

CONSENT 2 – POLICY OPTIONS COLLABORATIVE MODEL ACT – OHIO ANALYSIS

INTRODUCTION

One focus of the Consent 2 – Policy Options Collaborative is to explore the viability of four options that states could enact to resolve barriers to the exchange, including electronic, of protected health information (PHI) among states that have conflicting state laws governing consent to use or disclose PHI. These barriers can be summarized as the civil or criminal liability that may accrue to health information exchange (HIE) organizations or healthcare providers for using or disclosing PHI in contravention of state consent laws.

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

A model state act is promulgated by the Uniform Law Commission (*ULC*). “An act may be designated as “model” if the principal purposes of the act can be substantially achieved even though it is not adopted in its entirety by every state.”¹

DEFINITIONS/ASSUMPTIONS

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

Definitions:

- Authentication – means the method or methods to verify the identity of a person or entity authorized to access PHI.
- Authorization – means the level of access an individual or entity has to PHI and includes a management component—an individual or individuals must be designated to authorize access and manage access once access is approved.
- Consent – means the patient’s signed approval for the use or disclosure of PHI, which may also be referred to as an “authorization” or “permission” under HIPAA or other state laws.
- Health - is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.²
- Health care - is the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions.³

¹ Frequently Asked Questions about NCCUSL, National Conference of Commissioners on Uniform State Laws, 2002, <http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=5&tabid=61>

² World Health Organization, www.who.int/about/definition/en/

³ Wikipedia definition, http://en.wikipedia.org/wiki/Health_care

- Health information exchange (HIE) – The electronic movement of health-related information among organizations according to nationally recognized standards.
- Requesting state – the state that is requesting medical information.
- Responding state – the state that has received the request for medical information and is responding.
- Protected health information (PHI) – is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

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

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

PROCESS FOR DEVELOPING THE OPTION

Discussion

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

Proposals for new acts are considered by the ULC Committee on Scope and Program, which accepts suggestions from the organized bar, state governments, private interest groups, uniform law commissioners and private individuals. It may assign a suggested topic to a study committee which studies the topic and reports back to the Committee. The Scope and Program Committee sends its

recommendations to the Executive Committee. A proposed act need not be designated as “uniform” or “model” until a draft is actually submitted to the Executive Committee for consideration at its annual meeting. With the ULC Executive Committee’s approval, a drafting committee is selected from the membership and a reporter/drafter – an expert in the field – is hired.

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

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

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

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

Although not with the detailed procedures of the ULC, the American Law Institute and the American Bar Association also promulgate model acts. For the ALI, each proposed act is assigned to a “Reporter.” who prepares the various drafts to be reviewed by ALI subcommittees and the ALI membership. Once a model act is approved, the Reporter prepares the ALI’s official version for publication. The ABA, through its various sections, divisions, forums and committees pursues the improvement of various laws, including the drafting of model acts, via similar procedures.

Pros

The procedures for adoption of model acts, like those for the adoption of uniform laws, involve a significant amount of participation by state representatives and make it more likely that the model act will be well received by the individual states when submitted for adoption. In addition, if a proposed uniform law becomes too controversial to be adopted as a uniform law, it may find better success as a model act.

Cons

The largest drawback to the model act approach is the greater likelihood that there will be significant variations from state to state - which although unlikely to be as diverse as the current situation, would not appear to be as useful as a uniform act in addressing the need for uniform standards for the electronic movement of health-related information among organizations.

LENGTH OF TIME REQUIRED TO FORMULATE

Discussion

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

Pros

The procedures for adoption of model acts, like those for the adoption of uniform laws, involve a significant amount of participation by state representative which make it more likely that the model act will be reasonably well received by the individual states when submitted for adoption.

Cons

As indicated by the report of the ULC's Study Committee, the process can take several years before the decision is made to begin the process to promulgate a model act. The actual process of promulgating a model act will take an additional two years at a minimum. The process of adoption by individual states will likely take several more. Other approaches may be quicker.

IMPLEMENTATION REQUIREMENTS

Discussion

In order to implement a model act in Ohio, we would need to identify General Assembly proponent(s), prepare and provide proponent testimony as necessary in both houses, obtain a majority in each house and obtain the Governor's signature (or override if vetoed). The implementation could use the existing connections between members of the Ohio HISPC and the Legal Working Group.

In working with the General Assembly, we could liaison with existing infrastructure for lobbying and analysis through medical and legal associations. For example, the General Assembly often turns to the Ohio State Bar Association, the Ohio State Medical Association, the Ohio Hospital Association and local medical and hospital societies for advice and counsel on healthcare legislation so support and understanding from these groups would be key. The OSBA Healthcare Law Committee would be a good forum to work within as that group includes many of our Legal Work Group members and is an existing vehicle for input to the OSBA, which in turn is highly regarded by the legislature for legal analysis.

In addition, our many LWG members from State agencies (ODH, ODJFS, BWC) and our members who sit on the Governor's Health Information Partnership Advisory Board (HIPAB), a component of the Governor Strickland's health information technology plan could serve as liaisons to develop support at the executive branch strategy.

After adoption, the model act would need likely need implementing regulations, which would be handled by a government agency. The government agency would need to be sufficiently empowered and funded to ensure that the model act is appropriately implemented.

Pros

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

Cons

The implementation of a model act may allow for state variation that defeats the stated objective of uniformity. Developing a consensus for issues when strong (sometimes emotional) ideas are held will

be challenging (e.g., use and disclosure of sensitive health information).

IMPACT ON STAKEHOLDER COMMUNITIES

Discussion

Stakeholder communities will include consumers, providers (physicians, hospitals, labs, pharmacies, long-term care, home health, etc), public health, payors, RHIOs, QIOs, and professional associations as well as particular types of professionals within healthcare who can provide needed expertise (CIOs, HIM and risk management to name a few). All of these communities will be impacted and a strategy to seek input from them would be helpful to ensure that any impacts, especially pertaining to patient care, are identified and addressed. The hearings that OHHIT held in conjunction with developing the statewide health IT plan would be a good forum to engage stakeholder communities but broad-based buy in will be necessary.

Positive Impact

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

Negative Impact

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

FEASIBILITY

Discussion A model act will not achieve the goals of a uniform law that will allow the sharing of information. In a model act, there is often variability in the final product which may result in some of the same road blocks to sharing of information that the states face now.

Arguments For Feasibility

Arguments Against Feasibility. The NCCUSL website specifically states that an act should be designated as uniform rather than model if:

- (A) there is a substantial reason to anticipate enactment in a large number of jurisdictions; and
- (B) "uniformity" of the provisions of the proposed enactment among the various jurisdictions is a principal objective.

Further, the NCCUSL indicates that an act shall be designated as a Uniform Law Commissioners' Model Act if:

- (A) "uniformity" may be a desirable objective, although not a principal objective;
- (B) the Act may promote uniformity and minimize diversity, even though a significant number of jurisdictions may not adopt the Act in its entirety; or
- (C) the purposes of the Act can be substantially achieved, even though it is not adopted in its entirety by every State.

DOES THE OPTION ADDRESS LIABILITY CONCERNS

Discussion Similar to the uniform law, the model act could address liability concerns. The model act content would need to address any concerns relating to existing consents, the need for new consents, etc. Thus as the model act is developed, liability concerns should be considered and addressed.

Pros

Cons

RAMIFICATIONS OF ACCEPTANCE/REJECTION

Discussion

The ramifications of acceptance and rejection will largely depend on how other states react to the model act and the number of changes that states make to a model act.

Acceptance

The benefit of adopting a model is that it would create common framework from which states could create a consent law. Having the common legal structure could streamline the information exchange process because states would not need to constantly be analyzing and monitoring other states' laws with respect to consents for the use and disclosure of health information. However, acceptance of a model act will have limited impact if there is a wide variation among the states in the language used to implement the consent law.

In addition, adoption of a model act would cause Ohio to have a specific and detailed approach to handling consents to the use and disclosure of health information. A model act is an opportunity to address issues that may be unclear in the law and (presumably) would allow health care providers to look to a single source to determine the type of consent that may be needed – whether it is a single consent for all health information or separate consents for different types of health information.

Rejection

The impact of rejection of a model act will leave the status quo, which is an inconsistent array of laws that is difficult to manage and interpret. Rejection of a model act may have a larger negative impact on Ohio if a model act is established and Ohio does not join other states in the passage of the model act. Inconsistencies and inefficiencies will arise for both requests made from other states for health information in Ohio and made by Ohioans for health information in other states. For example, it could lead to patients having to sign multiple consent forms. Inconsistent states' laws also increases the probability of misinterpretation or inconsistent interpretation of laws related to the disclosure of health information. These problems could lead to liability for health care providers who improperly disclose health information. Note, however, that even if a model act is adopted, these same issues will arise if there is not uniformity in how the model act is adopted.

CONFLICTS WITH STATE OR FEDERAL LAWS

Discussion

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permits providers, insurance companies and other health-care entities to exchange information necessary for "treatment, payment or operations of health care business" (TPO). Although HIPAA established strict guidelines for the use and disclosure of protected health information ("PHI") by covered entities, those protections must be read in conjunction with the privacy protections for an individual's health information set out in each state. In general, states have more *stringent laws* regarding certain types of records related to mental health, addiction, HIV and genetics.

Conflicts with Federal laws: Under the Supremacy Clause of the Constitution, no state law can take precedence over federally-imposed requirements. However in enacting HIPAA, Congress did not desire to supersede State laws that are not contrary to and impose more stringent standards with respect to privacy of individually identifiable health information. In other words, this preemption exception furthers the principle that the HIPAA Privacy Rule will defer to any state privacy law that is not contrary to the HIPAA Privacy Rule (meaning that a covered entity can comply with both the state

and federal rules), and provides individuals greater privacy protection. 45 CFR 160.202 and 45 CFR 160.203(b)

Conflicts with State laws: A model act is “a statute...proposed as a guideline legislation for the states to borrow from or adapt to suite their individual needs.” Black’s law Dictionary 1025 (8th ed. 2004) Since a model act permits each state to amend the Act, there is potential for conflict between state laws. In order to resolve the conflict between state laws, the choice-of-law principles may apply. Under the choice-of-law principles:

- (1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.
- (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include
 - (a) the needs of the interstate and international systems,
 - (b) the relevant policies of the forum,
 - (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
 - (d) the protection of justified expectations,
 - (e) the basic policies underlying the particular field of law,
 - (f) certainty, predictability and uniformity of result, and
 - (g) ease in the determination and application of the law to be applied.⁴

As stated under the section 1 of choice-of-law principles, the statute itself may direct the choice of law. Therefore the model act of each state should provide a provision that directs the process and consent to release of patient information across state lines. The directive should indicate that the requesting state is subject to the laws of the responding state.

Conflict with Existing State Laws: The model act would need to contain a provision that it supersedes existing state law that conflicts with the model act. Alternatively, steps would need to be taken to harmonize existing state law that may conflict with the model act.

Pros

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.

Cons

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.

LEGAL FRAMEWORK/RULES OF ENGAGEMENT

Discussion

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

⁴ Restatement (Second) of Conflict of Laws § 6 (1971)

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

PROCESS FOR WITHDRAWAL

Discussion

Withdrawal from a model act is accomplished by the legislature passing the law and the governor approving the repeal of the law.

Pros

Promotes the ability to get the law passed initially, as states are not definitely locked in, they can later change their minds. There is some limitation on withdrawal in that the executive branch in the state may veto legislative attempts at later change. Might be more attractive for quick acceptance if states could modify the terms of the act (which, of course, would have the problem of destroying uniformity).

Cons

Allows for the possibility that the whole system can fall apart at any time. Consistency is dependent on 50 state legislators and governors. Withdrawal could destroy commonality.

STATE RESPONSIBILITIES

Discussion

State government would have to enact model act legislation, either "as is" or with changes. To the extent any model act was consistent with current status of consent law in a state, there should not be significant obstacles to adoption "as is." If a model act were significantly different from current state law, passage with changes would be more likely.

Pros

Potentially easier acceptance by states of model act over a uniform law, due to ability to make changes, or to adopt part but not all of model act.

Cons

Greater likelihood of inconsistency among states due to potential multiple variations of **model act** being adopted.

STATE'S RIGHTS

Discussion

State government has greater control over text of model act to be adopted.

Pros

Offers greater deference to individual states & state sovereignty, due to ability to make changes, or to adopt part but not all of model act.

Cons

Less likely to reach objective of facilitating exchange of information across states; end result could be similar to current situation (status quo).

ENFORCEMENT

Discussion

Under a model act, the enforcement mechanism could defer these decisions to the states or it could specify a uniform enforcement mechanism, determining which state's law would apply and providing remedies.

Pros

If there is no enforcement mechanism specified, then it would probably make passage by the states easier and faster since states won't be locked into a mechanism they may not like.

Cons

If there is no enforcement mechanism specified, then there may be widely varying enforcement mechanisms from state to state. Unless there is some resolution on which state's law applies with regard to enforcement (i.e., the receiving or the responding state's laws) then there may be forum shopping, conflicting state decisions and varying remedies.

OTHER CONSIDERATIONS

CONCLUSION

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 federal legislation is the best approach.

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