

CONSENT 2 – POLICY OPTIONS COLLABORATIVE

UNIFORM LAW – 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 “uniform law” could eliminate these barriers. A uniform law would offer states the option to enact the same law governing consent issues, which would supersede any conflicting laws between adopting states.

“A uniform state law is a statute that has been promulgated by the Uniform Law Commission (*ULC*). Although other organizations may adopt the term ‘uniform’ when describing their own acts, generally, when the term ‘uniform’ is used, it is highly likely that it is a law that has been drafted and approved by the ULC. A uniform act is one in which uniformity of the provisions of the act among the various jurisdictions is a principal and compelling objective.”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 applicable federal or 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/

- 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, uniform laws are understood to be the proposals promulgated by the National Conference of Commissioners on Uniform State Laws (NCCUSL) – also referred to in its own materials as the Uniform Law Commission, or ULC. The ULC is a non-profit unincorporated association, comprised of state commissions on uniform laws from each state, the District of Columbia, the Commonwealth of Puerto Rico and the U.S. Virgin Islands. Ohio has seven commissioners on the ULC.

According to the ULC, a uniform act is one in which uniformity of the provisions of the act among the various jurisdictions is a principal and compelling objective. Alternatively, 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.

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

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. 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 and a reporter/drafter – an expert in the field – is hired. Advisors and participating observers are solicited to assist every drafting committee.

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.”

Pros

The process for the adoption of a uniform law, by including the opportunity for comment and feedback by representatives from all 50 states and the favorable vote by at least a majority of the states present (and not less than 20 states), makes it more likely that an act will receive favorable treatment when finally presented to each state legislature.

Cons

By requiring so much participation by the representatives of each state, the act of promulgating a uniform law can be sidelined by opposition by several states and can be delayed if the act needs to be redrafted to meet various objections. In addition, because the uniform law is intended to be adopted without changes, it may meet more resistance to adoption by states than the more flexible model law.

LENGTH OF TIME REQUIRED TO FORMULATE

Discussion

As noted by the ULC, each draft of a uniform act receives a minimum of two years consideration, sometimes much longer. Once a uniform act is past by the ULC, the individual commissioners are expected to take the act back to their home states and encourage the adoption of the act, a process that can take an additional several years.

Pros

The process for the adoption of a uniform law, by including the opportunity for comment and feedback by representatives from all 50 states and the favorable vote by at least a majority of the states present (and not less than 20 states), makes it more likely that an act will receive favorable treatment when finally presented to each state legislature. Ohio has been generally accepting of uniform laws, one of the more recent examples being the adoption of the Uniform Electronic Transactions Act.

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 uniform law 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 uniform law 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 uniform law is appropriately implemented.

Pros

This avenue takes advantage of existing networks for rapid deployment. All of the above committees

and group members are highly regarding by policy makers.

Cons

A strategy to involve consumers must be developed to supplement the strong provider base that has developed. Again, using existing consumer advocacy groups and individuals from the HIPAB, the HISPC, and state agency ombudspersons would be an effective way to network with this important group. 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

Engaging all of the stakeholder communities and understanding and cataloging their input would help expedite consensus.

Negative Impact

Since a broad cross-section of the state would be represented in these stakeholder communities, it will take significant time and effort to address the many different perspectives raised. There is no guarantee that all stakeholders will be satisfied with a uniform approach.

FEASIBILITY

Discussion A uniform law is more likely to minimize diversity of content and therefore the goal of sharing of information should be promoted by a uniform law rather than a model act. There is typically a one year study process and 2 year drafting process with no guarantee that the uniform law will be adopted by all the states legislature. This could be an expensive and ultimately unsatisfying approach.

Arguments For 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 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.

Arguments Against Feasibility Time, expense and no guarantee that the process will work.

DOES THE OPTION ADDRESS LIABILITY CONCERNS

Discussion If the uniform law is adopted in every state, the option could address liability concerns. The uniform law content would need to address any concerns relating to existing consents, the need for new consents, etc. Thus as the uniform law is developed, liability concerns should be considered and addressed.

RAMIFICATIONS OF ACCEPTANCE/REJECTION

Discussion

The ramifications of acceptance and rejection will largely depend on how other states react to the uniform law.

Acceptance

The obvious benefit of adopting a uniform law is that Ohio would have a common legal structure with other states that adopt the uniform law. Having the common legal structure will 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. In addition, adoption of a uniform law would cause Ohio to have a specific and detailed approach to handling consents to the use and disclosure of health information. A uniform law 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.

It should be noted, however, that although the intent is for uniform laws to be adopted without change, in reality the states that adopt a “uniform law” may make modifications.

Rejection

The impact of rejection of a uniform law will leave the status quo, which is an inconsistent array of laws that is difficult to manage and interpret. Rejection of a uniform law will have a larger negative impact on Ohio if a uniform law is established and Ohio does not join other states in the passage of the uniform law. 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.

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: Since a uniform law is an "unofficial law proposed as legislation for all the states to adopt as exactly as written" Black's law Dictionary 1566 (8th ed. 2004), therefore if fully adopted by all states there would be no conflict between states. In reality, however, unless all jurisdictions adopt the uniform law, there will be conflicting laws among the states, which will lead to the problems discussed above in Ramifications of Acceptance/Rejection. The uniform law would need to contain a provision that it supersedes existing state law that conflicts with the uniform law. Alternatively, steps would need to be taken to harmonize existing state law that may conflict with the uniform law.

Pros

The uniform law may impose more stringent laws than the current Federal Standards, as long as they are not contrary to the current HIPAA laws. Therefore, the uniform law must be no less stringent than HIPAA. The question is whether the uniform law should adopt provisions that include the most stringent state laws, in order to provide greatest level of privacy to patients.

Cons

It may be difficult to obtain a consensus across states.

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 uniform law. 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 uniform law is possible. Forseeable barriers to administering and enforcing the uniform law will be operational in nature. In all likelihood, the move to a uniform law 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 uniform law should address how to handle exchange of information with states that have not adopted the uniform law. This issue will almost undoubtedly arise, so states should be prepared how address it.

PROCESS FOR WITHDRAWAL

Discussion

Withdrawal from a uniform law 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.

Cons

Allows for the possibility that the whole uniform system can fall apart at any time. Uniformity is dependent on 50 state legislators and governors.

STATE RESPONSIBILITIES

Discussion

State government would have to enact the uniform law without change. To the extent any uniform law was consistent with current status of consent law in a state, there should not be significant obstacles to adoption. If the uniform law were significantly different from current state law, passage might be more difficult.

Pros

A uniform law would potentially offer greater consistency among states and greater ease of information transfer across states than a model act.

Cons

A uniform law offers much less flexibility; greater likelihood states would refuse to enact uniform law than a model act.

STATE'S RIGHTS

Discussion

State government has little to no control over text of a uniform law to be adopted; "take it or leave it" is only option to exercise state sovereignty.

Pros

A uniform law would potentially offer greater consistency among states and greater ease of information transfer across states than a model act.

Cons

A uniform law offers less deference to individual states and state sovereignty.

ENFORCEMENT

Discussion

Under a uniform law, 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

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 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 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.

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