

PROCESS FOR DEVELOPING THE OPTION:

Discussion

CA quoted an ABA publication describing the 5 Keys to success in summary:

1. Inclusive process
2. A good “sales pitch”
3. Well-planned marketing strategy
4. Develop a network of champions
5. Develop a proactive transition plan

IL quoted the Council of State Governments National Center for Interstate Compacts on 5 steps for developing compact: *Advisory Group; Drafting Team; Education; Enactment; and, Transition.*

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

OH also addressed the issue of Congressional approval. The OH analysis indicates that it appears “approval would be necessary...”

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

IL discussed Congressional approval in the **OTHER CONSIDERATIONS** section. CA raised the issue in the **LENGTH OF TIME REQUIRED TO FORMULATE** section.

OH also raised the issue of continued monitoring of technological advances.

PROs

IL

- Adoption by multiple states standardizes the process and is more effective in addressing the barrier to HIE
- Issues can be examined in depth

CA

- Informal and legislative approved development will foster sponsors

OH

- Allows states to draw the parameters

CONs

IL

- Long negotiation process in dealing with issues such as privacy
- Lot of work for little results if not adopted by majority of states leaving the barrier to HIE largely in place

CA

- CA would need strong presence to ensure consistency with CA ideals

OH

- Congressional approval may lead to federal interference by fed govt. and courts

LENGTH OF TIME REQUIRED TO FORMULATE:

Discussion

OH indicated that it could take years.

CA and IL cited CSG study discussing around 5 years

PROs

IL

- Process provides enough time to examine issues

CA

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

OH

- Length of process could offset later problems with compact terms

CONs

IL

- Process could get bogged down
- Removal of HIE barrier delayed

OH

- Removal of HIE barrier delayed

IMPLEMENTATION REQUIREMENTS:

Discussion

CA discussed the CSG developmental process. IL and OH indicated legislative approval for admission or delegation of authority for admission to Executive.

PROs

IL

- Process familiar with legislatures

OH

- Participating states should be able to reach some consensus in advance as to the most effective way to get state participation as early as possible.

CONs

IL

- Ratification process could delay implementation of HIE
- During compact transition period, providers need to be educated raising cost issues

OH

- Delay

LEGAL FRAMEWORK/RULES OF ENGAGEMENT:

Discussion

In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a compact may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;” Approach 2 – the laws of the “Requesting State Prevails;” and, Approach 3 – the compact defines the procedures in what was labeled “Compact Defined Consent.”* IL also set up two sub groupings – scenarios defining how strict the consent laws of the responding or requesting state were – with Scenario 1 analyzing situations where the responding state’s laws were more stringent, and Scenario 2 discussing the reverse.

OH addressed the issue of Congressional approval again and noted that a compact acts like a contract.

PROs

IL

- A1 – easiest to implement.

- A1 – information could flow quickly once the requesting state submits a request that meets the responding state’s requirements
- A1S1 – If the consent was obtained at the time of collection of the data, it would be irrelevant that the requesting state’s consent was not as robust because the responding state had already obtained a more stringent consent, thereby encouraging freer flow of information.
- A1S1 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A1S2 – Information could flow easily and quickly if the requesting state complies with its own, more stringent, laws
- A2S2 – Privacy is best protected because the information cannot be disclosed unless the requirements of the more stringent law are met.
- A2S1 – Information will flow easily and quickly without the requirement that the responding state seek additional consent from the patients if the requesting state submits a consent that complies with its own laws. It would be irrelevant that the responding state’s laws would not have permitted the disclosure
- A2 – Requesting states need only to be familiar with their own state’s laws
- A3 – A uniform process easier to understand in the context of interstate exchange of PHI
- A3 – A consistent set of documentation to permit access and disclosure of information.

OH

- Superior in force and effect to prior and subsequent state statutes

CONs

IL

- A1S2 – There is a lesser focus on privacy concerns which could be objectionable to privacy advocates
- A1S1 – May delay the release of PHI if the requesting state submits a consent that does not meet the higher standards of the responding state
- A2S2 – Access to PHI in the requesting state will be delayed while healthcare providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards
- A2 – Healthcare providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- A2S1 – May raise objections from responding states that do not wish to release PHI under less demanding consent requirements
- A2 – No advance planning because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information

- A3 – Difficult to find consensus, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approaches 1 or 2.
- If the compact-defined consent requirements are not implemented properly, the failure to provide adequate education would result in confusion by healthcare providers
- States with lenient consent requirements, compact-defined consent could be objectionable if the imposes new, more stringent requirements
- States with robust consent requirements may object to less stringent compact-defined requirements

OH

- Drafters must satisfy all potential adopters - consistent terms; effective administration defined; timeframe for legislative action; potential need for Congressional approval

IMPACT ON STAKEHOLDER COMMUNITIES:

Discussion

IL and CA discussed how the ratification process would give stakeholders an opportunity to provide input.

OH indicates that stakeholder impact appears to be mixed at best

Positive Impact

IL

- Impose the same rules on member states resulting in great connectivity
- Providers get better understanding of complying with laws
- Assist in protecting providers from inappropriate disclosures/help with evidentiary documentation if required to defend the disclosure
- Improve the quality of healthcare for patients and assist in more efficient delivery of health care
- Gives stakeholders a voice
- Increase buy-in
- Eliminate ambiguity.

CA

- Depends on the scope of the compact

Negative Impact

IL

- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Some groups may organize against the compact
- Providers need to adapt to compact requirement
- A compact that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A compact with a more stringent environment could inhibit the free flow of information
- Compacts with extensive differences would mean that providers and patients may not initially be familiar with the requirements for HIE

OH Pros and Cons by Stakeholders

- Consumer Interests
 - Consumers which experience diminished protections and rights may forgo treatment or seek it in different jurisdictions
- Health Care Providers
 - Provides added certainty about what law to apply reducing disputes among providers, concerns surrounding liability and professional hesitation due to patient confidentiality obligations
 - More immediate remedy than would a national solution
 - Larger health care providers could realize more exponential gains by consistency in law
 - Uncertainty that state courts would interpret compact terms consistently, may still deter interstate exchange
 - Time, expense and potential confusion in complying with compact would also be an obstacle to interstate health information exchange
 - Smaller health care providers may be experience more problems with resources, compliance programs and liability concerns
- Health Plans and Other 3rd Party Payers
 - Added certainty may be especially beneficial to larger multi-state health plans
- State Government
 - Some traditional sovereignty would necessarily be reduced in reaching the collective's objectives
 - Political problems –
 - State's lost ability to pass new and dissimilar laws
 - Executive branch appointments to the interstate council or advisory board may be contended
 - Distribution of funding requirements may be problematic and especially for those states with limited health care budgets
- Employers
 - Similar concerns to health plans

FEASIBILITY:

Discussion

IL and CA overtly discussed feasibility in terms of “cost” and “political viability.” IL also raised the question as to whether the option was “technically possible.” OH touched on costs in its analysis as well.

With respect to cost, \$1.2 million in support provided for the “Adult Compact” versus the approximate \$100,000 cost of the “Interstate Compact for the Placement of Children. IL also referenced discussed the higher costs embodied in its “Approach 3.”

Regarding political viability, IL noted that compacts afford states the opportunity to address the problem without federal interference. CA noted a compact’s responsiveness to local needs. The analysis also identified the need for flexibility in the compact to address future developments.

PROs

IL

- Costs – Approach 1 would be least costly
- Political Viability – A compact would be a state-driven solution with Approach 1 possibly more viable because of the minimum of disruption to health care providers
- Technically Possible – Compact may be one of the best ways to address the barrier

CA

- Federal participation could add revenue

CONs

IL

- Costs
 - Educating providers on the compact will be costly
 - Providers will resist higher costs
 - State governments are experiencing financial problems
 - Approach 2 would be an expensive option for providers and HIO who want to be able to effectively exchange health data because they would have to understand other state laws
 - Approach 3 could be viewed as less costly than Approach 2 because it would entail learning one new system, although it would still be a costly burden on providers
- Political Viability
 - There will be political difficulty in getting states with a history of more stringent consent requirements to adopt a compact viewed as loosening standards

- Conversely, states with less stringent requirements may balk at a more stringent compact
- Technically Possible – Approach 3 will require healthcare providers in all states to adapt to the compact’s requirements

CA

- CA has so many health information laws, developing a compact in accordance with CA law may be difficult
- Federal participation could add delays

DOES THE OPTION ADDRESS LIABILITY CONCERNS:

Discussion

All states indicated that a compact should address liability concerns.

PROs

IL

- Properly drafted the compact would clarify and minimize provider liability concerns
- Education is the central issue in ensuring providers follow the compact and benefit from the liability protections

CA

- State law should dominate
- If the compact requires consent, then it would alleviate other concerns

OH

- Liability concerns would be appropriately addressed in order to accomplish higher ranked political and social goals

CONs

IL

- An interstate compact may result in more litigation being heard in federal courts
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion

CA

- If not protective of privacy rights, not likely to succeed

OH

- It remains to be seen if there are local or state issues or constituencies that would prevent satisfactory standardized liability protection in multi-state compact language.

RAMIFICATIONS OF ACCEPTANCE/REJECTION:

The state analyses identified the benefit of acceptance as an elimination of barriers to HIE. Rejection will leave those barriers intact.

CONFLICTS WITH STATE OR FEDERAL LAWS:

Discussion

The states noted that the compact would supersede conflicting state laws, but not federal law.

PROs

IL

- This mechanism provides for consistency and removes conflict among differing state laws.

OH

- This results in a collaborative approach among the states to resolving issues created by conflicting state laws, and may encourage the federal government to also collaborative resolve differences with federal law
- The process of entering into a compact may result in individual states review and revising their current privacy laws and statutes

CONs

IL

- The more state laws are in conflict with the interstate compact, the more likely the adoption process will not succeed

CA

- California has so many laws that cover health information that, such as breach notification and mental health protections, developing a compact to be in accordance with California law could be difficult

OH

- The downside of a compact's pre-emption of state laws is the fact that it does not permit a state to enact policies that reflect unique cultures or climates that exist in that state

PROCESS FOR WITHDRAWAL:

Discussion

The state analyses noted that withdrawal basically involves the repeal of the ratification statute. However, the compact terms may contain notification or transition processes impacting on the withdrawal.

PROs

IL

- It is essential to adapt to changes in circumstance over time

OH

- Not easily renounced by other members

CONS

IL

- Withdrawal would create uncertainty over the handling of PHI and create problems for healthcare providers as well as undermine patient assurance regarding privacy, particularly if prior consent laws were also repealed as part of the adoption of the interstate compact
- Keeping track of which states have adopted or withdrawn from the compact will be difficult. Questions may arise as to what prevails if a state has withdrawn and whether the date of the consent is the deciding factor.

CA

- Will need to cover the impact on exchanges that occurred previous to the withdrawal

OH

- Complex and potentially lengthy process to modify terms or withdraw

STATE RESPONSIBILITIES:

Discussion

The states highlighted the need to educate stakeholders regarding compact requirements. CA also noted the possible costs if an administrative body were created as part of the compact. OH discussed the promotion of the compact and ratification legislation.

PROs

IL

- The education of stakeholders regarding the consent requirements will result in buy-in

CA

- Will need to ensure transparency on decision making process
- Strong advocacy to ensure state rights

OH

- As the primary driver of a compact, state government injects a higher level of stability and predictability into the expectations of HIE
- Stability and predictability can be bolstered by the force of law as each member state insures compliance with the processes and mechanisms established through the compact
- These efforts and any subsequent educational campaigns should have minimal fiscal impact in the long-term.

CONs

IL

- A compact may be pursued without providing adequate funding and content analysis to support an initiative to educate stakeholders - estimated to cost providers \$120,000
- Funding support by the state will be a critical component for increasing buy-in by providers

OH

- Bureaucracy
- Variations in governmental structures from state-to-state, will cause some inconsistencies as to the entity managing compact issues or concerns

STATE'S RIGHTS:

Discussion

The states referenced the rights of a state to enter and withdraw from a compact.

PROs

IL

- An interstate compact is a reasonable, state-directed solution to the problem of conflicting state laws

CA

- Need a strong presence in the drafting

OH

- An effective compact will lessen or eliminate the need for federal government intervention – thus assist in preserving the rights of the states to have control over the policies governing access to medical records

CONs

IL

- An interstate compact does not ensure a solution for every state – this would require a federal standard
- A compact will also require another layer of legal analysis for providers.

CA

- Need to ensure retain jurisdiction for disputes involving state laws

OH

- A compact will limit the rights of the member states to alter the policies or procedures to access medical records

ENFORCEMENT:

Discussion

IL and CA analyses discussed the issue of enforceability in relation to enforcing the terms of the compact and in terms of enforcing consent requirements. The structure of the compact affects the enforcement of the consent requirements. For example, IL’s Approaches 1 and 2 envisioned the acceptance of one of the party states standards and presumably enforcement. Approach 3, the creation of a compact standard would clearly indicate a need for a more detailed enforcement mechanism to be spelled out.

OH focused some of its discussion on the tie between enforceability and Congressional approval. The OH analysis noted that “without such approval, the compact is nonbinding and legally unenforceable upon the members.” The analysis also points out that “a compact, in and of itself, does not directly alter the intrastate legal expectations.”

PROs

IL

- Enforcement is necessary to achieve compliance and gives the compact a sense of importance

CA

- Possible to create a certification process to ease implementation
- Can design flexibility with enforcement; maybe medication or ADR

OH

- Enforcement needs to be spelled out in the compact

CONs

IL

- States will be required to coordinate their state law with what the compact dictates
- There will be additional costs if an arbitration process is created
- This may also create third-party rights where none previously existed.

CA

- Can not depend on OIG-Civil Rights for enforcement, will need additional state enforcement
- Permissive standards may lack enforceability.

OH

- Failing to address enforcement in the compact fosters litigation and ambiguity
- Without a clearly defined enforcement provision, federal courts are confounded as to the appropriate remedies

OTHER CONSIDERATIONS:

IL

- One of the overarching issues to be resolved for an interstate compact is whether Congressional consent is required.
- An interstate compact concerning consent requirements for the release of PHI does not appear to affect federal interests. The interstate compact does not shift power between the states and federal government; in fact, the intent is to remain compliant with federal consent law, such as HIPAA. The interstate compact does not encroach on a power reserved to Congress; instead, it seeks to rationalize laws that individual states currently enforce. Certainly, the states are already empowered to pass laws concerning privacy protections for their citizens and persons within their jurisdiction. It appears likely that the contemplated interstate compact to standardize the application of state law to PHI requests would not require Congressional consent. In the event that Congressional consent is deemed appropriate, such consent has been implied after the fact and explicitly given after the fact. The drafting and legislation of the interstate compact could proceed, and consent could be sought, if needed, after a final version of the interstate compact has been adopted. Alternatively, Congressional consent could be obtained preemptively, such as by passing an Act, but seeking such an advance consent is likely outside the scope of this project.
- Congressional approval, or lack thereof, can be expected to be an issue in litigation challenging the exchange of PHI in a manner consistent with the interstate compact, but not with the requesting state's consent laws.

OH

- Must consider need for Congressional approval of compact and effect thereof – affects whether compact will be considered federal law, and aspects of jurisdiction and enforcement; should consider careful design of compact administration to be effective and efficient
- A question for discussion is how will the standardized system to secure patient consent under the compact be effected when exchanging PHI with non-compact states?

CONCLUSION:

IL

- HISPC – Illinois determined that the process for developing interstate compacts, described by the Council of State Governments, was a reasonable and appropriate process. Being able to work through a number of state legislatures will allow for the main relevant issues to surface during the drafting process. The outcome of enacting the compact will allow for the efficient exchange of needed personal health information, as states will have a process for making patients aware of exchanges of personal health information and obtaining patients' permission to share health information. The overarching concern with this mechanism remains the length of time required to trigger enactment as well as the burden on providers to adopt the new privacy standards. Enactment could be hindered if state legislatures are slow to adopt the compact. Illinois providers report a current consent process this is working for them, and are leery to take on the cost of implementing new standards that seem unneeded.

OH

- An interstate compact is, by its very nature, a contract among the states. Typically, the compacts are narrowly drawn to a specific purpose but often have far reaching implications. A compact on HIE will be no exception. The scope of such a compact could be unprecedented; however, the limits of its scope are not yet clear. While an interstate compact has both advantages and disadvantages, the most significant difference appears to be related to the forum in which the details of HIE would be addressed.