

PROCESS FOR DEVELOPING THE OPTION:

Discussion

IL: National Conference of Commissioners on Uniform State Laws (NCCUSL) has a process to develop legislation with a wide group of stakeholders, including state commissioners. The process entails a Study Committee, Drafting Committee, and approval by an Executive Committee and at least 20 state representatives at an annual meeting of the Commissioners. The Study Committee recommends whether to draft an act and whether to designate it as “Uniform” or “Model”.

Additionally, other associations and interest groups may draft Model Acts. These acts are then submitted to the state legislatures for approval. Unlike a Uniform Law, Model Acts are not expected to be adopted verbatim, but provide guidance on language for state approval. NCCUSL Commissioners are obligated to promote adoption to achieve necessary and desirable uniformity. Even if state legislatures incorporate a Uniform or Model Act verbatim into their respective state statutes, the state courts may interpret the identical statutes very differently. IL describes in this section a number of examples of Model Acts that have been passed.

OH: Also described the NCCUSL process, as well as examples of other groups that develop Model Acts. Provided a description of the existing Study Committee on Health Care Information Interoperability that waiting for the results of the HISPC Collaborative prior to moving forward on interstate consent issues.

CA: Also described the NCCUSL process as well as examples of other groups that develop Model Acts. Described the CA process for approving legislation.

PROs

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

OH: Similar to IL. Noted that the flexibility in adoption of the language may make it easy to pass the various state legislatures.

CA: None noted.

CONs

IL: States are not equally represented on the NCCUSL, given the range in the number of appointed commissioners. May be a lengthy process will no requirement that states ultimately adopt the drafted legislation in a consistent manner. The lack of emphasis on verbatim adoption of the Model Act may result in confusion.

Model Act

OH: Similar to IL.

CA: None noted

LENGTH OF TIME REQUIRED TO FORMULATE:

Discussion

IL: Five to seven years. Noted the Study Committee on Health Care Information Interoperability at NCCUSL, suggesting that this may help speed up the process. Gave an example of the Turning Point Collaborative, whose Model Act took 3 years to be released for approval by states.

OH: Several years.

CA: Years. Gave two examples.

PROs

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

OH: Length of process makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Described an expedited process, which would reduce the timeline for development to one year, after which it would be released to the states for approval.

CA: None listed.

CONs

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

OH: Other approaches may be quicker.

CA: None listed.

IMPLEMENTATION REQUIREMENTS:

Discussion

IL: Implementation of this mechanism requires the passage of the legislation by the Illinois General Assembly and the approval of the Governor, or an override by the

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legislature if Governor would veto the bill. Illinois has enacted over 95 Uniform and Model Acts according to NCCUSL.

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

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

PROs

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

OH: A model act would allow any Ohio nuances to be taken into account to the extent not accounted for in a uniform law.

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

CONs

IL: If the Model Act is complicated, a state will have extra work to amend old laws to bring them up to date. Providers and patients will need to be educated about the requirements, which will be both costly and time-consuming. There is no guarantee that courts in various jurisdictions will interpret a Model Act consistently, thereby reducing its effectiveness as a solution for inconsistent laws. Significant time may have been spent to create a good Model Act, yet it can be rejected or changed by the states' legislatures.

OH: The implementation of a model act may allow for state variation that defeats the stated objective of uniformity. Diverse stakeholder groups may make consensus difficult.

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

LEGAL FRAMEWORK/RULES OF ENGAGEMENT:

Discussion

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

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requirements for the release of PHI than that of the requesting state; and, (2) Scenario 2, in which the requesting state has more stringent consent requirements for the release of PHI than that of the responding state.

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

CA: Did not include this section in their document.

PROs

IL

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

OH

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

CONs

IL

- A1S2 – There is a lesser focus on privacy concerns which could be objectionable to privacy advocates
- A1S1 – May delay the release of PHI if the requesting state submits a consent that does not meet the higher standards of the responding state

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- A2S2 – Access to PHI in the requesting state will be delayed while healthcare providers bring data collected in the less restrictive environment of the responding state into conformance with the requesting state’s higher standards
- A2 – Healthcare providers in the responding state will be required to determine the requirements of the requesting state’s laws before they release the information, which could delay the release of data for HIE purposes.
- A2S1 – May raise objections from responding states that do not wish to release PHI under less demanding consent requirements
- A2 – No advance planning because it is impossible to predict which state will request the information. Therefore, the determination of whether the requirements of the law have been met must occur at the time of disclosure of the information
- A3 – Difficult to find consensus, drawing out the process and making buy-in more complicated. This also requires an additional layer of analysis for providers in all states that ratify the compact, rather than a subset of states in Approaches 1 or 2.
- If the compact-defined consent requirements are not implemented properly, the failure to provide adequate education would result in confusion by healthcare providers
- States with lenient consent requirements, compact-defined consent could be objectionable if the imposes new, more stringent requirements
- States with robust consent requirements may object to less stringent compact-defined requirements

OH

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

IMPACT ON STAKEHOLDER COMMUNITIES:

Discussion

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

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

CA: Similar to IL. Noted the involvement of stakeholders in the process leads to ample opportunities to provide education.

Positive Impact

IL

- Impose the same rules on member states resulting in great connectivity

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

OH: To the extent Ohio presents any nuances not accounted for in a uniform law, a model act will allow for more stakeholder input.

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

Negative Impact

IL

- Length of time for adoption may result in longer period of uncertainty for healthcare providers
- Input may delay the approval process since a diversity of voices will be heard at multiple points
- Providers need to adapt to the new requirements of the Model Act
- A Model Act that provides a less stringent environment for the exchange of information, may result in privacy advocates' concerns not being adequately addressed
- A Model Act with a more stringent environment could inhibit the free flow of information
- Special interest group promulgation of the Model Act may result in narrow issues being addressed that do not meet the needs of all stakeholders

OH: Again, a model act's allowance of this input may perpetuate state variances that a uniform law is better designed to address.

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

FEASIBILITY:

Discussion

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

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

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

The Model Act is technically possible mainly if it is adopted by all states with few modifications. Flexibility can be useful for implementation.

OH: In a model act, there is often variability in the final product which may result in some of the same road blocks to sharing of information that the states face now.

CA: Raised similar discussions questions that were addressed in the IL version, but did not answer those questions.

PROs

IL: The Model Act will provide needed guidance even if the states enact it with some variation. The approach will work best if it is less expansive and does not cover certain special categories of protected health information.

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

OH: None listed.

CA: None listed.

CONs

IL

- Costs
 - Educating providers on the uniform law will be costly
 - Providers will resist higher costs
 - State governments are experiencing financial problems
 - Approach 2 would be an expensive option for providers and HIO who want to be able to effectively exchange health data because they would have to understand other state laws
 - Approach 3 could be viewed as less costly than Approach 2 because it would entail learning one new system, although it would still be a costly burden on providers
- Political Viability

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- The potential that the act could be enacted with significant variation reduces its feasibility as a solution to varying consent laws.
 - There will be political difficulty in getting states with a history of more stringent consent requirements to adopt a compact viewed as loosening standards
 - Conversely, states with less stringent requirements may balk at a more stringent compact
- Technically Possible – Approach 3 will require healthcare providers in all states to adapt to the compact's requirements

OH: Provided the description by NCCUSL on the criteria for creating a Model Act vs. a Uniform Law.

CA: None listed.

DOES THE OPTION ADDRESS LIABILITY CONCERNS:

Discussion

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

OH: The option could address liability concerns.

CA: Similar to IL

PROs

IL: Additional guidance in the uniform law will be beneficial.

OH: None listed.

CA: None listed.

CONs

IL

- Liability concerns in the paper vs. electronic transfer are different so the uniform law will have to address special concerns.
- Adoption of new standards could increase the liability for some healthcare providers if the compact imposes a more restrictive level of consent - requiring providers to learn and implement new requirements could initially

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lead to increased liability for providers that do not understand them and implement them in an incorrect fashion.

- Unless the Model Act is adopted consistently in various states, the law would be unlikely to be able to address liability concerns when a state that has not adopted the Model Act is involved in HIE.

OH: None listed.

CA: None listed.

RAMIFICATIONS OF ACCEPTANCE/REJECTION:

IL and OH identified the benefit of acceptance as an elimination of barriers to HIE. Rejection will leave those barriers intact. OH noted that variation in how the Model Act is adopted may also result in additional confusion going forward. CA did not comment in this section.

CONFLICTS WITH STATE OR FEDERAL LAWS:

Discussion

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

OH: Notes that states may have more stringent requirements than HIPAA. If not uniformly adopted, conflicts with state laws may still occur. Listed the choice-of-law principles as a method to resolve conflict between states with inconsistent language in their Model Act.

CA: The drafter of the Model Act will research conflict with federal law. Individual states will research conflicts with their existing laws during the legislative approval process. If there is a direct conflict, then the federal preemption may be an issue.

PROs

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

OH: In order to prevent conflict, the model act should include a section that provides that the law of the responding state be applied. This permits the responding entity and/or state to consistently comply with the applicable laws of their state.

CA: None listed.

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CONs

IL: If the Model Act is not uniformly adopted across the states, it is uncertain as to whether or not it will conflict with state and federal laws. The more state laws are in conflict with the Model Act, the more likely the adoption process will not succeed.

OH: It may be difficult for the requesting state to obtain the information that they desire, if the responding state prohibits such release. Also, if a state that adopts the model act does not provide a choice of law directive, then in the event of a conflict between states the courts will have to intervene and conduct an analysis under the seven factors listed above. This can result in costly and time consuming litigation.

CA: None listed.

PROCESS FOR WITHDRAWAL:

Discussion

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

PROs

IL

- Provides states with control

OH

- Promotes passage

CA: None noted.

CONs

IL

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

OH

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

CA: None noted.

STATE RESPONSIBILITIES:

Discussion

IL highlighted the need to educate stakeholders regarding consent requirements. OH and CA noted the need by states to review whether or not the Model Act was significantly different from existing laws.

PROs

IL

- Provider prefers a mandate.

OH

- Flexibility to adopting the language may make it easier for states to adopt, in comparison with Uniform Law.

CA: None noted

CONs

IL

- Cost will be a burden for providers and patients. If the Model Act is only an overlay to the laws concerning paper, then providers will have to determine if they need two processes in place to handle the difference between EHR transfer vs. paper transfer.

OH

- Greater likelihood of inconsistency among states, given the potential for multiple variations.

CA: None noted

STATE'S RIGHTS:

Discussion

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

PROs

IL

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

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OH

- Similar to IL

CA: None noted

CONs

IL

- If states do not adopt it uniformly, the current problems may continue. It may only work well for those states whose acts are similar. This may detract from the overall impact of the Model Act.

OH

- Flexibility may inhibit ability to ensure free exchange, leaving the situation similar to the current state.

CA: None noted

ENFORCEMENT:

Discussion

All states noted that enforcement issues fall within the purview of the adopting states. The use of a Model Act could help standardize the individual state statutes.

PROs

IL: Each state retains the ability to decide enforcement issues. The formation of a quick, deliberative advisory body to enforce the law will circumvent time delays, as well as define parameters to avoid having tort litigation define the law.

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

CA: None noted

CONs

IL: If not drafted appropriately, the Model Act could create additional confusion over enforcement issues and lead to competing legal jurisdictions ruling on consent policies. A judicial remedy for enforcement might arise which would take a longer time period. Additionally, jurisdiction will determine which state's statute will be applied. The applicable state statute will likely change during the life cycle of the PHI.

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OH: Similar to IL

CA: None noted

OTHER CONSIDERATIONS:

IL: Noted a variety of groups working on health IT at the federal level, and suggest a need for the Model Act to take these activities into consideration during the drafting period.

OH: None noted

CA: None noted

CONCLUSION:

HISPC – Illinois determined that there are a number of difficulties with the Model Act mechanism. Significant work and time may have been spent to create a good Model Act, yet it can be rejected or changed by the states’ legislatures. While the process for drafting and adoption is credible, the lack of emphasis on verbatim adoption may result in confusing and conflicting state laws that hinder efficient interstate transfer of personal health information. Costs to draft, adopt, educate and implement will be considerable, yet the risk of a lack of uniform adoption is fairly high. The best outcome for this legal mechanism may be as an example for states that are looking for models on how to handle interstate transmission.

OH: While a model act may be a step in the right direction, it is not a solution to the existing problem – that is, inconsistency among the states regarding necessary consent for the use and disclosure of health information. If each state tweaks the model act to meet the needs of its constituents, we will be in the same place that we are today – with a “crazy quilt” of inconsistent state laws. The model act may lessen the differences among the states, but it will not bring the uniformity that is necessary to provide the consistency and certainty that is needed. Another potential problem with the model act is the time for creation and implementation. It can take years for the process to run its course, which leads to a conclusion that other options (e.g., federal legislation) may be more viable.

CA: None noted.