org/pubs/StatetoStateIssueRpt.pdf, p. 4 (noting that "[t]he most prominent obstacle to the interstate health information exchange is differences among states in the laws and practices related to health information exchange").

[56] See HIE Policies and Practices, supra note 54, at p. 2.

[57] See generally Dullabh, Prashila and Molfino, Maria, prepared for Agency for Healthcare Research and Quality, "Liability Coverage for Regional Health Information Organizations: Lessons from the AHRQ-Funded State and Regional Demonstration Projects in Health Information Technology and

Risk of Break Down if Reciprocity Approach Results in Less Immunity for Providers. This approach can break down, depending upon the state laws in place. A case study of a data exchange between two health information networks in different states, performed by the State-Level Health Information Exchange Consensus Project, provides the following illustration:

- Oklahoma has passed a law wherein providers who use the approved state authorization form will be immune from liability. Ironically, while OK's law may be an incentive for intrastate HIE, it may actually slow down interstate HIE.
  - If patient and the provider are both in OK, a patient signs OK state authorization form to release information to the provider in MN. Patient uses the OK state authorization form as per usual practice by the provider, motivated by immunity from liability. The MN provider may reject the OK authorization because of differences between the OK and MN requirements for consent/authorization. This type of thing occurs frequently today.
  - If the patient and provider are both in MN and requesting information about previous health care from an OK provider, the MN patient executes and MN provider sends a MN consent form with a request for release of information to the OK provider. However, the MN state consent form does not grant immunity to the OK provider. Consequently, the OK provider may ask the MN provider to complete the OK state authorization form. In this situation, the process has slowed down and the issues of the differences in state consent requirements arise once again.[58]

Risk if Reciprocity Approach Results in Less Privacy Protection for Consumers. If the responding state's consent law affords the consumer a higher level of consent at the time the information is collected than the requesting state's law does, then the consumer may perceive that his or her privacy will be compromised by the exchange (due to the possibility that the receiving state will not maintain sufficient privacy protections over the information) and refuse to allow the responding state to send the information. Furthermore, states which have enacted more restrictive consent laws may not join the compact if other participating states do not agree to provide the same level of privacy and security protection to the information as the sending state does.

Harmonization Approach

Administrative Framework. This approach likely would require a larger governing body with greater or more robust authority than the reciprocity approach. For example, the governing body would most likely need to establish several policymaking committees in order to ensure broad stakeholder participation in the development of common consent policies, definitions, privacy practices, and educational requirements. The governing body also would likely be authorized to adopt rules to enforce its policies.

Other Community Efforts," June 2009, available at http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_874953_0_0_18/09-0071-EF.pdf.

[58] Id. at pp. 7–8.

Given the broader range of regulatory activities that would fall within the scope of a governing body under the harmonization approach, this approach might be more costly than the reciprocity approach.

Challenge to Maintain Policies that Reflect Current HIE Trends and State Needs. Under this approach, because a new consent framework would be developed and administered by the governing body, the governing body may be better able to respond to changes in federal law or new trends in health information technology and HIE. However, the governing body would need to ensure that its committees include thought leaders from each participating state who have expertise in current HIE technology and health care delivery trends. Ongoing participation of such leaders would be key to ensuring that the compact's rules about consent reflect the needs of all participating states and are continuously updated to reflect current technology, the changing health care regulatory environment, and other trends that affect consumer and provider confidence in HIE.

Challenge to Instill Confidence in the Value and Credibility of HIE. Harmonization of privacy policies and consent options across participants in the compact, if developed through broad stakeholder participation, may be more likely to instill greater trust among providers (about the completeness, accuracy and reliability of the PHI) and consumers (about the privacy and security that will be afforded their information), and among both groups regarding the value of HIE.

Impact on RHIOs and Other Entities with Cross-Jurisdictional Presence. Under this approach, assuming that all the states in which the RHIO or cross-jurisdictional entity is located agree to participate in the compact, HIE among participants within the RHIO or the entity would be subject to the same consent rules and policies, as well as the same privacy principles and practices. This predictability, in turn, could lead to a common, threshold level of awareness among consumers of the standardized privacy practices that would apply to HIE. As a result:

? Provider training and consumer awareness education may be less confusing due to standard rules and policies (and therefore less costly)

? The greater predictability due to such standard rules and policies may foster greater stakeholder and consumer confidence in HIE

? Alternatively, a change in consent laws and practices may not meet with provider approval, because the need to learn new policies and practices may be viewed as administratively burdensome and costly

? This approach may result in lesser liability concerns (because standardization of consent policy and practice may decrease confusion about which law applies)

Risk of Break Down if Harmonization Approach Results in Less Immunity for Providers. If the governing body is unable to convene broad stakeholder representation in developing standardized policies pertaining to provider immunity that are acceptable to all

providers within the compact's jurisdiction, then providers may be more reluctant to participate in HIE.

Risk if Harmonization Approach Results in Less Privacy Protection for Consumers. If the governing body is unable to convene broad-based consumer representation in developing consent policies that are acceptable to most consumers within the compact's jurisdiction, then consumers may be more reluctant either to participate in HIE or to seek needed treatment.[59]

2.2.4 Feasibility and Potential Challenges of Each Approach (North Carolina Perspective)

Reciprocity Approach

Facilitation of HIE: Under this approach, the governance structure may not require broad stakeholder collaboration, as the governing body could have less need for such collaboration due to its more limited role. If that possibility ensues, the absence of such collaboration may result in loss of consumer and provider trust and confidence in HIE, which would appear to be counter to some of the key goals of the compact.

Ease of Use.

1. This approach is more like the status quo and therefore may require less training and education, may be less costly to administer, and may appeal more to providers.
2. This approach may not achieve the objective of providing clarity or predictability regarding which consent law or policy applies in a given HIE scenario. There still may be ambiguity regarding whether the information is being received, sent, transmitted or held by a participating entity in a given state.
3. The possibility of confusion about which state's consent law applies may lead to a delay in exchanging information.

Privacy and Security. Under this approach, the consent requirements of the least restrictive state in the compact appear to become the de facto requirements for all health information sent to that state. In effect, the laws or rules of the state with the most permissive consent laws become the standard for all of the states and territories participating in the compact. When data is received by the state with the least restrictive consent laws, all more restrictive laws that previously applied to the use and disclosure of that data may no longer apply. This could result, initially, in several groups of states which have similar consent requirements deciding to enter into discrete interstate compacts with similarly-situated states; however, once information is exchanged between a state with significant consent requirements and a state with minimal consent requirements, those states which place a greater emphasis on individual privacy and patient self-determination

[59] See National Committee on Vital and Health Statistics, letter to the Honorable Michael O. Leavitt regarding individual control of sensitive health information accessible via the Nationwide Health Information Network for purposes of treatment, February 20, 2008, available at http://www.ncvhs.hhs.gov/080220lt.pdf, p. 3.

may no longer be able to assure their citizens that their health information will be protected to the extent of the more protective state's laws. Absent such assurance, more consumers may be unwilling to participate in HIE or fail to seek necessary treatment.

Harmonization Approach

Facilitation of HIE.

1. Broad stakeholder collaboration is necessary for the success of the governing body under this approach. This collaborative process is likely to engender consumer and provider trust and confidence in HIE. Without such collaboration, however, this approach likely will not succeed.
2. Such collaboration requires strong leadership and consensus-building skills, willingness to compromise, and time and other resources. Without each of these attributes or elements, the approach may not succeed.
3. Under this approach, the governing body could adopt consent standards and practices for those information exchanges all participating states agree should be governed by the compact. If agreement cannot be reached on, for example, consent requirements for exchange of sensitive health information, then the compact may not include such information exchanges and, in that case, would provide a more limited solution to the current consent barrier to HIE than the reciprocity approach.
4. Standardizing consent policy among all participating states is likely to result in less delay in HIE.
5. Not all providers, payers, and public health entities utilize electronic health records (EHRs), and some states may not be ready to agree to participate in a compact that would have the effect of modernizing their consent laws to promote interoperability.

Ease of Use.

1. This approach represents a change from the status quo and accordingly would require development of, and training and education on, new consent standards. It therefore may be more costly to administer, and providers may be resistant to learning or implementing new consent requirements.
2. This approach likely provides for greater flexibility. If compact states cannot agree on appropriate consent standards for a particular type of information exchange (e.g., substance abuse information; exchange for secondary uses), then the compact can exclude that type of information exchange from the compact language or rules (or postpone inclusion of such exchange until consensus can be reached). The downside to this possibility is that states might then be in the same position they currently are with respect to those information exchange types that are excluded from the reach of the compact, with all the attendant fragmentation, uncertainty, delays in information exchange, and liability concerns that the status quo brings.
3. A standardized consent policy and process likely is easier for health care stakeholders, including consumers, to understand. A consistent process for obtaining and documenting consent also may be preferable to most stakeholders. Additional certainty regarding the consent requirements for HIE among multistate health care organizations, RHIOs, and payers may reduce the costs of implementing EHRs, training about consent requirements, and implementation of the process of obtaining and documenting consent.

4. This approach may permit states to pool resources to establish a governance structure for interstate HIE and thereby create economies of scale. Under this approach, each state participating in the compact would not need to put additional resources into BOTH establishing a governance structure for intrastate HIE AND assisting with the costs of developing an interstate compact to govern choice of consent law.
5. This approach also could be used to develop a framework for the exchange of vital records among the states participating in the compact. States which share vital statistics information are concerned about whether the receiving state is using the health information in accordance with the sharing state's privacy provisions. To alleviate this concern, the compact's governing body could create rules pertaining to the transmission and use of the vital statistics information.
6. The governing body in this approach has sufficient infrastructure to convene stakeholders to address questions and concerns, remove barriers, and create incentives for participation in HIE. It likely could institute policies and incentives that could promote Health IT adoption and HIE.
7. This approach would likely promote the use of standardized semantics for data exchange between and among health care organizations in the participating states.
8. The governing body in this approach may have the authority to adopt standards that allow different systems to communicate and share information in compatible formats that facilitate privacy and security protections. Without harmonization, the information transfer can become inefficient and tedious, discouraging information exchange efforts due to a variety of standards, languages, and system architectures.

Privacy and Security.

1. Because this approach requires broad stakeholder participation, it is more likely than the reciprocity approach to have transparent practices regarding the development of rules and polices pertaining to the use and disclosure of consumer health information. By definition, the governing body would be charged with seeking compact-wide consensus on health information privacy and security issues. In doing so, it would facilitate the development of interstate working relationships and trust, including among consumers.
2. In addition, the more robust governance framework could develop policies on consent for secondary uses of information and other issues related to privacy and security of health information that are of interest to providers and consumers in the participating states.

2.2.5 Comments (North Carolina Perspective)

Reciprocity Approach

No additional comments.

Harmonization Approach

This approach permits states to come together and pool resources to build a comprehensive framework that implements core, consensus-based privacy principles and establishes oversight and accountability mechanisms. Doing so likely will require the compact to enact rules that serve as preemptive changes to existing state laws, balanced consent polices

regarding "many to many" electronic exchange of PHI, and stronger enforcement mechanisms. This approach essentially allows like-minded states to establish a multistate governing body to facilitate the sharing of health information within the legislative authority of the interstate compact.

A standardized approach might require a state to withdraw from the compact if it wanted to enact a consent law that was inconsistent with the compact language or rules enacted thereunder, unless such law pertains to an exchange that is not governed by the compact.

2.2.6 References (North Carolina Perspective)

- ? Association of State and Territorial Health Officials, "Privacy Issues in Public Health Information Exchange Across State Lines," February 27, 2007, available at http://www.astho.org/pubs/StatetoStateIssueRpt.pdf.
- ? Council of State Governments, "Developing the Right Structure for Success: Compact Governance," available at http://www.csg.org/programs/ncic/documents/Success.pdf.
- ? Council of State Governments, "A Guide to Development, Content, and Format Interstate Compacts," available at http://www.csg.org/programs/ncic/documents/Format.pdf.
- ? Dullabh, Prashila and Molfino, Maria, prepared for Agency for Healthcare Research and Quality, "Liability Coverage for Regional Health Information Organizations: Lessons from the AHRQ-Funded State and Regional Demonstration Projects in Health Information Technology and Other Community Efforts," June 2009, available at http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_874953_0_0_18/09-0071-EF.pdf.
- ? Foundation of Research and Education of AHIMA, State-Level Health Information Exchange Consensus Project, "HIE Policies and Practices: Developing Options and Implementation Guidance to Foster Consistency," Interim Report, August 15, 2008, available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043512.pdf.
- ? Markle Foundation, "Consumer Consent to Collections, Uses and Disclosures of Information, June 2008, available at http://www.connectingforhealth.org/phti/docs/CP3.pdf.
- ? Markle Foundation, "Enforcement of Policies," June 2008, available at http://www.connectingforhealth.org/phti/docs/CP9.pdf.
- ? McGraw, Deven, prepared for The O'Neill Institute for National and Global Health Law at Georgetown University, "Privacy and Health Information Technology," 2009, available at http://www.law.georgetown.edu/oneillinstitute/projects/reform/Papers/Privacy.pdf.
- ? National Center for Interstate Compacts, The Council of State Governments, available at http://www.csg.org.
- ? National Committee on Vital and Health Statistics, letter to the Honorable Michael O. Leavitt regarding individual control of sensitive health information accessible via the

Nationwide Health Information Network for purposes of treatment, February 20, 2008, available at http://www.ncvhs.hhs.gov/080220lt.pdf.

- National Governors Association Center for Best Practices, National Opinion Research Center, University of Massachusetts Medical School Center for Health Policy and Research, Report to the State Alliance for e-Health, "Public Governance Models for a Sustainable Health Information Exchange Industry," February 17, 2009, available at http://www.nga.org/Files/pdf/0902EHEALTHHIEREPORT.PDF.
- Voit, William Kevin, Council of State Governments; Nitting, Gary, University of Kentucky (1998). "Interstate Compacts and Agencies," available at http://www.csg.org/programs/ncic/documents/CompactsAgencies98.pdf.

2.2.7 Purpose and Description of Governing Body of an Interstate Compact (Illinois/Ohio Perspective)

An interstate compact serves as a formal agreement on matters that affect the interests of multiple states or the interests of the citizens of multiple states. The language of the compact incorporates the terms of the agreement and limits a signatory state to unilaterally establish policy in matters covered under the terms of the compact.

When an interstate compact is established to address matters beyond simple multilateral agreements, such as regulatory issues that transcend individual states, or to facilitate a uniform solution to emerging regional issues, the interstate compact needs a strong governing body and administrative structures to achieve its purpose. The governing body of such a compact can serve to ensure accountability, training, compliance, enforcement, rulemaking, information gathering and sharing, and overall staffing in order to achieve the terms of the agreement adopted under the compact. The compact governing body should have specific powers and duties to achieve the purpose of the agreement and should be authorized, pursuant to the terms of the compact, to adopt rules to address the specifics of state interaction and to make adjustments as needed throughout the life of the compact. The governing body may be a third-party organization and should be clearly described in the compact language, including details about:

- Creation
- Name
- Membership
- Ex-officio membership (if any)
- Voting rights
- Voting majority
- Meeting frequency
- Structure
- Committees (e.g., executive, compliance, IT, finance, rules, etc.)

- ? Records maintenance
- ? Public access
- ? Meeting notice requirements
- ? Manner of acting
- ? Closed meetings (if permitted)
- ? Information sharing system

Specific powers and duties of the governing body may include:

- ? Dispute resolution
- ? Rulemaking
- ? Oversight, supervision, and coordination between states
- ? Enforce compliance with compact rules
- ? Establish/maintain offices
- ? Buy/maintain insurance
- ? Hire personnel
- ? Establish committees
- ? Elect/appoint officers/employees
- ? Establish budget
- ? Borrow/raise money/spend money
- ? Initiate legal action
- ? Adopt bylaws
- ? Annual reports to member states
- ? Coordinate training and education

Governance models include:

- ? Compact Administrators (an individual is responsible for coordinating a state's participation in the compact, so have a multi-state association of administrators)
- ? Intergovernmental Commission (commission to govern the agreement and activities between states; common for compacts which require significant coordination, rulemaking, and interstate communications)
- ? Existing Agency administers (state agency administers the compact)

2.2.8 Summary of Purpose of Governing Body for Two Potential Approaches to the Use of an Interstate Compact to Facilitate HIE Between States with Varying Consent Laws (Illinois/Ohio Perspective)

As discussed in the introduction, there are two potential approaches that an interstate compact may take to resolve consent barriers to the interstate electronic exchange of health information. Reciprocity is a general term used in this paper to describe a compact that is structured to permit PHI to be exchanged if one of two scenarios is adopted by the compact. One, the compact agrees that the consent laws of the state in which the entity sending the PHI resides would govern the transaction; or two the compact may determine that the consent laws of the state where the entity requesting the PHI resides would prevail. Harmonization refers to a compact where the members agree to a new consent framework that would apply to all member states.

These approaches would necessarily require different directions for the compact governing body.

Reciprocity Approach

A governing body under this approach would be expected to be more ministerial than regulatory. The compact may also provide for some arbitration role for the governing body to address any conflicts that may arise.

The governing body could be authorized to:

1. Adopt bylaws and perform administrative duties as necessary;
2. Establish and appoint committees as necessary to address issues that member states or their stakeholders identify
3. Develop database of all participating state laws and rules governing consent, noting how those laws are interpreted by each state in the event of a dispute; the database would serve less of a purpose should the compact stipulate the requesting states law would be enforced.
4. Assist states, public health authorities, providers, RHIOs, payers, and consumer groups to become familiar with the relevant consumer consent laws of the participating states;
5. Coordinate training and education of providers, entities, state governments, etc.; and
6. Perform other functions as necessary to execute the provisions of the compact.

Harmonization Approach

In that this type of compact is providing for a new consent framework for all member states, the governing body would be expected to take on a regulatory role to establish rules, policies, and guidance governing the implementation of the new consent provisions.

Depending upon the scope of the compact terms, the governing body, with participating state feedback, could determine which information exchanges the compact would propose to govern.

Generally, the governing body for this type of compact could be authorized to:

1. Adopt bylaws and perform administrative duties;
2. Establish and appoint committees to address issues that member states or their stakeholders identify;
3. Oversee, supervise and coordinate operational issues between states;
4. Establish uniform definitions applicable to those information exchanges addressed by the compact;
5. Adopt rules pertaining to the uses and disclosures for which consent is required;
6. Adopt rules pertaining to when disclosure without consent is permitted;
7. Adopt rules pertaining to when disclosure without consent is required;
8. Adopt rules pertaining to the minimum administrative procedures necessary to obtain consent;
9. Establish the minimum necessary data elements of consent (perhaps for each type or category of information exchange governed by the compact);
10. Develop a model consent form;
11. Adopt rules pertaining to who must obtain consent, how consent is documented and maintained, and who can rely on it once it's documented and available to other entities;
12. Develop model privacy practices based on consensus building around HIE privacy principles;
13. Develop minimum standards for consumer awareness of and education about compact's privacy practices and consent;
14. Develop minimum standards for provider education on how to implement the compact's privacy principles/practices;
15. Adopt rules pertaining to consumers' rights and responsibilities to revoke consent and the durability of consent absent revocation;
16. Adopt rules or guidance regarding related privacy and security safeguards;
17. Adopt rules to enforce compact policies and procedures;
18. Adopt dispute resolution and/or appeal procedures; and
19. Perform other functions as necessary to execute the provisions of the compact.

2.2.9 Implications of Each Approach With Respect To the Governance Structure (Pros/Cons, Risks and Benefits) (Illinois/Ohio Perspective)

Reciprocity Approach

Administrative Framework. This approach might require a smaller/less robust governing body—meaning that the governing body might have less overall authority—because the compact would appear to be largely self-administering once it was determined which state's laws applied.

It appears that the authority of the governing body would not include enforcement — meaning that each participating state would enforce its own laws. The governing body would, however, be accountable for ensuring all participating states are in compliance with the guiding principles of the compact.

The costs to the governing body could include (but not be limited to) those costs associated with compiling, monitoring, and maintaining a database of participating states' consent laws, regulations, and rules.

In general, the costs for this approach would appear to be lower than those for the harmonization approach.

Challenge to Maintain Policies that Reflect Current Trends and State Needs. Under this approach, the governing body might not have the authority to react on behalf of the compact to changes in federal law involving the health information privacy and security environment.

Harmonization Approach

Administrative Framework. This approach likely would require a larger governing body with greater or more robust authority than the reciprocity approach. For example, the governing body would most likely need to establish several policymaking committees in order to ensure broad stakeholder participation in the development of common consent polices and educational requirements.

The governing body also would likely be authorized to adopt rules to enforce its policies.

The governing body would need to establish a financial plan to pay its administrative expenses, including staffing for the committees, publishing and communicating its policies and rules, establishing structures to enforce compliance with its rules, etc.

Accordingly, a governing body under this approach might be more costly than under the reciprocity approach.

Challenge to Maintain Policies that Reflect Current Trends and State Needs. Since the harmonization approach involves the development of a new consent framework where implementation details will likely be delegated to the governing body would have the

flexibility to respond better to changes in federal law or new trends in health information technology.

2.2.10 Conclusions (Illinois/Ohio Perspective)

Reciprocity Approach

This approach does not appear to require a governance framework, however, the establishment of a governing body would be valuable in providing an educational function, and serving as a potential arbiter of disputes.

Harmonization Approach

A governing body would be an essential component of a compact based upon a harmonization approach. While the terms of the compact will set the general consent framework to be used by all member states, the governing board would be key in addressing implementation issues.

2.2.11 References (Illinois/Ohio Perspective)

- ? National Center for Interstate Compacts, The Council of State Governments. (http.//www.csg.org)
- ? Report to the State Alliance for e-Health, "Public Governance Models for a Sustainable Health Information Exchange Industry"

2.3 Certification for Data Privacy and Security to Support Interoperable Health Information Systems

2.3.1 Purpose

The provisions regarding Data Privacy and Security are necessary because this process will allow disclosing and receiving entities to understand and verify the other party's compliance with the data privacy and security requirements for the data to be shared. Additionally, the creation of a data privacy and security certification process will expedite data sharing by allowing disclosing entities to rely on the certification of systems instead of evaluating the data privacy and security posture of each receiving party.

2.3.2 Summary of Various Approaches

There are two primary options to consider when determining security policy for interstate health information exchange, and these are (1) using the existing security provisions under the privacy and security regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (the "HIPAA Privacy and Security Rule(s)") as well as any additional privacy or security requirements promulgated as a result of the Health Information Technology for Economic and Clinical Health Act ("HITECH"). (2) developing or adopting a security standard.

The current model of data sharing generally involves a step in which the data sender verifies the data privacy and security processes and controls of the data receiver. Health information is shared only after this analysis. Additionally, the data sender will have concerns about the safeguarding of the health information in the event that the data receiver is unable to keep the health information private and secure. We recommend replicating these aspects of the data sharing process to make it easier for a data sender to share information with a data receiver. Therefore, both of the options below include the creation of a certification mechanism to validate the data privacy and security posture of data receivers and an insurance program that covers the cost of data breaches.

Use HIPAA Security Rule and Health Information Technology for Economic and Clinical Health (HITECH) Act Enhancements

? Require out-of-state receiving party to comply with the privacy and security regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (the "HIPAA Privacy and Security Rule(s)") as well as any additional privacy or security requirements promulgated as a result of the Health Information Technology for Economic and Clinical Health Act ("HITECH").

? Create certification process to evaluate the data privacy and security capabilities of the receiving entity. This allows disclosing entity to rely on certification rather than evaluating the receiving entity's data privacy and security posture.

? Establish insurance program that would cover costs of data breaches.

? This option is the existing model for data protection today—with the exception of the certification and insurance components.

Develop a Data Privacy and Security Standard

? Form an interstate committee to review existing data privacy and security standards and develop a new standard for interstate data transfers.

? Create certification process to evaluate the data privacy and security capabilities of the receiving entity. This allows the disclosing entity to rely on certification rather than evaluating the receiving entity's data privacy and security posture.

? Establish insurance program that would cover costs of data breaches.

? This option is not in place today.

2.3.3 Implications, Pros/Cons, Benefits/Risks of Each Approach

The implications of the two approaches focus on the level of effort that will be required to comply with either approach. The primary drawbacks to the first option (HIPAA Security) are that current practices are variable (not scalable) and choice of law for interstate issues is not defined. The primary drawback to the second option (standard development/ adoption) is that additional work is required. The issue with scalability can be best addressed with the standards development option because it would provide a well defined

minimum requirement. The committee will need to address a standard for policies as well as technical implementations.

Another implication is that Option 1 (HIPAA Security) has been in place for a number of years and will continue to be updated and improved by federal regulators. On the other hand, Option 2 (standard development/adoption) may be difficult to draft because, on a practical level, state representatives on the committee may not easily or rapidly agree on another security standard.

HIPAA Security Rule and HITECH Enhancements

Pros

1. Use of the HIPAA Security Rule and HITECH enhancements
   - allows more flexibility for receiving entities to develop data privacy and security programs commensurate with their specific risks.
   - simplifies compliance by allowing the receiving entities to monitor changes in one set of requirements.
   - allows receiving entities to comply with one data privacy and security rule.
   - can be enforced by state attorney generals (AGs), who have been granted authority to enforce HIPAA per the HITECH Act.
2. The certification process makes it easier to share data because the disclosing party can share information with the understanding that the receiving party has adequate controls in place to protect the information.
3. The insurance component supports the sharing of information by socializing the breach notification costs across all entities participating in data transfers. Insurance revenues could help subsidize the certification process.

Cons

1. Use of the HIPAA Security Rule and HITECH enhancements
   - may not be equal among different types and sizes of entities because the risk analysis is scalable.
   - may not account for state-specific data privacy and security laws that are more stringent.
   - are not very proscriptive, at least yet. Receiving entities may choose to implement lax data privacy and security standards.
   - may need to also include the HIPAA Privacy Rule, which may be difficult to operationalize because the receiving entity may not be conducting a HIPAA-covered function for the disclosing entity.
   - have yet to be drafted and analyzed for effectiveness and feasibility of implementation.
   - requires discussion regarding choice of state venue.
2. The certification and insurance programs have not been developed and the administration of these programs may pose additional difficulties.

Develop a Data Privacy and Security Standard

Pros

1. Developing a Data Privacy and Security Standard
   - facilitates the creation of a new data privacy and security standard that accounts for state-specific data protection requirements.
   - allows states to create a more proscriptive approach to data privacy and security.
   - allows those states participating in the compact to create a safe harbor for compliance with state data privacy and security laws.
   - leverages the work that has been done in various arenas, such as the Uniform Security Standard, the Data Use and Reciprocal Support Agreement, and the Uniform Security Policy.
2. The certification process makes it easier to share data because the disclosing party can share information with the understanding that the receiving party has adequate controls in place to protect the information.
3. The insurance component supports the sharing of information by socializing the breach notification costs across all entities participating in data transfers. Insurance revenues could help subsidize certification process.

Cons

1. Developing a new data privacy and security standard
   - is a duplicative effort that steers resources away from other aspects of managing interstate data transfers.
   - adds another regulation that receiving entities must monitor, analyze, and implement.
   - requires the development of a new enforcement mechanism.
2. The certification and insurance programs have not been developed and the administration of these programs may pose additional difficulties.

2.3.4 Potential Challenges and Analysis of Feasibility of Each Approach

Challenges focus on the clarity of requirements in either option and the amount of effort to achieve this clarity.

HIPAA Security Rule and HITECH Enhancements

Challenges

? Variations in state law and choice of law are problematic

? Certification is a challenge

? Insurance is a challenge

? Large and small entities do not have standard safeguards and mitigations for risk; scalability is an issue

Feasibility

? Dependent on federal regulation and interpretation

- ? Enforcement may vary by state AG resources

Develop a Data Privacy and Security Standard

Challenges

- ? New processes are onerous
- ? Standards development is usually a technical issue not a policy issue
- ? Certification is a challenge
- ? Insurance is a challenge
- ? Enforcement may be an issue

Feasibility

- ? Cost could be subsidized by insurance
- ? Utility and pay off is long term

2.3.5 Comments

For Option 2, the committee could reference the activities of other HISPC work, specifically, The Uniform Security Policy (USP) for health information exchange among states, which has been completed for two of four security domains.

2.3.6 References

Data Use and Reciprocal Support Agreement (DURSA)

Health Information Technology for Economic and Clinical Health Act (HITECH Act)

Health Insurance Portability and Accountability Act (HIPAA) of 1996

2.4 Enforcement

2.4.1 Purpose

An interstate compact is essentially a contract among member states that may or may not have/need Congressional approval. If it does have Congressional approval, it is considered federal law. As with any contract, enforcement becomes an issue when the parties to the compact and/or affected third parties allege a breach or challenge the interpretation or applicability of a compact provision. Dispute resolution mechanisms and remedies may be set forth within the compact though, ultimately, a state or federal court may be called upon to address enforcement issues. Appropriate forum and applicable law may depend upon whether the compact has Congressional approval. Also, some disputes/issues under the compact may involve third parties whose rights are impacted by the terms of the compact. Third parties may challenge the authority of the compact members to affect their rights and remedies without affording them their day in court.

2.4.2 Summary of Various Approaches

1. Create compact administrative body charged with regulating and refereeing issues between the parties and involving third parties

   – Mandate disputes be resolved by this body

   – Permit disputes to be resolved by this body

   For example, the Interstate Compact on Educational Opportunity for Military Children establishes an interstate commission charged with enforcing compliance, promulgating rules, and pursuing court action when appropriate. The interstate commission pursues enforcement of compact terms first through arbitration or mediation, then through court action which may seek injunctive relief and/or damages.

2. Require mediation or arbitration of disputes

   Under the compact for Adult Offender Supervision, and the Interstate Compact on the Placement of Children, the respective interstate commissions provide for binding dispute resolution. Penalties may include fines. Remedial training or technical assistance, or suspension or termination of compact membership. Termination of membership, however, requires an affirmative from a majority of the compacting states.

3. Designate appropriate jurisdiction(s) and role of court for resolution of disputes.

   The Interstate Compact for Adult Offender Supervision also provides for court action, venued in the U.S. District Court for the District of Columbia, to enforce the provisions of the compact, and its rules and regulation. The prevailing party in that litigation is entitled to all costs of litigation, including attorneys' fees. The Interstate Commission on the Placement of Children provides for court action to be brought either in the D.C. District Court, or in the District Court where the interstate commission has its principal office.

4. Remain silent in the compact as to methods of enforcement, and delegate this determination and the promulgation of appropriate rules to the interstate commission.

2.4.3 Implications, Pros/Cons, Benefits/Risks of Each Approach

Overall, a consistent process or system, established in an interstate compact, to enforce the terms of a compact for health information exchange will result in uniformity of interpretation and application, providing predictability, and facilitating the comfort of providers' exchange of health information. Not only should this reduce the administrative burdens on healthcare providers, but should also facilitate the provision of appropriate, quality health care in a mobile society.

1. Delegating the details of enforcement to the interstate commission would provide it with the most flexibility to respond and tailor enforcement mechanisms that are most appropriate for the situations that arise. However, it may be less feasible to obtain legislative support for a compact if the penalties and enforcement mechanisms are not specified. Nevertheless, this approach provides consistency for resolution of issues and puts resolution in hands of "experts" relating to the subject matter and intent of the compact; fosters clear expectations among participants. The use of an

administrative body, such as with the interstate commission for Educational Opportunity for Military Children, gives that commission the ability to deal with enforcement issues in a flexible manner—resolving them through mediation, arbitration or pursuing court action, as may be most appropriate in the particular circumstance. This flexibility should encourage the resolution quickly in those situations in which timelines are necessary for the meaningful exchange of information.

2. Resolving a dispute quickly and without use of an expensive and lengthy formal court process is desirable, and in some cases may be the most efficient manner of handling the dispute. Requiring mediation or nonbinding arbitration in all cases, however, may not advance the resolution of the dispute if the parties firmly hold to their positions or no middle ground is feasible. In such instances, mandating mediation or arbitration creates additional steps and hurdles to resolving the matter, slowing the dispute resolution process down rather than increasing its speed. The financial burden of a mandatory step in the process would also be significant, particularly in situations in which it is unlikely to produce meaningful results.
3. If a significant amount of litigation arises under the compact, the designation of a jurisdiction would permit the court to develop some expertise and familiarity with the compact. This single jurisdictional approach would advance predictability and uniformity of decisions interpreting and applying the terms of the compact. On the other hand, it may be politically difficult for various states to agree upon a single forum.
4. Although a few compacts do not specify an enforcement mechanism, this approach would not, at the outset, provide for consistency of decisions and interpretation of the compact by the courts, and could result in lengthy litigation as to the proper venue and interpretation of the compact. This would vastly increase the time expended in enforcing the compact and the cost of administering it, in addition to potentially having conflicting interpretations of the compact provisions for a lengthy period of time.

2.4.4 Potential Challenges and Analysis of Feasibility of Each Approach

All of the approaches listed are feasible, and are currently in use by various compacts.

1. Powers granted to the administrative body cannot exceed the scope of authority delegated by members' legislatures [FTC v. Ruberoid Co., 343 US 470 (1952)]; delegation of authority should not be so broad that it violates constitutional principle of separation of powers [INS v. Chadha, 462 US 919 (1983)]
2. Some states, such as Ohio, have limitations on their ability to agree to arbitration. This may require any arbitration clause to require only the less effective "nonbinding" arbitration. Mediation, on the other hand, does not appear to be prohibited in any setting in Ohio.
3. States have the same responsibility to enforce terms of contract as do federal courts, though the US Supreme Court retains ultimate authority to interpret Congressionally approved contracts [West Virginia ex rel. Dyers v. Sims, 341 US 22 (1951)]; compacts not Congressionally approved must be construed as state law [McComb v. Wambaugh, 934 F.2d 474 (3rd Cir., 1991)], subject to authority of US Supreme Court where dispute between states [West Virginia ex rel. Dyers v. Sims, 341 US 22 (1951)]

4. Politically, state legislatures may have difficulty agreeing to a compact that is silent as to how it will be enforced, given that the silence will increase the costs of enforcement through potentially prolonged litigation, as well as decrease the uniformity of the application of the compact terms.

2.4.5 Reference

The Evolving Use and Changing Role of Interstate Compacts: a practitioner's guide, Caroline N. Brown, Michael L. Buenger, Michael H. McCabe, Richard L. Masters, ABA, 2007

2.5 Liabilities

2.5.1 Purpose

There are multiple reasons for forming an interstate compact, one of which is to address the liability exposure of persons (individuals and entities) abiding by the terms of the compact in the exchange of PHI. Thus, one goal of a compact is to provide legal protection to (A) persons of responding states if they provide PHI to legitimate users in a requesting state whose laws are less stringent than the laws of the responding state, as well as to (B) persons of requesting states if they receive PHI which is subsequently used or disclosed in a manner that would otherwise violate the responding state's laws. This section addresses the nature of such liabilities and assumes that state laws related to PHI use and disclosure, and related liability laws, differ in a manner that impedes PHI exchange.

Another assumption, because the real party in interest injured by the disclosure of PHI is the patient, is that each state (as the provider state) can reach the conclusion that the benefits to its citizens of allowing access to health records by out-of-state providers outweighs what would otherwise be a the violation of its privacy laws.

The liabilities could take the form of: (i) claims by a patient or other holders of rights with respect to PHI, (ii) claims by third parties seeking indemnification because of claims by the parties described in subpart (i), and (iii) claims by governmental entities, whether in a court or via an administrative action and whether civil and criminal in nature. The person seeking protection from liabilities could be either the person transferring the PHI or the person receiving the PHI.

2.5.2 Summary of Approaches

We have identified three approaches to address the liabilities of disclosers of PHI that may arise as PHI is transferred across state lines and subsequently used or disclosed.

First, liabilities could be eliminated by providing <u>immunity</u> in the providing state for specified conduct in the requesting state. In other words, a requesting person who follows his or her own state laws on use and disclosure of PHI would incur no liability in any state that is part of the compact [and the transferor to such person would incur no liability if the transfer was in accordance with the provisions of the compact]. A variation of absolute immunity might

be qualified immunity, such as protecting "good faith" behavior, or limited liability such as damage caps, with or without a mandated dispute resolution process such as arbitration before an interstate compact commission tribunal. State courts, however, are split on the constitutionality of damage caps.

A second approach would be to provide indemnification, whereby either the party in the requesting state or the party in the responding state [or both] agrees to defend and hold the other party harmless for any breach of [their home] state's laws regarding the exchange or disclosure of PHI. This right of indemnification could also arise as a matter of law rather than express agreement. A variation might be to limit indemnification, such as by amount (similar to a schedule of damages) and mandated dispute resolution or approval process before an interstate compact commission tribunal.

A third approach is to address liability through insurance. Under this approach, insurance coverage would be available to the parties for expenses incurred from liabilities. Several alternatives may be available to fund the insurance coverage—by private parties through mandatory requirements for coverage (like auto insurance), a state-funded pool (like a malpractice insurance guaranty association under Ohio Revised Code ["O.R.C." or "R.C."] §3955.06), or experience-based like worker's compensation or a combination of the above.

A variation of the insurance approach might be to limit coverage such as state-funded pools commonly do, or to mandate private parties carry specified amounts of liability insurance such as the $1-million limit that hospitals commonly require physicians to carry, with or without an explicit concomitant right of the injured party to seek additional compensation from the responsible party (tortfeasor).

2.5.3 Implications, Pros/Cons, Benefits/Risks of Each Approach

Immunity

This would have the potential of avoiding most, if not all of the litigation since it would preclude, or in cases of qualified immunity limit, recovery. The negative would be that persons harmed (whose PHI was disclosed) might not be compensated and this might encourage less care by persons handling the PHI. As a result, it seems likely that immunity would be more narrow than indemnification or insurance. In addition, immunity can be absolute or qualified/limited, and states may have different views of immunity. Immunity provisions appear throughout the Ohio Revised Code, and assumedly as frequently in other states, and the courts generally permit them. Some interstate compacts provide immunity but do not apply it broadly to private parties.

Immunity, whether limited or not, is politically difficult in some states, although every state uses limited immunity to protect certain state government programs under the 11th amendment of the U.S. Constitution, and separately to protect socially beneficial behavior such as that associated with good Samaritan statutes (see

http://en.wikipedia.org/wiki/Good_Samaritan_law). Privacy advocates, consumer groups, and the trial bar may oppose immunity provisions, whereas business groups including healthcare professionals are more likely to support such provisions. However, a majority of states have enacted and upheld noneconomic damage caps according to the American Tort Reform Association (www.atra.org).

Indemnification

Although persons harmed would be compensated, it might encourage litigation because of the possibility of recovery. Limiting the amount of indemnification and mandating an alternative dispute resolution (ADR) process before the interstate compact commission may reduce litigation. As with immunity, certain parties may oppose any limitation of damages recoverable through indemnification. Additionally, there would be costs associated with creation and use of an ADR process, although the costs could be borne by the parties using the process—and generally the costs of ADR are far less than traditional litigation.

Insurance

As in the case of indemnification, an insurance mechanism might encourage litigation, although that potential may be reduced if the amount of mandated insurance is limited and an ADR-like process before the interstate compact commission is required. Another negative is the cost that either private insurance or a state pool would add to health information exchange. The costs of mandated insurance may be opposed by some parties, and compliance with such mandates is unlikely to be universal (e.g., reportedly 20% of automobile drivers do not purchase liability insurance despite state mandates to do so). However, the success and widespread existence of state insurance guaranty funds (see http://www.medsave.com/state-insurance-guarantee-associations.htm) may signify a strategy worth pursuing.

2.5.4 Potential Challenges and Analysis of Feasibility of Each Approach

Immunity

The key challenge would be determining who and under what circumstances immunity would be granted. Absolute versus qualified immunity must be evaluated in terms of value, and whether full or limited immunity face unfavorable state constitutional law precedent in any of the compact states. As indicated above in section 2.5.3, some parties are staunchly opposed to granting immunity except in narrow situations such as addressed by Good Samaritan statutes.

Indemnification

The key challenge would be determining who bears the cost of indemnification. Do judicial precedents in each of the compact states permit indemnification to be limited in amount, or constrained by process such as mandating alternative dispute resolution (ADR) before the

interstate compact commission? Another issue is the identification of the indemnifying party. Many states do not themselves indemnify as a matter of law, at least Ohio does not for matters not budgeted for in the state's biennial budget. If indemnification is limited, some parties as indicated in section 2.5.3 are likely to be opponents.

Insurance

The key challenge would be funding and then administering the insurance coverage. Do judicial precedents in each of the compact states permit insurance mandates, recovery beyond mandated insurance minimums, and-or mandated use of dispute resolution processes such as required use of an interstate compact commission tribunal? The State of Ohio for the most part is self-insured. It may be difficult to convince the legislature to take on this potential liability and pay for or contribute to insurance to cover privacy breaches. On the other hand, state insurance guaranty funds where commercial parties "pay to play" may be a strategy to investigate.

2.5.5 Comments

Before addressing solutions to liability exposure from state to state, it should be determined if there are liability exposures because of differing PHI and HIE provisions or judicial precedent, and if any such differences can be eliminated by inclusion in the interstate compact provisions of standardized liability and related statutes.

Federal preemption (or, at the very least, leadership) may be the only viable solution to the states differing public policies causing them to enact different privacy laws and the resulting problems associated with attempting compliance with the differing state laws.

2.5.6 References

R.C. 3747.01—Midwest interstate compact and commission on low-level radioactive waste.

- Sovereign Immunity—Article VII (F): The immunity granted to state employees and agencies is dimensionally different than traditional immunity in Ohio. The statute does not incorporation notions of the Ohio Court of Claims, and appears to make immunity absolute by not recognizing the availability of the court of claims as a venue. Conversely, certain conduct is actionable and not subject to immunity. That actionable conduct is also different than conduct defined in R.C. 109.362. Because it is a different standard, it is unclear how this meshes with traditional state employee immunity; however, as this was enacted by the General Assembly it would be effective for a waiver of immunity.
- Commission and Commission members immunity—Article III(M): Commission is separate from the party states. Members are not personally liable for actions in official capacity. Liabilities of the commission are not liability to party states.
- Indemnification—Article VII(G) Generator indemnity, Article V(F) Pro rata Party State indemnity: If liability is established in spite of the immunity provided then the "generator" must indemnify the employee or state agency. If all else fails and the

pools don't cover the liability, then party states share the expense on a pro rata basis.

- ? Insurance pools—Articles III (P) Remedial Action Fund, and VI(O) Long-term Care Fund: These establish funds a liability or cost avoidance tool.

R.C. 3915.16 Interstate insurance product regulation compact, and

R.C. 5149.21 Interstate compact for adult offender supervision

- ? Each establishes a separate interstate commission. The commission can be sued.
- ? R.C. 3915.16 provides that the commission is solely responsible for its liabilities. R.C. 5149.21 does not contain the same term.
- ? Each has the same structure for qualified immunity, defense and indemnification.

Members, officers, director and employees are immune from suit and liability, personal or official capacity except for damage from intentional or willful and wanton misconduct.

The commission will assist in defense of commissioner (commission member) of/from a compacting state. The commission will indemnify commissioner of a compacting state except for gross negligence or intentional wrongdoing (or intentional or willful and wanton misconduct).

R.C. 5103.20 Interstate compact for placement of children

- ? Establishes a separate commission.
- ? Qualified immunity, defense and indemnification
- ? Commission staff director and employees are immune from suit and liability except for criminal acts or intentional or willful and wanton misconduct.
- ? Liability if established within a state cannot exceed the limits of liability set forth under the laws of the state where act occurred.
- ? The commission will assist in defense of commissioner (commission member) of/from a compacting state.
- ? Employees of the commission will be held harmless for acts within the scope of employment.

2.6 Parties to the Agreement

2.6.1 Purpose

This section describes the entities that will enter into the interstate compact (agreement). The Council of State Governments defines an interstate compact as "a contract between two or more states." So, literally, the parties to the agreement (i.e., the interstate compact) will be two or more states that agree to its terms.
An offer is made when one state, usually by statute, adopts the terms of a compact requiring approval by one or more other states to become effective. Other states accept the

offer by adopting identical compact language. Once the required number of states has adopted the pact, the "contract" between them is valid and becomes effective as provided.

However, what adoption means from a practical standpoint will vary depending upon the language of the compact itself. For example, the compact may require that each participating state enact its terms, verbatim, as part of the state's statutory law. See, e.g., Ohio Revised Code (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). Thus, as a practical matter, each state legislature has an active role in the negotiation and approval of the agreement through the typical legislative process.

Alternatively, the compact could be constructed in such a way that the participating states' governors or other designated officials (e.g., head of the state health department)are the signatories to the agreement. See, e.g., 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).

With either approach, the compact will ultimately carry the force of statutory law. In Ohio, 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, e.g., 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).

2.6.2 Summary of Approaches

In addition to the states who will literally be the parties to the interstate agreement, the parties that will have an interest in its development are many, and include consumers, healthcare providers, health plans, and third-party payers. Indeed, even within state and local government, various agencies represent different constituencies and regulate different aspects of healthcare delivery (e.g., the Ohio Departments of Health, Mental Health, Job and Family Services, and the Bureau of Workers' Compensation), and will need to work together to reach a statewide view regarding the transmission and protection of protected health information.

Naturally, the overriding concern of each of these constituencies will be the facilitation of informed medical care via HIE. But underlying that shared interest, each group has unique interests and concerns regarding the development of an HIE system. Consumers will be particularly concerned with the security of their health information and other confidential data and will want to be assured that those are protected. These concerns are perhaps pronounced more now than ever in the face of growing instances of identity theft and breaches of corporate security that have laid bare the details of individuals' credit accounts.

At the same time, providers will desire immediate access to a patient's entire medical history in order to avoid initiating a course of treatment or prescribing a medication that may be contraindicated by that history. Immediate access will require a system that is capable of high-speed data transfer, unhindered by bureaucratic requirements.

Health plans and third-party payers will want to know what the rules are for the new HIE system, in order that they can comply without fear of civil or criminal penalties as they develop business models and systems that will allow them to engage in HIE.

The various state regulatory agencies will be concerned with enforcing their own existing regulations. For example, the Ohio Department of Job and Family Services will want to ensure that its rules governing the Ohio Medicaid program, including the provision of services and the state-level mandate of consumer confidentiality, are followed and enforced. Concurrently, the Ohio Department of Mental Health has its own regulations of confidentiality mandates that it will want to see enforced, and both agencies may—and likely do—have information to which the Bureau of Workers Compensation would desire access in order to ensure the integrity of its system and avoid fraudulent claims. And, in many cases, each of these state agencies has to work within the framework of federal regulations, including HIPAA, to avoid the risk of federal penalties and/or the loss of federal funding.

Thus, at the earliest stages of interstate compact development, decisions will need to be made in each state as to how to best accommodate the interests of these various constituencies, even before a broader, multi-state drafting and negotiation effort commences.

With those issues presumably settled, work will then begin to develop the content of the interstate compact itself, perhaps along one of the following tracks:

1. One or more states wishing to enter into an agreement that describes how the state will obtain and implement consent to exchange health information across state lines will name stakeholders within each state who will meet and draft an interstate compact. The states will determine who will lead the group of stakeholders, if any. Once a multi-state stakeholder group is formed, the parties will determine a schedule and deliverables for meeting the goal of drafting an interstate compact that enables health information exchange across state lines.

2. Alternatively, one state may draft a proposed interstate compact to be disseminated to states with whom it wishes to exchange information. The draft agreement will then be negotiated by the interested parties until a final agreement is signed or otherwise approved.

Following the negotiation and agreement among states to the terms of an interstate compact, the federal government may also become a party if Congressional approval is required. Virginia v. Tennessee, 148 U.S. 503, 518-522 (1893). The need for such approval is likely if the compact affects the balance of power between the federal government and the states, or if the compact intrudes upon an area reserved or of interest to the federal government.

2.6.3 Implications, Pros/Cons, Benefits/Risks of Each Approach:

1. The first track (i.e., developing a multi-state stakeholder group to develop the compact) may take longer because the initial draft will be worked on by committee. However, if the initial product is developed with the input and buy-in by several states, it will hopefully offset later delays occasioned by individual states' objections to the provisions of the compact.
2. On the other hand, initial development of the compact by having a smaller group (a single state) create the initial draft will likely be quicker on the front end and result in a product to which other parties may then react and suggest changes. The review and revision period using this approach may take longer, but there may be some value in having an actual document earlier in the process to make the interstate compact "more real" to states' executive and legislative leadership.

2.6.4 Potential Challenges and Analysis of Feasibility of Each Approach

Both approaches are equally challenging in that they require parties to work through a contract negotiation process.

Either approach is feasible assuming willingness on the part of at least two states to negotiate terms.

In any event, resolution of the issue to allow the effective transfer of health and medical information through the creation and approval of an interstate compact will not be immediate. At each step of the process, the concerns and insights offered by the various constituencies identified above will need to be heard and considered in order to ensure effective implementation of the compact.

2.6.5 Comments

As the discussion above seeks to demonstrate, while the simple answer to the question, "who are the parties to the agreement?" is clear, each state will have to work within itself to determine whose voices matter and should be heard at the negotiating table.

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 education 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.

2.6.6 References

Council of State Governments, www.csg.org

2.7 Outreach to External Parties

2.7.1 Goal

To design an outreach program for engaging key stakeholders in the development of an interstate compact addressing consent to release health information for electronic health information exchange (HIE).

2.7.2 Desired Outcome Objectives:

- Identify possible conveners or a convener group to champion the development of an interstate compact and discuss approaches to engaging them in the process.
- Identify possible funding partners for the planning and development process and discuss approaches to seeking their participation.
- Identify possible participants to an advisory group, drafting team and steering committee, and discuss communication tools and outreach activities for recruitment.
- Discuss outreach tools for an education phase of the development and enactment phase of the interstate compact process.

2.7.3 Target Audience:

To support the development of an interstate compact addressing consent to release health information in the context of electronic health information exchange, it is critical to determine those individuals or groups that will most likely support the desired goal/outcome objectives.[60] This section outlines target audiences for various support roles in this process.

[60] Developmental Disabilities Outreach Plan. Retrieved from, www.itacchelp.org/uploads/Outreach_Plan_Template.doc.

Convener/Convener Group

Key to the development of the interstate compact is the identification of a convener or convener groups. This group will provide the initial leadership for bringing the necessary stakeholders together in a more formal structure that will need to be created to oversee the development and implementation of the interstate compact.

Possible Conveners

? National Governor's Association (NGA)

NGA is the collective voice of the nation's governors sharing best practices and addressing national policy as it impacts upon the states. NGA was involved in health IT and electronic health information exchange issues through the formation of the State Alliance for e-Health in 2007. The alliance funded by the Office of the National Coordinator for Health Information Technology (ONC), U.S. Department of Health and Human Services (USDHHS), served as a collaborative body to promote the efficiency and effectiveness of Health IT. Two taskforces created by the alliance, the Privacy and Security Taskforce and the Public Programs Implementation Task Force, have both now ended, in addition to the previous taskforces established prior to 2008.

The State Alliance for e-Health is currently commissioning a paper to explore multi-state agreements for addressing HIE consent issues. They expect to build upon the HISPC work on interstate compacts, and are interested in exploring options to bring our work together, with a particular focus on creating opportunities to include other states.[61]

? Nationwide Health Information Network (NHIN) Cooperative

An initiative of the federal government, NHIN is being developed to provide a secure, nationwide, interoperable health information infrastructure to connect healthcare providers, consumers and other aspects of the healthcare system. NHIN is currently operating with developmental funding from ONC. Representatives of the participants in this early developmental stage are considered part of a cooperative. Various work groups from this cooperative have been created to address various issues pertaining to NHIN, such as Policy & Governance, Specification & Innovation, and Production & Operations. The NHIN Cooperative also convened a work group to develop an agreement that would serve as the legal framework governing participation in the NHIN. This agreement was entitled the "Data Use and Reciprocal Support Agreement" (DURSA).

? National Conference of State Legislatures (NCSL)

NCSL serves the legislators and staffs of the states, commonwealths and territories, providing research, technical assistance and opportunities for policymakers to exchange ideas. This organization is monitoring Health IT and electronic health information exchange issues through an initiative called "Health Information Technology Champions" (HITCh). The HITCh project began in 2006, and is made up of legislators interested in Health IT, providing meetings and webinars focused on issues brought by the members. The HITCh website provides a link to a new report on their work over the past year and half. The report, titled "Health Information

[61] Personal Communication, Cara Campbell/Senior Policy Analyst, State Alliance for e-Health, July 21, 2009, ccampbell@nga.org.

Technology and States: A Project Report from the NCSL's Health Information Technology Champions", identifies and analyzes key trends in state Health IT policy. Although NCSL has worked on interstate compacts, their Health IT work has not specifically involved interstate compacts. HITCh may be more likely to convene a group of legislators for discussion on this topic, rather than convene the entire process. HITCh primarily takes a bottom-up approach, responding to legislators and sorting out existing privacy laws so no laws are violated.[62]

? Council of State Government (CSG)/National Center on Interstate Compacts (NCIC)

CSG is an organization for state leaders to address policy issues and to develop innovations for state governments. NCIC is an information clearinghouse, providing training and technical assistance to interested parties on the development and operation of interstate compacts. NCIC can also act as the primary facilitator in assisting states to draft or review interstate compacts. CSG has been assisting in this area for 70 years.[63]

? State-level Health Information Exchange (SLHIE) Leadership Forum

In 2006, SLHIE was established under a contract from the Office of the National Coordinator for Health Information Technology (ONC). The project focuses on state-level activities to advance HIE with the goal of creating a mechanism for a group of stakeholders to take an HIE policy issue and create a best practice standard. They have established a structure and are now interested in working on specific policy projects that advance HIE adoption. The American Health Information Management Association (AHIMA) Foundation is an integral part of this effort.[64]

? eHealth Initiative and the Foundation for eHealth Initiative[65]

The eHealth Initiative and its Foundation (eHI) are Washington D.C.-based, independent, nonprofit affiliated organizations whose missions are the same: to drive improvements in the quality, safety, and efficiency of healthcare through information and information technology. The initiative engages the multiple stakeholders in healthcare both at the national level, and within states and communities across the country, to develop and drive the implementation of a common set of principles, policies and best practices for mobilizing information electronically to improve health and healthcare, in a way that is responsible, sustainable, responsive to each stakeholder's needs, and which builds and maintains the public's trust.

2.7.4 Funding Partners

The process for developing an interstate compact is a costly one. It is necessary to identify stakeholders willing to help finance the structure and education needed to effectuate an interstate compact. The National Center on Interstate Compacts estimates costs of $350,000–$500,000 for a compact development process.

[62] Personal communication, Donna Folkemer/HITCh Group Director, July 2, 2009, donna.folkemer@ncsl.org.
[63] Personal communication, Keith Scott Executive Director and Rick Masters, Special Counsel, June 9, 2009. kscott@csg.org, rmasters@csg.org.
[64] Personal communication, Lynn Dierker, Project Director, July 2, 2009. Lynn.Dierker@ahima.org.
[65] www.ehealthinitiative.org

Possible Funding Partners

? NCSL

? NGA

? Foundations

- Duke Endowment
- Bill and Melinda Gates Foundation
- Henry J. Kaiser Family Foundation
- John D. and Catherine T. MacArthur Foundation
- Markle Foundation
- Robert Wood Johnson Foundation
- The Commonwealth Fund

? States anticipating membership in an HIE focus interstate compact

? National health care insurers

- BlueCross BlueShield Association
- UnitedHealthCare
- Kaiser Permanente

2.7.5 Membership Outreach for the Advisory, Drafting and Steering Committees

The Process for Development section outlined the need for an Advisory Group, a Drafting Team, and A Steering Committee. An important goal of the outreach program is to help recruit policy-makers, stakeholders and other key leaders to serve as members for these groups.

Possible Participants

? Employer and Consumer Groups

- AARP
- Consumers Union
- Families USA
- Health Care for All
- National Partnership for Women and Families

? Government

- Governors—This group is formally represented by the NGA. Representatives can come from recommendations from the organization or from interested governors who have championed HIE.
- State legislators
  - Legislative drafting experts for drafting committee

  - State Medicaid agencies
  - State/local public health agencies
  - Attorneys General—Staff representatives from Attorneys General would be helpful on the drafting committee
  - State Departments of Health and Human Services
- Healthcare Stakeholders
  - American Medical Association or representatives from state affiliates
  - American Hospital Association or representatives from state affiliates
  - American Academy of Family Physicians or representatives from state affiliates
  - Pharmaceutical company and pharmacy representatives
  - Laboratory representatives
  - Long-term care facility representatives
  - The Healthcare Information and Management Systems Society (HIMSS) or representatives from state affiliates
  - The American Health Information Management Association (AHIMA) or representatives from state affiliates
  - Third-party payer representatives
- HIE Organization Representation
  - NHIN Cooperative
  - RHIOs not yet affiliated with NHIN

2.7.6 Education

Once completed, the interstate compact will 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.

Possible Education Participants

- Consumer groups
- Legislators
- State health care provider organizations
- State Chapters HIMSS
- State Chapters of AHIMA

Message

It is essential to establish a foundational body of knowledge on the concepts that should be included, or considered for inclusion in an interstate compact addressing consent in the context of electronic health information exchange. Creation of an Interstate Compact will provide a scalable structure to link the national, state and local efforts. To use a metaphor:

the Interstate Compact will create and define the structure for the interstate highway system as well as set the guidelines for use of the highway, but the specific type and nature of the "vehicles" utilizing the highway is a matter to be addressed privately. So long as the drivers obey the speed limit, the minimum driving age, the maximum load per vehicle, the minimum fuel efficiency, etc., they are free to travel the highway.[66]

Strategies

Outreach Tools

- ? List of outreach tools that will most effectively carry the message.[67]
  - Print: Print outreach tools are important for people to read and keep, these tools will focus on HISPC-IL research and factsheets. Print outreach tools include: Brochures, Fact sheets, News Releases, Feature Articles, Inserts, Flyers, Newsletters, Educational Curricula, Letters to Editor, and Direct Mailing.
  - Electronic: Many people receive their information from television and the internet, therefore electronic outreach tools provide an important opportunity for communication. Electronic outreach tools will primarily focus on websites and email, but may also include: Webinars, Blogs, (Radio Interviews, Community Access TV, PSAs, Videos, Television?)
  - Visuals: Visual outreach tools will be used during presentations and exhibits. The focus of visual tools will be on PowerPoint Presentations, Displays, and Posters.
  - Personal Contact: Personal contact outreach tools include: Workshops, Presentations, Lectures, Demonstrations, Meetings, Interviews, Surveys, Press Events, Conferences, and Face-to-face encounters.
  - Other: Partnerships, Cooperative Agreements, Council Members

Outreach Activities. The following groups were developed using recommendations from a conference call with Keith Scott, Executive Director and Rick Masters, Special Counsel of the National Center on Interstate Compacts in the spring of 2009, the NOAA Fisheries Outreach Strategic Plan,[68] and the Development Disabilities Outreach Plan.[69]

Pre-Advisory Stage

- ? Direct informational meetings

Advisory Committee & Drafting Committee

To be determined by convener

[66] "final-consent2CollaborativePhase4 OH-CA-8-11" in background documents CITE THIS???
[67] Developmental Disabilities Outreach Plan. Retrieved from, www.itacchelp.org/uploads/Outreach_Plan_Template.doc.
[68] NOAA Fisheries Northeast Region Outreach Strategic Plan. Retrieved from, *www.nero.noaa.gov/nero/outreach/outreachplan-final.pdf.*
[69] Information and Technical Assistance Center for Councils. (n.d.). Developmental Disabilities Outreach Plan. Retrieved from www.itacchelp.org/uploads/Outreach_Plan_Template.doc..

Education and Enactment

Meetings and Events

- ? Conduct educational meetings focused on project target groups, i.e. state legislators, governors and state Medicaid and public health agencies.
- ? Arrange for speakers
- ? Develop partnerships
- ? Attend outside HIE-related meetings

Web site

- ? Monitor/update organization's website
- ? Produce website materials
- ? Create "hot news" homepage
- ? Produce an educational homepage

To Produce and Distribute

- ? Design Regional displays
- ? Develop presentations
- ? Develop information sheets for target groups
- ? Produce internal resource factsheets and talking points
- ? Assemble media/press packets
- ? Press releases

Transition

To be determined by convener, advisory committee, drafting committee and/or stakeholders

2.7.7 Timeline

Outreach efforts should mirror the estimated timeline for the process of developing the interstate compact

2.7.8 References

eHealth Initiative. (n.d.). Retrieved from www.ehealthinitiative.org.

Information and Technical Assistance Center for Councils. (n.d.). Developmental Disabilities Outreach Plan. Retrieved from www.itacchelp.org/uploads/Outreach_Plan_Template.doc.

Mertz, Kory. (2008, November). National Conference of State Legislatures.

NOAA Fisheries Northeast Region. (n.d.). NOAA Fisheries Northeast Region Outreach Strategic Plan. Retrieved from www.nero.noaa.gov/nero/outreach/outreachplan-final.pdf.

3. NEXT STEPS, FUTURE RESEARCH

3.1 Illinois' and Ohio's Perspective

Part of the mission of the Intrastate and Interstate Policy Collaborative in Phase 3 was 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. Short of a federally mandated solution, the Collaborative identified the creation of an interstate compact as one of the best approaches to addressing the barrier to HIE caused by conflicting state consent laws. In that regard, a report, was prepared that noted this recommendation, coupled with suggesting a need for furthering the efforts to support the creation of an interstate compact.

In the short time allotted for the HISPC Challenge and Innovation Extension Phase the Collaborative adopted the goal of establishing a foundational body of knowledge about the significant concepts that should be included, or considered for inclusion in an interstate compact. This report represents the Collaborative's best effort to accomplish this goal. It also discusses the process for developing a compact and provides suggestions on outreach efforts to foster the development of a compact and encourage states to become members.

The original analysis of an interstate compact performed by the "Interstate" portion of the Collaborative, consisting of California, Illinois and Ohio, identified three structural approaches to developing an interstate compact. The description of two of these structures was combined for simplification purposes and referred to as "reciprocity," while the third has been termed "harmonization." Pros and cons of the approaches were noted in the Collaborative's March 31, 2009 report.

Regardless of the approach, absent a federal solution, the issue of addressing the differing state consent laws to ensure the efficient and timely electronic exchange of health information must be addressed by the states. To address it, some group or consortium of groups need to take up the role of convener as described in this paper and pursue the necessary research and stakeholder involvement to come to an accepted response.

The Ohio HISPC project team is prepared to work with or facilitate a convener group such as the State Alliance for E-Health operating under the direction of the National Governors Association Center for Best Practices to solicit support from the Office of the National Coordinator for development of a reciprocity-based Interstate Compact.

3.2 North Carolina's Perspective

North Carolina proposes the following next steps and future research on consent issues following July 2009:

1. Investigate and test the current technological and policy feasibility of electronic consent directives as a means of eliminating the legal barrier of consent from the exchange of patients' information within and between states.

   North Carolina's participation in the HISPC Intrastate and Interstate Consent Policy Options Collaborative taught us that in the current health care delivery system, obtaining patient consent for treatment and for release of records related to that treatment is key, due to the importance of patients understanding (1) the need for, and agreeing to, third parties' release of their health information for certain purposes, and (2) that such third parties will safeguard the privacy, security, and integrity of that information.

   Patients understand that it is beneficial for caregivers to electronically share information with those who need it, but patients also want to specify who is granted access to what information and under what circumstances. If patients could give consent for certain access to, and use and disclosure of, their health information and that consent could follow—or be embedded in—the information in question, providers and caregivers would be able to implement and enforce the patient consent directives, minimizing if not eliminating concerns about differences among state laws. This, in turn, would resolve the conundrum of how to address consent within both the DURSA and inter-organizational agreements (IOA).

2. Investigate whether a harmonizing interstate compact may be an effective mechanism for the exchange of public health information among states.

   The use of a health information organization (HIO) to expedite the sharing of public health information across state lines may facilitate multistate coordination of public health surveillance initiatives and would improve public safety and public health. However, a 2008 assessment of privacy practices and current and emerging issues (as reported by state public health privacy officials) cited the lack of portability of privacy across state lines as a major barrier to the implementation of HIOs.[70] State privacy officials reported additional multistate privacy issues impacting the interoperable exchange of public health information, including:

   – The lack of a consistent understanding of the privacy of public health information exchanged between states and local health departments and various federal agencies;
   – The lack of clarity regarding the permissibility of and appropriate safeguards for re-release of information provided from one state to another or by a state to the federal government;
   – The need to standardize the variations in definitions, interpretation, protection, and implementation of "sensitive" health information; and
   – Specific areas of interstate exchange of public health information that need to be resolved include: (1) the sharing of newborn screening test results; (2) the consistent application across states of authority to share communicable disease information to prevent the spread of disease; and (3) the sharing of immunization registry data.[71]

---

[70] Suarez, Walter, Public Health Data Standards Consortium, "Health Information Privacy in Public Health Agencies: An Assessment of Current and Future Issues Affecting Public Health Practice," May 2009.

[71] Id., pp. 28–29.

Currently, states and local health departments are executing interstate data use agreements to facilitate the exchange of public health information. The NC team proposes to study privacy issues related to the exchange of public health information across state lines, and to determine whether an interstate compact may be a more effective legal mechanism for such exchange than the interstate agreements. We believe that the interstate compact has potential as a legal tool to establish a public health privacy framework across partnering states which would supersede conflicting laws and facilitate a consistent understanding of the privacy of public health information exchanged across providers, local health departments, state departments of health, and federal and international public health agencies.

3. Continue exploring the National Committee on Vital and Health Statistics' recommendation to former Secretary Leavitt that individuals be permitted to restrict the flow of their health information by categories when that information is to be placed into a health information organization.

   The National Committee on Vital and Health Statistics, in its February 20, 2008 letter to former Secretary Leavitt, recommended that policies be adopted for the Nationwide Health Information Network permitting individuals to have limited control, in a uniform manner, over the disclosure of certain sensitive health information for purposes of treatment. The letter further suggested that public dialogue should inform the specifics of these policies and that pilot projects be initiated to test their implementation. Permitting individuals to sequester their sensitive information by category, as recommended in the letter, will both (a) increase individuals' trust in the NHIN and their willingness to be honest with providers about their sensitive health conditions, and (b) increase health care providers' trust in the contents of the records and alleviate some of their concerns about liability, because providers would be notified that certain sensitive information has been withheld, thereby permitting providers to discuss individually with patients those categories of sensitive information that may be pertinent to that episode of treatment.

   We believe that this approach also could be effective to address concerns about consent to release information in health information organizations which cross state lines.

4. Further evaluate the effect of health record banking as a means of eliminating the legal barrier of consent from the exchange of patients' information within and between states.

   Health record banks currently are being explored by several states and health information organizations as a means to provide patients increased control over (and ensure greater privacy and security of) their health information. Consider evaluating the legal effect of current consent laws on this type of health information exchange and creating a pilot program to test the feasibility of the technology and the public acceptance of health record banks as a preferred alternative to the traditional model of entity-controlled health information exchange.