

PROCESS FOR DEVELOPING THE OPTION:

Discussion

IL: National Conference of Commissioners on Uniform State Laws (NCCUSL) has a process to develop legislation with a wide group of stakeholders, including state commissioners. The process entails a Study Committee, Drafting Committee, and approval by an Executive Committee and at least 20 state representatives at an annual meeting of the Commissioners. It is then submitted to the states. Approval of an act as a Uniform Act obligates Commissioners from each state to promote verbatim adoption by their respective legislatures. Even if state legislatures incorporate a Uniform or Model Act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently.

OH: Also described the NCCUSL process. Provided a description of the existing Study Committee on Health Care Information Interoperability that waiting for the results of the HISPC Collaborative prior to moving forward on interstate consent issues.

CA: Also described the NCCUSL process. Included information about a California State Commission on Uniform State Laws.

PROs

IL: NCCUSL is a respected organization with a sound process, which allows for in-depth examination as well as sufficient review by a significant number of states. Successful completion of the process is likely to lead to a national standard.

OH: Similar to IL.

CA: Similar to IL. Noted that NCCUSL would likely receive support by external groups like the National Governor Association, which will help create a sound process.

CONs

IL: States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. May be a lengthy process will no requirement that states ultimately adopt the drafted legislation.

OH: Similar to IL. Additionally noted that the large number of states required to participate may cause a lengthy drafting process.

CA: None noted

LENGTH OF TIME REQUIRED TO FORMULATE:

Uniform Law

Discussion

IL: Five to seven years. Noted the Study Committee on Health Care Information Interoperability at NCCUSL, suggesting that this may help speed up the process. Also provided a comparison chart of other Uniform Laws, length of time and number of adopting states.

OH: Several years.

CA: Gave detailed description of the Study Committee on Health Care Information Interoperability at NCCUSL. Also described the legislative process of the state of California in detail.

PROs

IL: Process provides enough time to examine issues, by multiple reviewers and stakeholders.

OH: Length of process makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Noted that Ohio is generally accepting of Uniform Laws.

CA: Identified the NCCUSL process as successful.

CONs

IL: Process is lengthy and has the potential for limited success. Involvement of multiple interest groups may slow down the process, particularly those with a high concern for patient privacy.

OH: Other approaches may be quicker.

CA: None listed.

IMPLEMENTATION REQUIREMENTS:

Discussion

IL: Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the Governor, or an override by the legislature if Governor would veto the bill. Illinois has enacted over 95 Uniform and Model Acts according to NCCUSL.

OH: Described the process for legislative passage in OH, as well as named the stakeholder groups that could participate. Suggests that a government agency be empowered and funded to appropriately implement the legislation.

Uniform Law

CA: Implementation will require the review of existing consent laws.

PROs

IL: If the Uniform Law is simple, the state will simply repeal the old language and replace it with the new act, limiting the amount of additional work.

OH: The network of stakeholders will support implementation.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

CONs

IL: If the Uniform Law is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time-consuming. There is no guarantee that courts in various jurisdictions will interpret a Uniform Law consistently, thereby reducing its effectiveness as a solution for inconsistent laws.

OH: Diverse stakeholder groups may make consensus difficult.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

LEGAL FRAMEWORK/RULES OF ENGAGEMENT:

Discussion

IL: In addition to describing IL law with respect to the release of PHI, the analysis looked at different approaches for how a Uniform Law may operate. These are: *Approach 1 – the laws of the “Responding State Prevails;”* *Approach 2 – the laws of the “Requesting State Prevails;”* and, *Approach 3 – Uniform Consent.* For this analysis, there are two scenarios: (1) Scenario 1, in which the responding state has more stringent consent requirements for the release of PHI than that of the requesting state; and, (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state.

OH: In all likelihood, the move to a Uniform Law will include the adoption of a uniform consent form.

CA: Did not include this section in their document.

PROs

IL

Uniform Law

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

OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

CONs

IL

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

Uniform Law

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

OH

- None listed, but discussion section had statements that could be interpreted as pros and cons.

IMPACT ON STAKEHOLDER COMMUNITIES:

Discussion

IL: Stakeholders involved significantly. Impact depends on the approach selected. Less stringent states will need to change their procedures. Stakeholders who advocate for privacy will want more stringent requirements, while those advocating free flowing information will advocate less stringent requirement.

OH: Described the wide variety of stakeholder groups that will need to be included.

CA: Similar to IL

Positive Impact

IL

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

OH: Need to identify stakeholder groups and get their input

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

Negative Impact

IL

- Length of time for adoption may result in longer period of uncertainty for healthcare providers
- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Providers need to adapt to the new requirements of the Uniform Law
- A Uniform Law that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A Uniform Law with a more stringent environment could inhibit the free flow of information

OH: It will take sufficient time to engage and satisfy the concerns of all the stakeholders groups. There is no guarantee of majority buy-in.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

FEASIBILITY:

Discussion

IL: Discussed feasibility in terms of “cost” and “political viability” and whether the option was “technically possible.” OH touched on costs in its analysis as well.

With respect to cost, \$100,000 is typical for a one-year study and two-year drafting process. Additional process expenses are covered by NCCUSL. There may be considerable costs for both the stakeholders and the public for implementation.

Regarding political viability, NCCUSL reports that need rather than complexity often dictates the successful adoption by states. Privacy advocates vs. free-flow advocates will also weigh in politically.

The Uniform Law is technically possible mainly if it is adopted by all states in uniform way, rather than with modifications.

OH: A Uniform Law is more likely to minimize diversity of content.

CA: Provided a discussion similar to IL. Noted that CA has a strong interest in patient privacy rights. CA has enacted Uniform Laws 50% of the time. Reported the same information as IL on “technically possible.”

Uniform Law

PROs

IL: The approach will work best if it is less expansive and does not cover certain special categories of protected health information.

- Costs – Approach 1 would be least costly
- Political Viability – A Uniform Law would be a state-driven solution with Approach 1 possibly more viable because of the minimum of disruption to health care providers
- Technically Possible – Creates a standard for all states to follow

OH: Provided the definition by NCCUSL of when to designate an act as uniform vs. model.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

CONs

IL

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

OH: Time, expense and no guarantee of success

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

DOES THE OPTION ADDRESS LIABILITY CONCERNS:

Discussion

IL: Liability is based upon the content adopted, the amount of uniformity between states, the concomitant changes to other state law, statutory construction and court interpretation.

OH: The option could address liability concerns.

CA: Similar to IL

PROs

IL: Additional guidance in the Uniform Law will be beneficial.

OH: None listed, but discussion section had statements that could be interpreted as pros and cons.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

CONs

IL

- Liability concerns in the paper vs. electronic transfer are different so the Uniform Law will have to address special concerns.
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.
- If the law is not adopted uniformly, this could cause more liability.

OH: None listed, but discussion section had statements that could be interpreted as pros and cons.

CA: None listed, but discussion section had statements that could be interpreted as pros and cons.

RAMIFICATIONS OF ACCEPTANCE/REJECTION:

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

CONFLICTS WITH STATE OR FEDERAL LAWS:

Uniform Law

Discussion

IL: Federal law sets a minimum standard with HIPAA requirements, as well as confidentiality protections to certain categories of persons. The rules of statutory construction would generally provide that the newly enacted Uniform Law would prevail.

OH: Notes that states may have more stringent requirements than HIPAA. If not uniformly adopted, conflicts with state laws may still occur.

CA: The study committee will research conflict with federal law. Individual states will research conflicts with their existing laws during the legislative approval process.

PROs

IL

- This mechanism provides for consistency and removes conflict among differing state laws. Potential conflict with federal law would be reviewed and resolved by the study committee.

OH

- HIPAA creates a minimum standard and the Uniform Law should consider the most stringent standard, in order to provide the greatest privacy protection.

CA: None listed.

CONs

IL

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

OH

- It may be difficult to obtain consensus across states.

CA: None listed.

PROCESS FOR WITHDRAWAL:

Discussion

The state analyses noted that withdrawal basically involves the repeal of the ratification statute.

PROs

Uniform Law

IL

- Provides states with control

OH

- Promotes passage

CA: None noted.

CONS

IL

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

OH

- Allows for the possibility that the system will fall apart at any time.

CA: None noted.

STATE RESPONSIBILITIES:

Discussion

The states highlighted the need to educate stakeholders regarding consent requirements.

PROs

IL

- Providers prefer a mandate.

OH

- Greater consistency and ease than a model act

CA: None noted

CONS

IL

- Cost will be a burden for providers and patients

Uniform Law

OH

- Offers less flexibility and more states might refuse to participate

CA: None noted

STATE'S RIGHTS:

Discussion

The states referenced the rights of a state to establish requirements as they see fit.

PROs

IL

- States still have the option to establish requirements that are more responsive to their needs

OH

- Could result in greater uniformity and ease of exchange

CA: None noted

CONs

IL

- If states do not adopt it uniformly, the current problems may continue

OH

- Offers less deference to individual states

CA: None noted

ENFORCEMENT:

Discussion

Enforcement issues fall within the purview of the adopting states. OH noted that the Uniform Law could adopt a uniform enforcement procedure.

PROs

IL

- Each state retains the ability to decide enforcement issues

OH

Uniform Law

- If enforcement is not specified, passage is easier so that states can retain their right to establish their enforcement mechanism

CA: None noted

CONS

IL

- If not adopted uniformly, it could create additional confusion over enforcement

OH

- Similar to IL

CA: None noted

OTHER CONSIDERATIONS:

IL: General Assembly is likely to try and improve upon the Uniform Law introduced

OH: None noted

CA: None noted

CONCLUSION:

HISPC - Illinois determined that the process for developing Uniform Law, described by the National Conference of Commissioners on Uniform Laws, was a reasonable and appropriate process. Adoption of the NCCUSL Uniform Law has the potential of creating uniformity with respect to how adopting states require health care entities to obtain a patient's consent to allow their PHI to be exchanged electronically. It may also resolve the question of whether or not patient consent is required to enter or share PHI in an electronic health exchange. The NCCUSL has representation from every state, and the process allows for the necessary issues to be raised and resolved. Yet the length of time required to develop and adopt a Uniform Law would mean a longer period of uncertainty for healthcare providers, and the end result may not be adoption by the majority of states. In addition, the potential for inconsistent application and interpretation of the Uniform Law by different states could result in inconsistent consent requirements. If not adopted, a Uniform Law may provide needed guidance through its example even if states enact it with some modifications. The approach might work best if it is less expansive, yet if the Uniform Law is only an overlay to the laws concerning paper, then providers will have to figure out if they need two processes in place to handle the difference between the electronic transfer vs. paper transfer. The drafters should also consider cost to providers for implementation when creating the legislation.

Uniform Law

OH: A Uniform Law approach has the benefit of providing a common, consistent legal structure among jurisdictions. This approach will lessen administrative burdens because all states would be working under the same set of rules and expectations. It would also offer the opportunity to have a nationally recognized and utilized consent form that would be common among all health care providers. Public education could be consistent and, thus, consumers' understanding of the impact of providing consent would be enhanced. That said, it would be challenging to establish a Uniform Law that meets with a broad enough consensus to get buy in from the states. Also, simply establishing a Uniform Law does not mean that all 50 states will adopt it. Unless all 50 states adopt it, we will be in a situation similar to where we are today – that is, having inconsistencies among states. As noted above, it is not uncommon for states to modify a Uniform Law – so even if a Uniform Law is promulgated by the NCCUSL, it is possible that state legislatures may pass a medical consent law in a manner that destroys the uniformity. Another potential problem with the Uniform Law is the time for creation and implementation. It can take years for the process to run its course, which leads to a conclusion that other options (e.g., federal legislation) may be more viable.

CA: None noted.