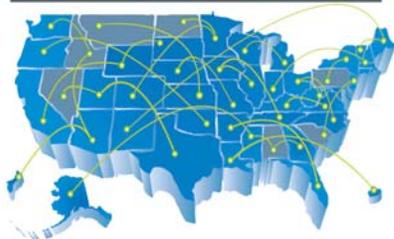


INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

Appendix L: Interstate Guidebook

Health Information Security & Privacy

COLLABORATION



Purpose

This guidebook provides directions for states interested in researching state-driven legal mechanisms to resolve barriers to the interstate electronic exchange of health information and have conflicting laws and requirements governing patient consent.¹ This guidebook will also assist states in determining how each mechanism may (1) serve as a model for addressing a major barrier to the electronic exchange of protected health information (PHI), or (2) clarify which states' laws take precedence when PHI disclosures are requested between states with conflicting laws.

Background

The Intrastate and Interstate Consent Policy Options Collaborative (the Collaborative) explored the viability of four legal mechanisms that states could use to resolve barriers to interstate electronic health information exchange. The four specific legal mechanisms reviewed included:

Uniform state law—A uniform state law is a legislative proposal approved by the National Conference of Commissioners of Uniform State Law (NCCUSL). The uniform law is proposed to state legislatures by NCCUSL for their adoption, usually in its entirety, to uniformly govern a matter of interest among adopting states. A uniform law would offer states the option to enact the same law governing consent, which would supersede any conflicting laws between adopting states.

Model Act—A model act is a legislative initiative proposed by the NCCUSL or an advocacy or trade group for adoption by state legislatures on a matter of interest to all states. The difference between a model act and a uniform law is that a model act may or may not be adopted in its entirety. States frequently modify a model act to meet their own needs, or they may adopt only a portion of the model act.

Choice of law—A choice of law provision is a provision that states could adopt to specify which state's law governs consent when PHI is requested to be exchanged between states with conflicting laws.

Interstate compact—An interstate compact is a voluntary agreement between two or more states which is designed to meet common problems of the parties concerned. Compacts that usurp federal power receive consent of the U.S. Congress as specified in Article I, Section 10 of the Constitution.

¹ As used in this guide, "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.

Compacts usually address issues such as conservation, boundary problems, education, port control, flood control, water rights, and penal matters. An interstate compact addressing consent to the interstate exchange of PHI would supersede conflicting laws between states that join the compact.

The Collaborative researched each of these approaches to assess their relative abilities to streamline electronic health information exchange among the states. Through the use of this guidebook, states are provided with a systematic process for choosing a mechanism that may best align their consent requirements with those of other states that have conflicting privacy laws.

Template Development

To assist states in conducting their research, the Collaborative developed Interstate Analysis Templates (Appendix L-1). These templates provide a foundation for completing a comprehensive and consistent method of evaluation. The Collaborative developed a series of review criteria that require an analysis of state law combined with identification of the pros and cons for pursuing a specific legal mechanism.

Several questions may arise regarding how to complete the templates, and this guidebook will provide a suggested approach, with interpretive guidance of the evaluation terms used for each reviewing state's consideration.

As mentioned previously, for the purpose of consistency each evaluation template uses the same review criteria. A specific definition of each criteria label has not been developed, primarily to allow each state interpretive license without external influence. There is value in diverse interpretation, and our intent was not to impose excessive structure through the definitions. However, recognizing that there may be a need for some guidance, the following interpretations represent common points of consideration of each review criteria when conducting the analysis and review.

1. *Process for Developing the Option*

For each of the four proposed mechanisms, identify the implementation processes your state must complete. The processes may help identify the pros and cons of using a proposed mechanism and may well vary according to each state's law(s).

2. *Length of Time Required to Formulate*

Given that each state's legislative process is governed by different laws, rules, and procedures, what is the typical timeframe for obtaining legislative or other governance approval to implement each proposed mechanism?

3. *Implementation Requirements*

Identify the balance between pros and cons for the steps required to implement each proposed mechanism. Completing this section will require a thorough understanding of

the existing legislative and political or legal policy infrastructures in each state, as well as the resources that would be necessary to implement each proposed mechanism.

4. *Impact on Stakeholder Communities*

This section recognizes that the pros and cons for each proposed mechanism will affect various stakeholder communities in different ways. The intent is to identify affected stakeholders and the impact that adopting each proposed mechanism will have on those stakeholders.

5. *Feasibility*

Based on the legislative timetables, agenda, processes, costs, political realities, and public interest for enacting legislation to implement the mechanisms, identify the likelihood that each proposed mechanism could be implemented successfully and within a timely manner.

6. *Does the Option Address Liability Concerns*

Liability issues appear to be one of the biggest obstacles to agreeing upon any standard approach to consent. Identify how issues of liability for inappropriate release of health information have been resolved within your state. Identify the relative merits of each mechanism in resolving these liability concerns.

7. *Ramifications of Acceptance/Rejection*

Based upon the anticipated impact within your state of acceptance or rejection of each proposed mechanism, identify the pros and cons of accepting and of rejecting each proposed mechanism.

8. *Conflicts With State or Federal Laws*

Initial review should focus on conflicts between each proposed mechanism and existing state law, followed by an evaluation of potential conflicts between each proposed mechanism and federal law. On numerous occasions, there is wide license applied when interpreting federal law, and we hope to once again recognize differences in opinion or interpretation.

9. *Legal Framework/Rules of Engagement*

Consider how the mechanism is structured to work in order to analyze its various ramifications. For example, a mechanism may be simply drafted to provide that the requesting state or responding state's law applies to resolve conflicts. A more complex approach would be for the development of a new consent framework that would govern interstate exchange of PHI. Based on your state's laws and regulations, describe the applicable infrastructure for the proposed mechanism and the rules for state participation.

- Are there any specific enablers or quirks in your state's legal or regulatory scheme that might affect the development and implementation of the mechanism?
- Assuming that a particular mechanism is enacted by your state, evaluate any foreseeable barriers to administering and enforcing each proposed mechanism.

10. Process for Withdrawal

Assuming that the proposed mechanism is implemented, what is the corresponding process for withdrawal/repeal of the mechanism should it be deemed necessary?

11. State Responsibilities

What would state government or policymakers have to do to promote adoption and enforcement of each mechanism? How likely is this to occur?

12. State's Rights

This is a discussion of rights and responsibilities within each proposed mechanism and includes state sovereignty as well as state legislative control over the text of the legislation.

13. Enforcement

How difficult will it be to enforce each proposed mechanism, if enacted, and which state agency or organization will assume enforcement responsibilities? How are the state's laws regarding inappropriate release of information or failure to obtain appropriate consent to release information currently enforced, and how, if at all, would the implementation of each proposed mechanism modify enforcement authority?

14. Other Considerations

This is a catchall category to express ideas or concerns that were not addressed in the previous discussion points.

15. Conclusions

Summarize the key findings in the analysis. It should convey the essence of the analysis for the readers.

Recommended Approach

Based upon the experience of the Intrastate and Interstate Consent Policy Options Collaborative, the following approach is recommended to accomplish the review of legal mechanisms. **Exhibit A** presents a general overview of this approach.

1. While your state may have a steering or governing committee, it's equally important to establish a legal review work group to conduct the research and analysis. This work group should be comprised of members representing as many stakeholders of the health care delivery system as possible, including both the public and private sectors. While attorneys represent a key component of this work group, you should also include non-attorneys for stakeholder group representation. In addition, the work group should include a project coordinator to assign and track progress.
2. Reach a consensus on the legal mechanisms the state will review. The Intrastate and Interstate Consent Policy Options Collaborative identified four legal mechanisms; however, your state may identify additional legal mechanisms to evaluate. The nature of the templates is such that the number of alternatives is irrelevant as long as the review criteria used for the evaluation remains consistent.

3. Develop a research agenda in consultation with the steering or governing committee and the legal review work group. Research is essential to an effective evaluation process.

Tip

Search out those persons with firsthand knowledge of the research subject. For example, each state has commissioners who belong to the Uniform Law Commission. An interview with one of these commissioners can provide valuable information for the Uniform Law or Model Act mechanisms.

4. Review the “definitions” and “assumptions” sections to agree on a consistent approach to the analyses.
5. Come to an agreement on the expectations involving the review criteria.
6. The legal review work group, in consultation with a steering committee when appropriate, should determine how the analysis process should be undertaken.
 - Should the review be assigned to a sub-group focused on each mechanism? If so, it is recommended that at least one representative from each stakeholder community participate in the evaluation of each mechanism. To ensure an unbiased review, it is recommended that no single representative participate in more than two review groups.

Tip

Allow the initial reviews to be conducted by a sub-group of the entire legal work group. This will allow the analysis of multiple mechanisms to be conducted in parallel, creating a more efficient evaluation process.

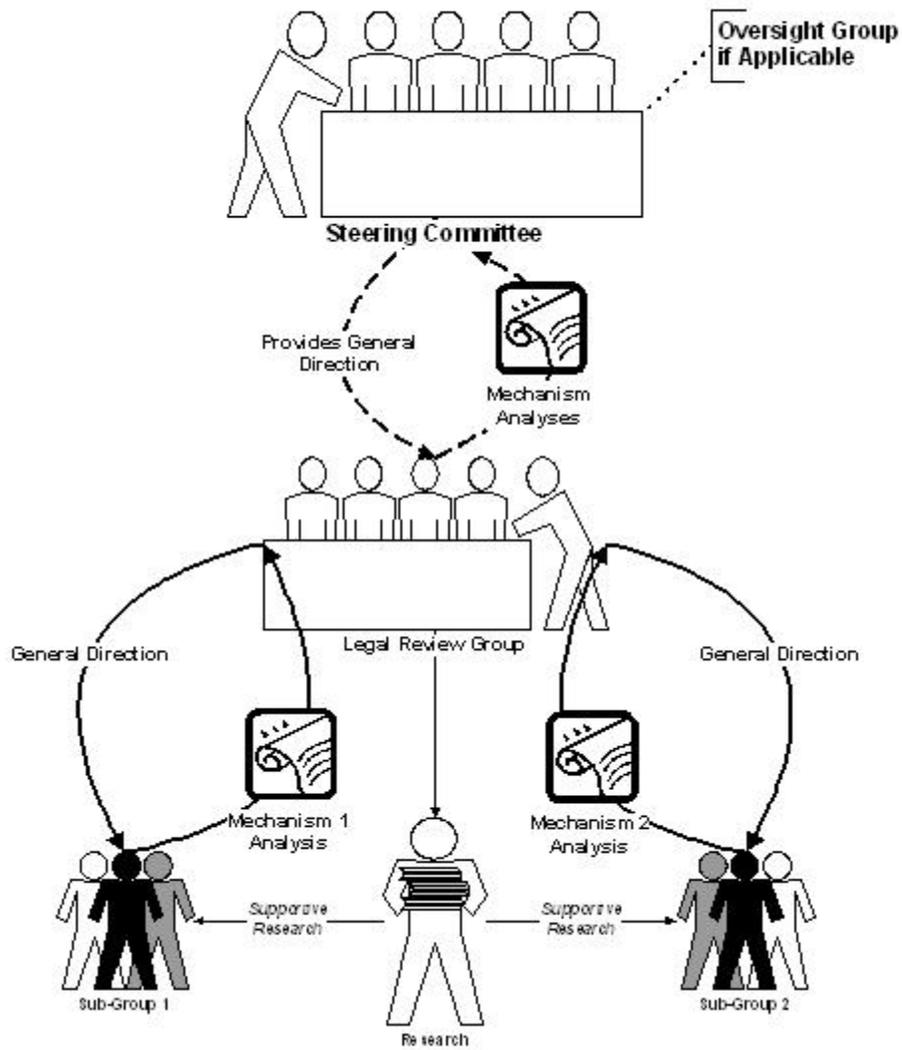
7. Each legal mechanism should be analyzed against the review criteria such that the pros and cons of the mechanism as well as the implementation considerations are identified and well documented for the comparative summary analysis.
8. If developed by a sub-group, submit the reviews to the entire work group for input, questions, comment, as well as guidance in the preparation of the conclusion of each of the selected mechanisms.

Tip

Prior to submitting draft populated templates to the entire legal working group for review, reconvene the subgroup representatives to fully vet the populated templates and make any necessary revisions.

9. Compile all the comments collected from the analysis of each mechanism onto a single template to eliminate redundancies and leave a unique set of considerations for each legal mechanism.
10. The reviews should then be presented to the steering committee or other oversight group for approval, if applicable.

Exhibit A. Overview of Interstate Analysis Approach



Success

By following these steps, each state conducting the analysis will:

- Develop a clear understanding of the legal options and how they affect the state.
- Generate consensus on the best solution based on the analysis being conducted by a broad stakeholder base.
- Understand the legislative challenges associated with implementing the legal mechanisms.
- Create collaboration with neighboring states interested in similar exchange principles.
- Establish a replicable process that can be used to conduct similar analysis of the requirements for intrastate exchange between state agencies and private exchange initiatives.

Appendix L-1: Interstate Analysis Templates

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COLLABORATION



INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

UNIFORM LAW ANALYSIS [ENTER STATE NAME]

Introduction

One focus of the Intrastate and Interstate Consent 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 health care 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.”²

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.

² 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>

- 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.³
- 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.⁴
- 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 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 of 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.)

³ World Health Organization, <http://www.who.int/about/definition/en/index.html>

⁴ Wikipedia definition, http://en.wikipedia.org/wiki/Health_care

Process for Developing the Option

Discussion

Pros

Cons

Length of Time Required to Formulate

Discussion

Pros

Cons

Implementation Requirements

Discussion

Pros

Cons

Impact on Stakeholder Communities

Discussion

Positive Impact

Negative Impact

Feasibility

Discussion

Arguments for Feasibility

Arguments Against Feasibility

Does the Option Address Liability Concerns

Discussion

Pros

Cons

Ramifications of Acceptance/Rejection

Discussion

Acceptance

Rejection

Conflicts With State or Federal Laws

Discussion

Pros

Cons

Legal Framework/Rules of Engagement

Discussion

Pros

Cons

Process for Withdrawal

Discussion

Pros

Cons

State Responsibilities

Discussion

Pros

Cons

State's Rights

Discussion

Pros

Cons

Enforcement

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Pros

Cons

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INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

MODEL ACT ANALYSIS [ENTER STATE NAME]

Introduction

One focus of the Intrastate and Interstate Consent 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 health care 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.”⁵

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.

⁵ 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>

- 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.⁶
- 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.⁷
- 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 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 of 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.)

⁶ World Health Organization, <http://www.who.int/about/definition/en/index.html>

⁷ Wikipedia definition, http://en.wikipedia.org/wiki/Health_care

Process for Developing the Option

Discussion

Pros

Cons

Length of Time Required to Formulate

Discussion

Pros

Cons

Implementation Requirements

Discussion

Pros

Cons

Impact on Stakeholder Communities

Discussion

Positive Impact

Negative Impact

Feasibility

Discussion

Arguments for Feasibility

Arguments Against Feasibility

Does the Option Address Liability Concerns

Discussion

Pros

Cons

Ramifications of Acceptance/Rejection

Discussion

Acceptance

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Conflicts With State or Federal Laws

Discussion

Pros

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Legal Framework/Rules of Engagement

Discussion

Pros

Cons

Process for Withdrawal

Discussion

Pros

Cons

State Responsibilities

Discussion

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INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

CHOICE OF LAW ANALYSIS [ENTER STATE NAME]

Introduction

One focus of the Intrastate and Interstate Consent 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 health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether a “choice of law provision” could eliminate these barriers. A choice of law provision is a provision that states could adopt to specify which state law governs consent when PHI is requested to be exchanged between states with conflicting laws on whether and what consent is needed for such exchange.

A **choice of law provision** may be a **clause** in a contract which specifies which law (i.e., the law of which state) will be applied to resolve any disputes arising under the contract. It may also be a statute or codified preference for which state’s laws apply to a given circumstance (usually, it is the enacting state’s laws). It may also be a codified general preference for the application of a particular state’s laws.

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.⁸
- 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.⁹
- 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 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 of PHI.
- The **responding state** and the **requesting state** will have an agreement that addresses:
 - The exchange of data regarding persons authorized to access PHI
 - The authentication of users
- The **responding state** has more stringent consent requirements 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.)

⁸ World Health Organization, <http://www.who.int/about/definition/en/index.html>

⁹ Wikipedia definition, http://en.wikipedia.org/wiki/Health_care

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Arguments Against Feasibility

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INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

INTERSTATE COMPACT ANALYSIS [ENTER STATE NAME]

Introduction

One focus of the Intrastate and Interstate Consent 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 health care providers for using or disclosing PHI in contravention of state consent laws.

This analysis addresses whether an “interstate compact” could eliminate these barriers. An interstate compact may accomplish this goal by establishing a framework for resolving conflicts, which member states agree to adopt.

The Council of State Governments defines an interstate compact as “a contract between two or more states. It carries the force of statutory law and allows states to perform a certain action, observe a certain standard or cooperate in a critical policy area. Generally speaking, interstate compacts:

- establish a formal, legal relationship among states to address common problems or promote a common agenda;
- create independent, multistate governmental authorities (such as commissions) that can address issues more effectively than a state agency acting independently, or when no state has the authority to act unilaterally; and
- establish uniform guidelines, standards or procedures for agencies in the compact’s member states.”¹⁰

Definitions/Assumptions

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

¹⁰ Fact Sheet, Council of State Governments, National Center for Interstate Compacts at <http://www.csg.org/> (keyword: interstate compacts).

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.¹¹
- 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.¹²
- 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.
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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 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 of 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

¹¹ World Health Organization, <http://www.who.int/about/definition/en/index.html>

¹² Wikipedia definition, http://en.wikipedia.org/wiki/Health_care

- The **responding state** has more stringent consent requirements 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.)

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