

March 31, 2009

Health Information Security and Privacy Collaboration

Final Report of the Interstate Disclosure and Patient Consent Requirements Collaborative

Prepared for

RTI International

230 W Monroe, Suite 2100
Chicago, IL 60606

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Office of Policy and Research

Office of the National Coordinator for Health IT

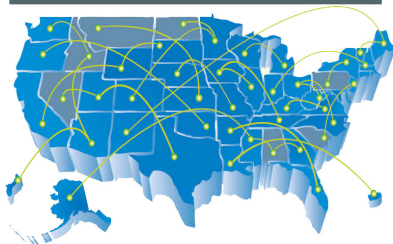
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Health Information Security & Privacy

COLLABORATION



Contract Number HHSP 233-200804100EC
RTI Project Number 0211557.000.007.100

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ACKNOWLEDGMENTS

Special thanks to project sponsors from the Office of the National Coordinator for Health Information Technology and RTI International.

Victoria M. Prescott and Diane Stone served as co-chairs of this Interstate Disclosure and Patient Consent Requirements Collaborative.

This final report was prepared by the Interstate Disclosure and Patient Consent Requirements Collaborative members listed below, who are listed with the state they represented in the project (in state alphabetical order):

Dan Dobbs (Indiana)	Robn Green (Oklahoma)
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Dev Culver (Maine)	Laura Ripp (Rhode Island)
Jonathan Harvell (Maine)	Amy Zimmerman (Rhode Island)
Diane Stone (Massachusetts)	Francesca Lanier (Utah)
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Teams within each of the 11 participating states also provided data on state laws needed during the information collection phase of the project, from which much of the analysis in this final report was based.

The Interstate Disclosure and Patient Consent Requirements Collaborative would also like to thank Alison Banger from RTI International for her contributions to the project's management and strategic direction.

The technical assistance received from Joy Pritts added valuable insights for the work conducted by the Interstate Disclosure and Patient Consent Requirements Collaborative, as well. Walter Suarez also provided feedback and support.

EXECUTIVE SUMMARY

This final report is a summary of the activities conducted by the Interstate Disclosure and Patient Consent Requirements Collaborative (the Collaborative) as part of the Health Information Security and Privacy Collaboration (HISPC). The Collaborative is an 11-state work group focused on assembling and analyzing detailed requirements stipulated in state laws, statutes, regulations, and rules pertaining to consent for the disclosure of protected health information (PHI) across a range of specific interstate health information exchange (HIE) scenarios. After extensive examination of 11 states' PHI disclosure laws, the Collaborative has clearly demonstrated the intricacies and complexities in state legal environments. This in turn contributes to the challenge of undertaking nationwide HIE on the scale envisioned to support transformational health reform. In this report, the Collaborative offers a range of options for moving forward that have implications for key HIE stakeholders, including health policy and lawmakers, health care organizations and clinicians, statewide and regional health information organizations (HIOs), and health information technology (health IT) vendors and service providers.

This final report summarizes the Collaborative's work, which includes using a uniform set of templates and sound analytic methods to conduct an 11-state information collection effort, a review of findings, and presentation of a range of potential options for serious consideration. The work of this project contributes to a growing body of knowledge intended to inform and accelerate development of effective and responsible solutions to enable interoperable HIE on a nationwide scale that supports the ultimate goal of improving the quality, safety, and efficiency of health care in the United States.

The final report is organized as follows:

- Section 1, [Purpose and Scope of the Final Report](#), describes the context of overall project goals, a statement of the problem and background on relevant issues such as state health information privacy laws, and report limitations. Using state law as the common basis for analysis helped provide clarity on variability in legal requirements among states; however, it was outside this project's scope to determine the extent to which organizational policies dictate more restrictive disclosure practices than required by law.
- Section 2, [Project Methodology](#), describes the Collaborative's four phases of work, core processes, methods, challenges, and lessons learned. A thorough, consensus-driven approach resulted in a meaningful representation of the insights and value that can be derived from collaborative work on interstate HIE issues. The logic model for information collection gives the reader a sense of the potential complexity of the decision paths for each of the basic interstate HIE scenarios studied by all 11 states.

- Section 3 describes notable [Findings](#) from qualitative and quantitative analyses. Summary statistics produced from the extensive quantitative analysis of PHI type/PHI source scenarios are represented by several select graphs to show the relative rates of PHI disclosure for very specific exchanges. Of particular interest is the spectrum of participating states presented on a consent continuum, i.e., a linear representation depicting each state according to the relative ease or difficulty that prevailing laws impose when exchanging data with other states. While some trends were identified, there are generally more differences than similarities across state laws. This section characterizes the true consent landscape as it relates to disclosure of PHI for treatment purposes. The facts challenge us as a nation to work harder to develop effective ways to promote health information exchange across state lines. After careful review of the data, all participants agreed that a range of strategies would likely be needed to reduce the variations in state laws.
- Section 4, [Implications of Findings and Options for Progress](#), reflects the Collaborative's recognition that the issues surrounding PHI disclosure are borne from a "consent culture" that can vary significantly from state to state. The current HIE environment is characterized by differences in state PHI disclosure laws, varying rates of progress, and a national HIE agenda driven forward under the stimulus bill. Activities to advance HIE will likely continue at both federal and state levels. The specific options described in this report were developed in response to a set of critical realities that emerged from the review of state laws and regulations. The options are intended to simplify the current complexity of varying state approaches to privacy and thereby enable and accelerate realization of the benefits of HIE. Options are organized based on whether they are driven by: (1) a single, nationwide approach, such as federal preemption and HIO-to-HIO disclosure laws; (2) a state-based approach such as amending state laws and focusing on enabling specific types of disclosure or; (3) a current-day approach, whereby variations in state law are assumed and options are offered to address and manage them such as using states' official position on disclosure law to develop a consent rules engine to support real-time reconciliation of consent requirements in electronic HIE.
- The report concludes with two **Appendices**. Appendix A is the blank information collection template used by each participating state and a guide to using the template. Appendix B is a series of data tables representing a portion of the state-submitted information on state laws.

While the results of the 11-state analyses cannot represent the full breadth or depth of the variation among state disclosure and consent laws, the project findings can especially predict: (1) the degree of effort required to accurately capture and maintain state-level information on prevailing PHI disclosure laws; (2) the general decision path, logic and complexity inherent in automating the identification and reconciliation of PHI disclosure /

consent requirements in a transactional environment; (3) PHI type/source exchanges that may be good candidates for testing consent management solutions; and (4) near and medium-term legal and policy implications for HIE across electronic networks. Given the learning that has occurred during all phases of the Collaborative's work, the participants are unified in their desire to advance shared goals and augment progress using the knowledge and insight gained through this project.

1. PURPOSE AND SCOPE OF THE FINAL REPORT

1.1 Background and Purpose of This Report

This final report is prepared by the Interstate Disclosure and Patient Consent Requirements Collaborative (the Collaborative), as part of the Health Information Security and Privacy Collaboration (HISPC) funded by the Office of the National Coordinator for Health Information Technology (ONC). Eleven states comprised the Collaborative (shown geographically in **Figure 1-1**): Indiana, Maine, Massachusetts, Minnesota, New Hampshire, New York, Oklahoma, Rhode Island, Utah, Vermont, and Wisconsin. Victoria Prescott (Indiana) and Diane Stone (Massachusetts) co-chaired the Collaborative.

Figure 1-1. States Participating in the Collaborative



The work of the Collaborative began in April 2008 and concluded in March 2009.

This final report contains the following:

- a brief description of the methodology used in and the activities of the project,
- a summary of the results of the Collaborative's analysis of information gathered, and
- the recommendations of the Collaborative to help advance interstate HIE.

1.2 Statement of the Problem and Purpose of the Collaborative

While the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule¹ set the federal “privacy floor” with respect to use and disclosure of protected health information (PHI),² it did not preempt state privacy laws that were more restrictive or protective. As a result, many states have laws that impose more stringent requirements for disclosure of PHI than the HIPAA Privacy Rule. Variations across states, in both legal and policy requirements, have made it difficult for organizations to determine, in the context of interstate electronic HIE, when appropriate disclosure requirements have been met that will permit the sharing of PHI.

The Collaborative’s focus was to provide valuable and actionable findings from its collection and analysis of detailed statutory and regulatory requirements pertaining to patient consent for the disclosure of PHI in specific, high-demand interstate HIE treatment scenarios. The goal of this project is to establish a model for identifying PHI disclosure and patient consent requirements across states, and to develop a foundational report that describes and provides key analytic elements for comparisons of participating states’ legal requirements for the disclosure of PHI. It also presents important approaches to reconcile and/or reduce variations, or manage going forward, the differences in each state’s disclosure requirements to enable timely and efficient interstate HIE that ensures compliance with state privacy laws and policies.

The work of this project contributes to a growing body of knowledge intended to inform and accelerate development of effective and responsive solutions to enable interoperable HIE on a nationwide scale, supporting the ultimate goal of improving the quality, safety, and efficiency of health care in the United States.

1.3 Report Limitations

The efforts of the Collaborative were limited to an analysis of certain state laws of the 11 participating states. While this final report references some specific wording in some federal statutes, such wording is provided only as a comparison of language in a few limited

¹ <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

² Protected health information. The Privacy Rule protects all “*individually identifiable health information*” held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information “protected health information (PHI).” “Individually identifiable health information” is information, including demographic data, that relates to: (1) the individual’s past, present or future physical or mental health or condition, (2) the provision of health care to the individual, or (3) the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number). The Privacy Rule excludes from protected health information employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act, 20 U.S.C. §1232g.

circumstances, and a thorough analysis and comparison with different federal laws was not undertaken or intended. The Collaborative elected to limit the scope of the requirements collected and analyzed in the report in order to focus on those issues identified as the most relevant drivers of consent variations across states. For this reason, the scenarios were limited to treatment only and state participants were asked to limit their responses to reflect only what is codified in state law, rather than policy. While different statutes use different terminology when referring to a patients' right to restrict disclosure of their PHI, for the purpose of this report, the terms "consent," "permission," and "authorization" have the same meaning and are used interchangeably. In addition, the review of state laws and regulations was completed in September 2008, and laws may have changed since that time.

Several categories of statutes were excluded from this analysis (e.g., disclosure laws related to minors, abortion records, laws specific to state employees, dental records, PHI held by correctional institutions). The specific data collected are described in the information collection template used by each state to record their information (see **Appendix A**).

The information presented in this report is not intended to be, nor does it constitute legal opinion or legal advice on statutes from participating states. The data presented are based on information provided by each participating state team and their understanding and interpretation of their respective state statutes. Other interpretations of the statutes may exist. In addition, the data tables and analyses in the report are intended to serve as references, and not as the basis for data sharing agreements or other legal works between states.

Although the 11 states participating in the Collaborative differ in geography, stage of HIE development, and privacy approaches, they are not assumed to be representative of all states. The states have varying levels of both health information technology (health IT) and health information organization (HIO) implementation, from none to statewide efforts. Some marketplaces are very driven by legislation and others, such as New Hampshire, have nearly no legislation "on the books."

2. PROJECT METHODOLOGY

2.1 Formation of the Collaborative

The Collaborative formed in fall 2007 with 11 participating states. The Collaborative decided to focus on studying state disclosure and consent requirements as a high priority area that could further interstate electronic health information exchange (HIE) via a better understanding of state laws. Project work began in April 2008 and subgroups were formed to accomplish various tasks for each phase of the Collaborative project. The Collaborative communicated through regular conference calls and four in-person meetings. Each of the 11 participating states assigned one or two individuals to attend the regular conference calls, to be responsible for ensuring completion of project work for the state, and to coordinate the activities and communications with the state's steering committee and/or others within the state who were providing support or expertise for the project work on behalf of the state. Over 50 individuals were involved in the Collaborative, in roles such as project managers, policy experts, technical experts, and attorneys.

During the project timeline from April 2008 through March 2009, the work proceeded in four phases, summarized below in **Table 2-1**.

Table 2-1. Project Overview

Phase	Activities
Phase 1	<ul style="list-style-type: none">• Developed three high-priority interstate HIE scenarios.• Developed an information collection template for each of the three scenarios and instructions for each state to guide completion.
Phase 2	<ul style="list-style-type: none">• Obtained information from each state using the completed information collection template to describe their state laws pertaining to disclosure and consent requirements for the three scenarios. Each state gathered the information in a manner that was best suited to their project.
Phase 3	<ul style="list-style-type: none">• Conducted analyses of commonalities and variations based on responses from the 11 participating states.
Phase 4	<ul style="list-style-type: none">• Articulated findings and formulated options to address variances identified. Initiated supporting research on statutory language and prepared final report.

2.2 Phase 1—Selection of the Scenarios and Development of Information Collection Template

2.2.1 Scenario Selection Process

Focus on Three Treatment Scenarios

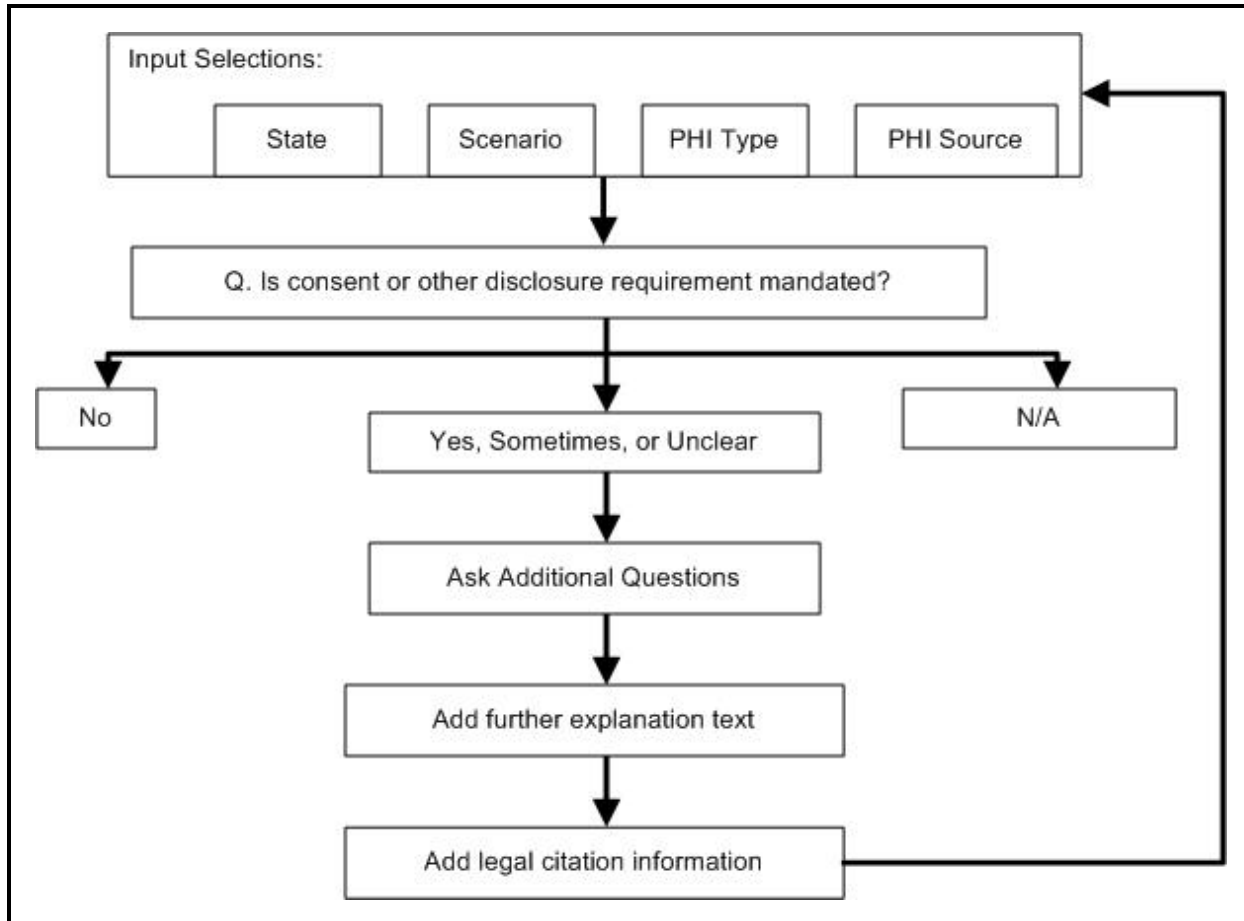
To successfully develop valuable findings and options for interstate sharing of health information, the Collaborative chose to focus on the consent requirements for the disclosure of protected health information (PHI) for treatment purposes. This included addressing consent issues in both emergency and nonemergency treatment situations, as well as a scenario in which state-held PHI (e.g., PHI held by a public health agency) was requested by a treating provider. The three scenarios selected are described in **Table 2-2**. Other important purposes for PHI disclosure, such as quality improvement and public health, were discussed, but could not be accommodated in the allotted timeframe.

Table 2-2. Scenarios Selected for Study

Scenario	Descriptions
1. Nonemergency treatment	An adult person from your state seeks nonemergency treatment from a health care provider in another state (e.g., doctor's office, a health care treatment facility such as a hospital or outpatient center). What is required by your state to allow the disclosure of any and all PHI on this patient held by the "PHI Sources" listed in the template to the health care provider in the other state?
2. Emergency treatment	An adult person from your state is seen by a health care provider in another state seeking emergent care. What is required by your state to allow the disclosure of any and all PHI on this patient held by the "PHI Sources" on listed in the template to the health care provider in the other state?
3. Release of PHI held by state government (e.g., public health)	Person from your state seeks treatment from a health care provider in another state (e.g., doctor's office, a health care treatment facility such as a hospital or outpatient center). What is required by your state to allow the disclosure of any and all PHI of the types listed in the template on this patient held by the state government to the health care provider in the other state?

Figure 2-1 depicts the logic model for data collection used for the three scenarios.

Figure 2-1. State Information Collection Decision Logic Model: All Three Scenarios (Nonemergent and Emergent Treatment and State-Held Data)



Focus on State Law

The Collaborative concluded that a focus on legal requirements would be the most effective way to tackle the variations between states related to consent and disclosure of PHI. States were asked to examine state law, but a review of interpretive case law was not required.³ Collaborative members recognized that laws constantly change at the state level. The greatest opportunity to assist states in harmonizing their laws is by identifying similarities and differences and then developing approaches for reconciliation.

The Collaborative agreed to limit their analysis to state law and not to address state policy regarding the disclosure of PHI, given that: a) there was likely to be intense variation between the states; and b) the scope of seeking and analyzing this data would be too much detail at this time. For this reason, the state-specific information presented in this report

³ In this report, “state law” will refer to the state’s constitution, statutes, regulations, or administrative rules.

cannot be assumed to be the only disclosure requirements that may apply to scenarios in a given state. In many cases, state or organization business practices and policies, regarding disclosure of specific types of health information, must be understood and followed before health information may be obtained from another state or an organization in that state.

Exclusion of Medicaid Law

The Collaborative also chose not to include disclosure rules for state Medicaid agencies within the scope of the project, because: (1) it was based more on the state's policy and the state's interpretation of federal Medicaid law, which may be more difficult to capture uniformly; and (2) many states did not yet have a defined policy on disclosure of PHI held by state Medicaid to providers for treatment (e.g., Medicaid has records of procedures and prescriptions filled because Medicaid pays these claims). Although the scope of the project did not include an analysis of state policy on disclosure of PHI contained in Medicaid claims, the Collaborative recognized the clinical importance of this PHI for treatment and suggests this area be examined in the future.

2.2.2 Development of the Information Collection Template

The Collaborative developed a template to collect information on each state's laws to provide a consistent and comprehensive display of the collected information and to facilitate comparison of requirements between states. The template was developed in Microsoft Excel® and Microsoft® Word and is attached as **Appendix A**. The template includes qualitative, open-ended questions, as well as a structured, quantitative matrix of multiple choice answers. For scenarios 1 and 2, this matrix was organized by PHI data source (e.g., hospital, physician office, pharmacy), and also by type of PHI (such as medications, HIV test results, mental health records). For scenario 3 (disclosure of PHI held by state government), the matrix was organized by type of state-held PHI (e.g., immunizations, medication history from the statewide controlled substance prescription monitoring program) and by the type of requestor to whom the PHI was being requested (e.g., physician, pharmacist).

Tables 2-3 and **2-4** below provide a summary and **Appendix A** provides the complete instructions and a more detailed listing of inclusions and exclusions from the information collection process.

Table 2-3. Sources and Types of Protected Health Information (PHI) Studied: Scenarios 1 and 2

PHI Sources	PHI Types
<ul style="list-style-type: none"> Hospital (nonmental health) Mental Health Facility—Inpatient Mental Health Facility—Outpatient (excluding provider licensing laws) Substance or Alcohol Abuse (nonmental health)—Outpatient or Inpatient Facility Other Outpatient Facility (nonmental health and nonsubstance or alcohol abuse) Mental Health Provider Licensing laws—Psychiatrist Mental Health Provider Licensing laws—Psychologist Physicians (other than psychiatrists) Pharmacy/Pharmacist Managed Care Organizations Commercial Payer (other than managed care organization) 	<ul style="list-style-type: none"> Patient ID and Demographic Information Medication History (excluding medications taken for HIV) Lab Test Order and Results (excluding HIV and genetic tests) Clinical Notes/Reports (excludes psychotherapy notes as defined in HIPAA) Diagnosis or Procedure Information (excludes HIV/AIDS diagnosis) Allergies/Adverse Reactions Claims Data (other than medication history)(excludes Medicaid claims) HIV Testing—ID of Person Taking Test HIV Test Results Medications Used for HIV Diagnosis for HIV/AIDS Other Indication of HIV/AIDS Status Other STDs Mental Health Records (excludes psychotherapy notes as defined in HIPAA) Substance Abuse (state law, not federal) Genetic (tests or information) Immunization History from Provider Record

Table 2-4. Sources and Types of Protected Health Information (PHI) Studied: Scenario 3

PHI Requestor	PHI Types
<ul style="list-style-type: none"> Hospital Other Inpatient or Outpatient Facility Physician Nonphysician Provider Pharmacist 	<ul style="list-style-type: none"> State Immunization Registry Medication History from Statewide Controlled Substance Prescription Monitoring Program, if applicable Newborn Screen—Metabolic Newborn Screen—Hearing Lead Results HIV Results STD Results/Registries Communicable Results/Registries Cancer Registries Hospital Admission Records Hospital Discharge Summaries

The information collection template included explicit instructions, definitions, and assumptions with each scenario to ensure a common understanding of the questions being asked and to enable accurate and comparable collection of the state law information. For each scenario, if consent was required to disclose PHI for treatment, further questions were asked to provide additional explanations and legal citations to further identify elements of the required consent.

During the template development process, the group took time to discuss the importance of setting clear parameters and using consistent design criteria for all Collaborative work products because of their interdependence and because subgroups would perform defined portions of the project. As a result of this discussion, the Collaborative agreed on guidance to support the development of work products and deliverables. The criteria developed were intended to serve as parameters for reference by team members and subgroups during the progressive development cycles of multiple interdependent deliverables. Specifically, the development criteria articulated the basic design principles and requirements for the spectrum of work products including: high-priority HIE scenarios, information collection templates, consent and disclosure analysis tools and methods, and the reference guide to PHI disclosure laws and consent requirements as documented in this final report.

Criteria were categorized as either end user requirements (i.e., the user of the work product) or technical/analytic requirements to help differentiate the more qualitative user-oriented factors from quantitative factors to be considered across the spectrum of work products to be developed. Goals for use of these agreed upon development criteria included:

- (1) Provide a consistent framework to guide qualitative and quantitative development of distinct work products by various Collaborative subgroups.
- (2) Provide clear, rational justification for decisions pertaining to content, format, and methods used in work product development.
- (3) Protect and preserve the quality and ultimate value of the interdependent work products throughout the development cycle.

In developing the criteria, effort was made to ensure that work products were unambiguous, easy to use, comprehensible, of high value, and high quality. When considering technical requirements, Collaborative members sought to ensure that data used in analyses were analyzable and that analytic instruments were created with high reliability, internal consistency, external validity, construct validity, the use of data validation rules, and that all outputs were interpretable to the greatest extent possible.

2.3 Phase 2—Information Collection by Each State

Each state's project representative coordinated and worked with a team within its state to gather the information requested to complete the information collection template. States

engaged their state-specific HISPC teams to complete the information collection. In addition, many states engaged additional individuals with specific expertise to answer various portions of the template (e.g., state government attorneys for scenario 3, general health care lawyers and privacy officers for scenarios 1 and 2) that could not be completely answered by either the state HISPC Project Director or the core state HISPC team.

The focus of this work effort was to secure content that would provide information for an analysis of state laws, regulations, and administrative rules governing the release of PHI and any patient disclosure requirements associated with this release process. The data collection process was developed to allow for flexibility in how each state approached the work effort. A *Project Director's Guide* (see **Appendix A**) was developed to support, and to the extent possible, standardize the information collection process across the Collaborative.

2.3.1 Individual State Methodologies

States engaged different members of their state teams with specific expertise to complete different portions of the template. For scenarios 1 and 2, the state teams drew on the expertise of their attorneys and legal work group members, government agency directors and managers, privacy advisory group members, consultants with health IT and/or privacy expertise engaged to support the Collaborative Project, and the project managers or directors of this Collaborative Project.

For scenario 3, the teams drew on a wider range of individual expertise to complete the tasks because the information was often not codified and specific agency leaders were needed for the collection and description of state laws pertaining to state-held PHI.

Overall, the state-level information collection was not intended to be a plain reading of prevailing laws; rather, it was intended to be comprehensive in addressing the specific questions of law and reflective of the most prevalent interpretation(s) of applicable state laws and regulations. States were responsible for validation of all information submitted and further validation of the resulting analyses.

2.3.2 Information Collection Challenges

Information collection results reinforced the fact that inconsistencies and differences exist among organizational policies, procedures, routine practices, and defined statute. In addition, state law can be complex and often difficult to organize and categorize to enable comparison across states. While every effort was made to consistently code all state-submitted responses, there can be potential problems in comparing the results depending on how an individual respondent interpreted an answer of “sometimes” or “unclear.”

2.4 Phase 3—Data Analysis

2.4.1 Analysis of State-Submitted Information

SAS® 9.1 and the SAS® v.9.1 (Cary, NC) Macro Language were used to import response information directly from each state's electronically completed information collection template. Data responses from each were mapped to a SAS-import-command format. Data points were reviewed to standardize responses. After the data cleaning and reconfiguration processes, data from all states were concatenated and merged to form a larger analytic data set for each scenario. The data were then imported into SAS using the Proc import statements, creating a macro to reconstruct the data in two dimensions: by PHI type and by PHI sources.

For quantitative analyses, frequency counts and percentages were calculated to show the proportion of the 11 states answering the same way for any combination of source and type of PHI within each matrix for the three different scenarios. A listing of the states that comprised each proportion accompanied the percentages. Array statements within SAS v.9.1 were used to compile all frequency statistics.

Qualitative data that were composed of general and specific questions and explanations were also concatenated. Data tables were assembled by question to display responses from each state. Following a grounded theory approach, a systematic process that enables researchers to identify categories of concepts from the data, two members of the analytic team independently reviewed the semistructured responses to identify key themes related to PHI disclosure. The team members met to develop a preliminary coding scheme, resolving any inconsistencies through discussion. Network analyses were conducted using this coding schedule. Responses were then coded using this scheme by one team member using the Atlas.ti software v5.5 while a second team member independently coded the responses manually. Results were then compared to ensure reliability. For the specific consent questions as follow-up to the "Yes/Sometimes/Unclear" responses in the matrices (i.e., consent required for certain PHI type or sources), the responses were more structured and can be systematically synthesized into tables showing commonalities and differences across states.

Both qualitative and quantitative results were reviewed by the Collaborative for feedback and modifications were made based on states' input.

2.4.2 Additional Research and Analysis of Statute Language

Further research was conducted by a subgroup of the Collaborative into statute language related to specific topics to compare such language for commonalities and variations across states. The Collaborative subgroup consulted with Joy Pritts, Director of the Center on Medical Record Rights and Privacy at Georgetown University who was simultaneously conducting a high-level review of laws in the 53 state and territories in the area of

disclosure requirements and patient consent to provide a listing of what statutes her project had found to date for the 11 Collaborative states. This information assisted the Collaborative in identifying additional legal citations of relevant statutes for further review. The Collaborative subgroup also conducted direct research to locate additional statutes in areas that were not within the scope of Ms. Pritts' project (e.g., disclosure requirements for PHI held by state government, such as a controlled substance prescription monitoring program). Based upon group discussion, the following are areas where additional limited review of statute language was conducted:

- "break-the-glass" exceptions to consent requirements;
- elements of a consent form;
- medication history from pharmacists/pharmacies;
- sensitive data:
 - HIV/AIDS
 - mental health
 - substance abuse treatment;
- disclosure requirements for PHI held by state government including
 - controlled substance prescription monitoring program (partial medication history);
 - immunization registry data.

The Collaborative has taken a very conservative approach to the use of any conclusions derived from the additional study of statute language due to the risk inherent in legal interpretation based on a plain reading of the law without detailed state review and validation relative to all applicable laws and regulations.

2.5 Phase 4—Development of Options

The options in Section 4 of this report represent a synthesis of perspectives from the Collaborative participants. These options were developed in response to a number of critical realities that emerged from an analysis of the eleven states' laws pertaining to interstate disclosure of PHI for treatment. The final sets of options were developed via multiple methods:

- An in-person meeting whereby options were initially discussed.
- Each individual state, as a part of the Collaborative, developed a set of options.
- A compilation document was created that included a synthesis of all options put forth.
- A second round of comments from states was conducted.

- Several conference calls took place to discuss and finalize the set of options.

The goal was to offer a wide variety of options to generate discussion that numerous options may need to be implemented to promote sharing of PHI across state lines.

2.6 Lessons Learned

The work of the Collaborative produced many insights and a deeper understanding of the nature and extent of variations in state laws pertaining to PHI disclosure. Further, the discussions and interactions of the Collaborative were valuable in highlighting important considerations when working in a multistate group. The following sections describe a series of lessons learned that address both content and group dynamics inherent in collaborative work.

2.6.1 Content Lessons

Working with such a large and varied group of states affected the scenarios selected. Some states had mature or rapidly developing HIOs whereas others did not. Some states were exchanging limited data with other states. The ultimate goal was to develop the treatment scenarios that would have the largest volume of HIE activity. This would benefit not only this Collaborative, but also people in other states that would eventually learn from this work.

Overall, the information collection template used in this project (to collect certain information on state laws) was found to be useful. Parts of the template may be useful for categorization of states' approaches and can be used as the basis for discussion of a framework for developing a disclosure rules engine. Specific suggestions for improving the information collection template include:

- Ask for explanation on the details sheet for "No" responses in the template. This would help to clarify the intent and reduce respondents' confusion as to whether the response is "No," in terms of conditions and consequences. This additional information would have also aided in the further research that was begun to compare actual statute language.
- There was wide variation in how the open-ended questions were answered, making it difficult to compare between states. For future versions, the Collaborative recommends that a limited set of the answers be available (e.g., multiple choice or chart to fill in), and that there should be a short text field provided for further explanation
- When requesting legal citations, both the hyperlinks to statutes as well as the actual statute language should be provided; this would expedite any review of statute language.

2.6.2 Collaboration Lessons

The diversity of the participating states' size, geography, and health care markets enriched the understanding of nationwide issues and the scope of options considered in developing

the scenarios and information collection methods. Participation and contribution from the large number of states helped to validate the utility and reliability of the scenarios selected. Although the Collaborative's size (11 states) was large for the initial tasks, the group was committed to working together successfully and established the requisite relationships and communication skills to meet goals and objectives.

The Collaborative recognized early in the project the crucial need to establish adequate and appropriate group norms and processes to enable communication and collaborative progress with cohesion and effectiveness and to capture the thoughts and ideas of the full group. This proved to be an effective strategy that helped in management of communication issues that might have been related to lack of formal delineation of authority or accountability. In addition, face-to-face meetings were a highly effective way of having meaningful discussions of substance (such as on topics involving strategy, direction, and group recommendations). Face-to-face meetings were more likely to have all the key people at the table, hold participants' undivided attention and focus, and ensure that all voices were heard. They also provided an easier platform for everyone to contribute and were more effective in reducing misunderstandings than conference calls and e-mails. Face-to-face meetings also helped promote teamwork and camaraderie that increased interest in participation and enhanced the success of the project.

Given the size of the Collaborative, compromise had to be seen as a win-win proposition. Developing a "group" information collection template for multiple states was challenging on several levels. Variation had to be respected, and differences had to be expected with respect to the selection of software, relevance of questions to specific states, specificity and clarity of questions to collect the intended information, and a comprehensive mode of information collection that can address varying levels of HIE adoption and use among the states.

Differences in interpretation of state statutes and regulations are to be expected when health information law questions are addressed. Processes to ensure that project representatives can provide an informed response on behalf of their project need to be put in place to reduce the potential for misinterpretation and misinformation.

The RTI project management team contributed greatly to ensuring that all opinions were aired, addressed, and managed. These are merely a few of the issues that the Collaborative identified and managed during the project. Most importantly, the Collaborative successfully navigated all the challenges.

3. FINDINGS

3.1 Overview

Analysis of the information each Collaborative state submitted confirmed the hypothesis that wide variation exists among participating states' legal requirements for interstate disclosure of protected health information (PHI) to a health care provider for treatment of a patient. The analysis also identified important challenges in trying to analyze and compare a complex collection of applicable legal statutes between states (as well as within states). One of the most significant challenges in trying to produce conclusions from the data was the degree to which states could provide a complete interpretation of the statutes relative to specific questions of law. Statutes are often interpreted differently by different legal experts, thus adding to variations in business practices implemented in response to law. Given this, the findings presented in this report are based upon the analysis of each state's interpretation of its respective laws submitted in a common information collection template. To ensure the accuracy of the data relative to the intended interpretation of prevailing laws, each state validated its data after they had been coded and analyzed.

While there may be differing views about the meaning of a given statute or the relevant laws and regulations pertaining to the questions posed in the scenarios, each state team was responsible for interpreting its laws and determining how the data would be recorded and validated. Further, a deliberate effort has been made to reduce any presumptive interpretations of state statutes referenced in secondary research that was undertaken or referenced to augment the findings derived from the state-validated data sets. References to such research efforts are intended to illustrate the range of variability in statutes and do not constitute complete interpretation relative to specific questions of law.

3.2 General Trends

As part of their work, this Collaborative collected an extensive amount of detailed and rich data. Some general trends have emerged that advance our understanding of the legal landscape around PHI disclosure and ultimately help inform potential options to address known challenges to accelerate interstate health information exchange (HIE). The following sections highlight the key findings and provide perspective on the general characteristics of state statutes and specific topic areas related to disclosure that were explored in more detail.

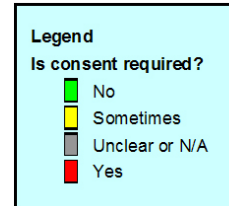
3.3 Summary Data

States vary markedly in their approaches to consent or other disclosure requirements for the release of PHI to a health care provider for nonemergency treatment purposes. The variation diminishes significantly when compared to requirements pertaining to disclosure of PHI for treatment in an emergency, although the definition of an emergency varied from state to state. Responses vary both within and among states based on the type of data being released, as well as the type of provider releasing the data. **Table 3-1** provides a high-level overview of the wide range of responses obtained from the states (total counts) and demonstrates the lack of clarity that may exist within statutes, as demonstrated by having an unclear or not applicable (N/A) response. The “stoplight” dashboard chart uses colored cells to represent each state’s answer to whether consent is required prior to disclosure, with green representing “no consent is required,” yellow representing “consent is required sometimes,” red representing “consent is required,” and grey representing “state law is unclear or not applicable.” The number of red and green answers does not reflect the total possible restrictions placed on PHI disclosure by the state, but rather provides insights into the relative degree of certainty, complexity, or ambiguity in a state’s laws relative to the specific questions in the information collection template. A complete listing of how each state answered the questions in the matrices is shown in **Appendix B**.

Figure 3-1 and **Figure 3-2** depict the same responses as in **Table 3-1**, but illustrate each individual state’s response. Each column represents the distribution of all the responses for a given state. The figures are arranged from left to right showing states having more consent requirements on the left to those with fewer consent requirements to the right. As shown in **Figure 3-1**, Indiana and Utah have the fewest restrictions for cases involving nonemergency treatment. New York and Minnesota have the most restrictions; consent is required for more than 80% of the data types or sources. For emergency treatment, **Figure 3-2** shows that 6 of the 11 participating states do not have restrictions on disclosure of health information.

Table 3-1. HISPIC Interstate Disclosure and Patient Consent Requirements Collaborative: Summary Charts on Disclosure Requirements

These two charts depict the responses from the 11 participating states to the question: *Is patient consent required in order to disclose PHI to another provider for treatment of the patient?* The answers are organized by type of PHI (row headings) and source of the PHI being disclosed (column headings). The first chart below is for nonemergency treatment, while the second chart is answering whether consent is required for PHI disclosure in emergency treatment. A complete listing of how each state answered the questions in the matrices are shown in **Appendix B**.

**Scenario 1 - Treatment (Nonemergency)**

	Hospital	Physicians Other Than Psys	Pharmacist	Mental Health Inpatient	Mental Health Outpatient	Substance Abuse	Other Outpatient Facility	Mental Health Psychiatrist	Mental Health Psychologist	Commercial Payers	MCO
Patient ID and Demographic											
Allergic Reactions											
Medication History											
Lab Test Order and Results											
Diagnosis of Procedure Info											
Clinical Notes/Reports											
HIV: Test Results											
Other STDs											
Mental Health Records											
Substance Abuse											
Genetic											
Immunization History											
Claims Data											

Scenario 2 - Treatment (Emergency)

	Hospital	Physicians Other Than Psys	Pharmacist	Mental Health Inpatient	Mental Health Outpatient	Substance Abuse	Other Outpatient Facility	Mental Health Psychiatrist	Mental Health Psychologist	Commercial Payers	MCO
Patient ID and Demographic											
Allergic Reactions											
Medication History											
Lab Test Order and Results											
Diagnosis of Procedure Info											
Clinical Notes/Reports											
HIV: Test Results											
Other STDs											
Mental Health Records											
Substance Abuse											
Genetic											
Immunization History											
Claims Data											

Figure 3-1. Is Consent Required for Disclosure of PHI for Nonemergency Treatment?

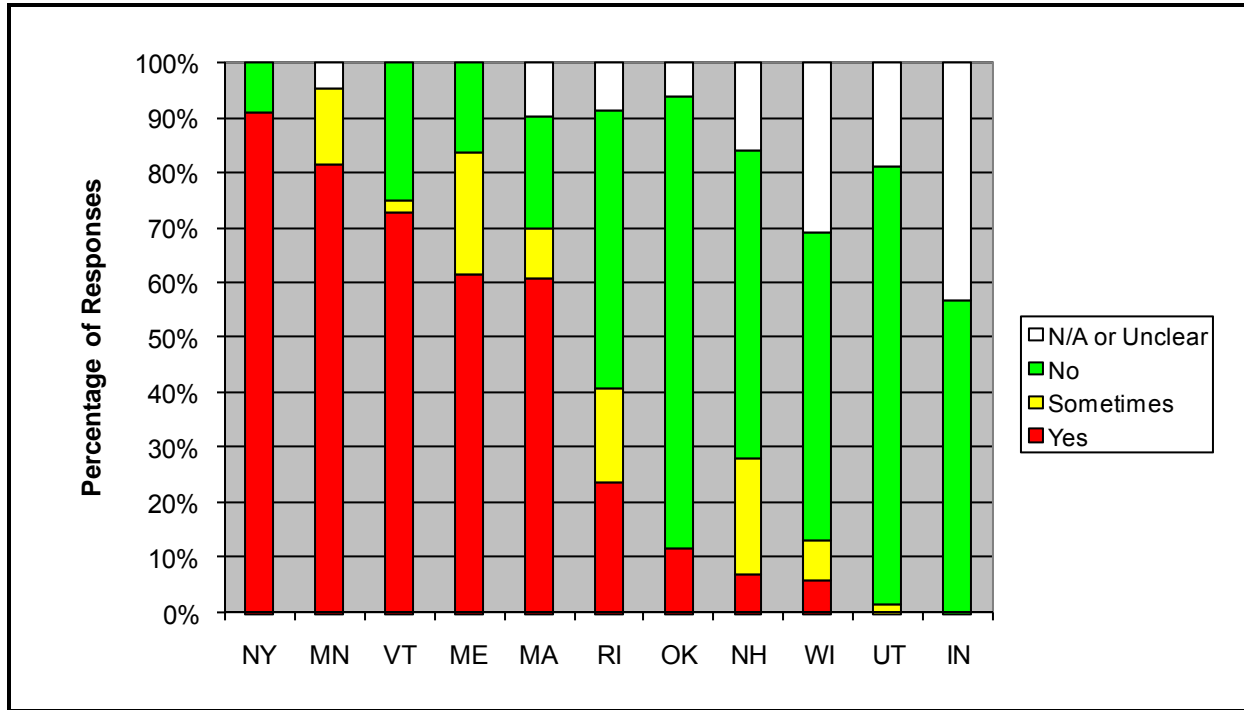
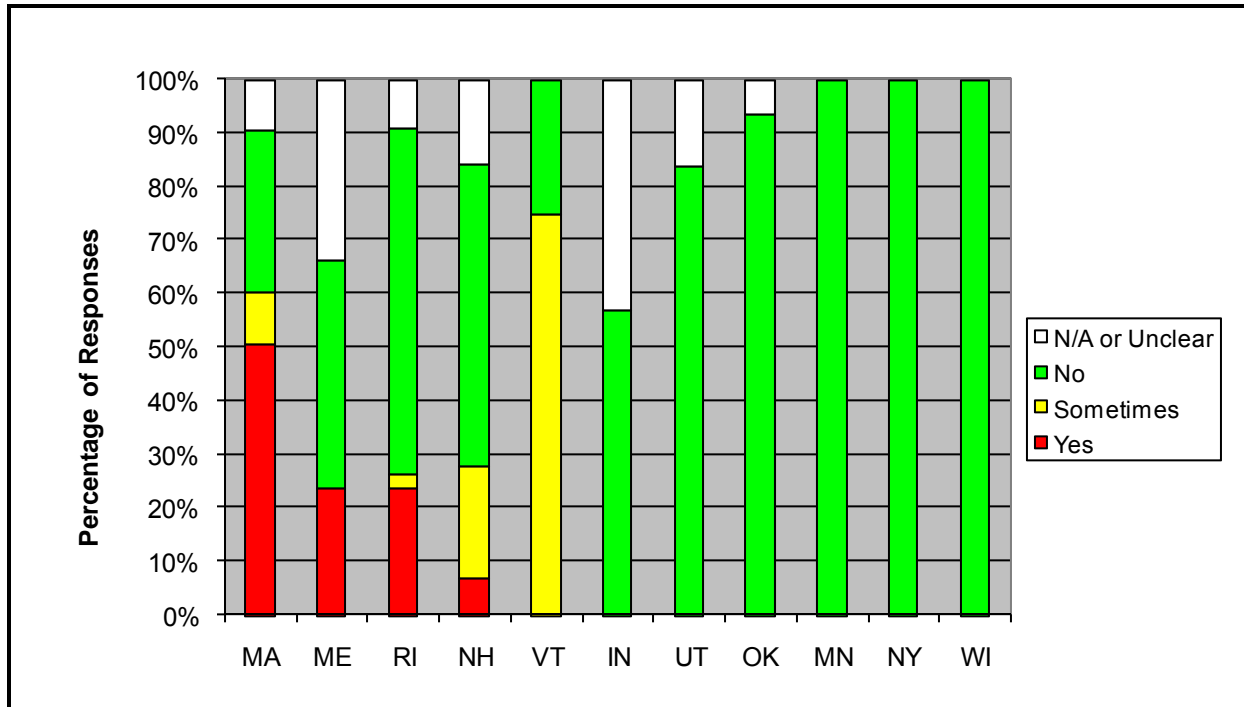


Figure 3-2. Is Consent Required for Disclosure of PHI for Emergency Treatment?



As evident in the above data, a wide range of approaches to consent for disclosure are used by the eleven states. **Figures 3-3** and **3-4** map the relative position of each of the 11 states on a spectrum of disclosure requirements that range from infrequently requiring consent to release PHI to frequently requiring consent for disclosure in nonemergency and emergency treatment situations, respectively. The spectra are presented on the same scale for ease of comparison. States were “scored” based on their number of *yes* responses (2 points), *sometimes* (1 point), and *no or not applicable* (zero points) and then aligned on a linear spectrum.

Figure 3-3. States’ Relative Positions on Privacy Protections for Nonemergent Treatment

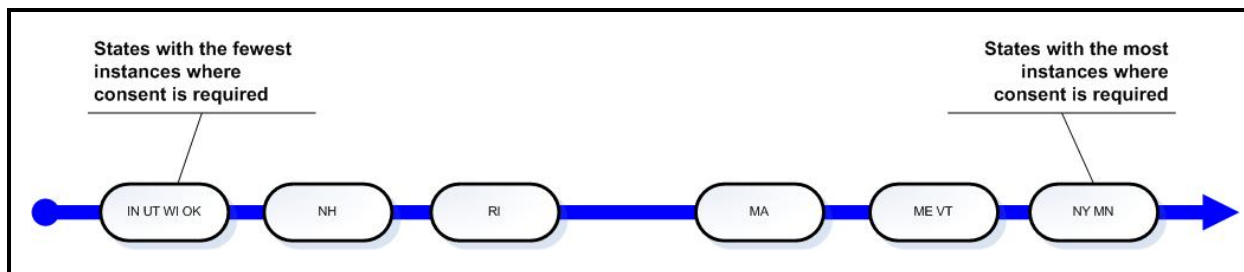
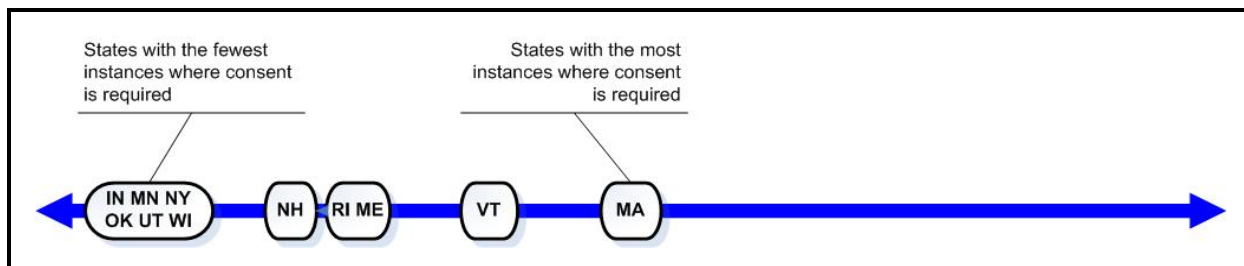


Figure 3-4. States’ Relative Positions on Privacy Protections for Emergent Treatment



In nonemergency treatment situations, the majority of the states tend to fall more towards one end of the spectrum or the other, as opposed to falling in the middle of the spectrum, suggesting some polarity in “consent cultures.” While there is less variability in emergency situations, the states still occupy a range of positions. In addition, several states (Minnesota, New York, Vermont, and Maine) jump from the “most restrictive” side of the spectrum to the “least restrictive” side.

While the 11 states participating in this Collaborative are a convenience sample rather than a probability sample and, therefore, we cannot make inferences from these findings to the

entire 50 states, they do represent the disparity in requirements that exists within and between states.

3.4 General Characteristics of State Statutes and Regulations

The analysis of state-validated responses pertaining to specific questions about PHI disclosure statutes and regulations produced a number of general findings that characterize the current interstate HIE environment.

1. **Ambiguity exists within and among state statutes.** The ability for states to clearly and objectively determine what a state law does or does not permit is not always simple or certain. At times, the results submitted by the states included some interpretation due to the ambiguity of state statutes/regulations. In one instance, two states had very similar statutory language, but each state had categorized the response differently—likely due to each state’s interpretations in the context of a broader statutory analysis. Additionally, some states had several state laws that were inconsistent or contradictory with their other state laws.
2. **Several state statutes demonstrated a high degree of complexity when addressing the disclosure of PHI.** Some statutes had exceptions embedded within exceptions (e.g., Maine allows general clinical PHI to be shared without consent, but has an exception requiring consent for disclosure of mental health PHI in a nonemergency situation and has an exception to that allowing a pharmacist and the treating physician to disclose mental health PHI without consent⁴). Some states, such as New York’s requirements regarding disclosure of mental health information, had requirements in addition to patient consent: “[PHI] shall not be released except as follows: with the consent of the patient ... to persons and entities who have a demonstrable need for such information and who have obtained such consent, *provided that* disclosure will not reasonably be expected to be detrimental to the patient ...”⁵). There were also complicated descriptions of what types of PHI were covered by the statute, (e.g., Maine: “healthcare information derived from mental health services, but excluding information from inpatient mental health treatment”⁶).
3. **Applicable laws (related to patient consent, etc.) are contained in a wide variety of state statutes and regulations.** The answers to whether state law requires patient consent for disclosure of PHI were often spread out in many different types of statutes/regulations. Examples of state statutes that may contain consent and disclosure clauses include:
 - general medical records statute;
 - health care confidentiality statutes;

⁴ Maine Rev. Stat. Ann. tit. 22, § 1711-C.

⁵ N.Y. Mental Hyg. Law § 33.13 (c) (7).

⁶ Maine Rev. Stat. Ann. tit. 22, § 1711-C(6)(A)(2).

- individual data types statutes such as those for HIV, (which may be different from STD, and/or communicable diseases), mental health, substance abuse treatment, genetic tests, etc.;
 - professional licensing statutes (e.g., pharmacists, physicians, or more specifically mental health providers which may or may not include psychologists);
 - facility licensing statutes (e.g., lab, hospital, inpatient mental health facility, substance abuse treatment facility; public and private); and
 - HIE/HIO specific statutes (Minnesota, Rhode Island).
4. **States statutes do not often distinguish between in-state and out-of-state treating providers.** None of the states indicated that their laws differentiated between disclosures of PHI within the state versus disclosures to a provider in another state.
 5. **Variation exists in what information is required in the consent process.** If consent was required, specific elements of the consent varied from state to state. Some states did not specify details of what should be included in the consent, while others set out lists of requirements and specific statements that must be included in the consent form. Some states had multiple consent forms, depending on the type of PHI being disclosed. A few states had consent forms officially approved by their state. Upon initial examination, there was some consistency in the range of elements that could be required in a consent form (e.g., duration of consent, purpose of the disclosure, identification of recipient, notice of limitation on redisclosure); however, detailed analysis was not performed because of time constraints.
 6. **Use of state-held PHI for treatment purposes is not commonly addressed in law.** Statutes governing PHI held by state government (e.g., reportable diseases, immunizations, newborn screenings, controlled substance prescription monitoring programs) were often written only with state government use in mind. For example, the statute would describe how the data would be submitted to state government, and what the state government would use it for internally, but was silent on whether the state-held PHI could be disclosed by state government to a health care provider for treatment of the patient. Thus, in many cases, disclosure by state government to providers treating the patient was not contemplated or addressed.

3.5 Findings in Specific Disclosure Topic Areas

The manner in which many states' disclosure laws have developed, with different laws applying to different types of PHI (typically PHI considered sensitive), as well as different PHI holders, is critical to understand if advancements in HIE are to be realized. These various laws, which at times conflict within the same state, contribute significantly to the variations observed in the analysis. Below are some descriptive findings from the analysis of disclosure and consent laws of the 11 states participating in the Collaborative that continue to illustrate the statutory landscape that must be navigated.

3.5.1 Different PHI Types

- All 11 states regulate some PHI disclosure by the type of data, most commonly mental health and HIV records, and have different disclosure requirements in cases of emergency.
- Among the PHI types examined by the 11 states, none could universally be disclosed without consent in nonemergency treatment situations
- On average, about half of the 11 states permit the disclosure of certain types of PHI without consent for nonemergency treatment. These PHI types include: diagnosis or procedure information (other than HIV/AIDS diagnoses), medication history (other than medications used for HIV/AIDS), immunization history (from provider record), allergies/adverse reactions, and patient identifiers and demographic information.
- Seven states (Maine, Massachusetts, New York, Oklahoma, Rhode Island, Utah, and Wisconsin) have state laws limiting PHI disclosures based on specific medical conditions (e.g., HIV, communicable diseases, mental health). Additionally, their laws address whether *minimum necessary* information requirements apply, and whether there are additional requirements for redisclosure of some PHI.

3.5.2 Different PHI Holders

- All states regulate, to some extent, PHI disclosure by who holds the PHI.
- There is no difference between PHI disclosure as permitted under state law for inpatient and outpatient mental health facilities for nonemergent treatment purposes. This is true in all 11 states.
- Eight of 11 states (Indiana, Maine, Massachusetts, Minnesota, New Hampshire, New York, Vermont, and Wisconsin) regulate disclosure of PHI held by private entities based on where the data were created (at facilities such as mental health agencies, pharmacies, insurers, and nursing homes). Six of 11 states regulate state government-held PHI based on where the data were created (Indiana, Minnesota, New Hampshire, Rhode Island, Vermont, and Wisconsin).
- PHI holders who are most likely to have permission under state law to disclose PHI without consent (for all PHI types studied) for nonemergency treatment purposes include commercial insurers (60%)⁷, managed care organizations (55%), and hospitals (52%). Physicians were the sixth most likely group to have permission to disclose PHI without consent (41%)⁸.
- When excluding more sensitive PHI types (genetic, substance abuse, mental health, HIV/STD information), PHI holders who are most likely to be permitted under state law to disclose PHI without consent for nonemergency treatment purposes include commercial insurers (72%), hospitals (68%), managed care organizations (67%), other outpatient facilities (nonmental health/substance abuse) (65%), and physicians (56%).
- All 11 states regulate state government-held PHI disclosure by the type of PHI (STD, HIV, Lead poisoning, immunizations, newborn screening, etc.). On average, at least

⁷ Percentages were calculated by totaling up all states' answers for all PHI types and then determining the percentage of "yes" answers.

⁸ Pharmacies/pharmacists ranked fourth (47%) and other outpatient facilities (nonmental health/nonsubstance abuse treatment facilities) ranked fifth (45%).

69% of 11 states' laws prohibit the disclosure of state government-held PHI without consent for the PHI types studied.

3.5.3 Different PHI Receivers

- Six of 11 states (Maine, Massachusetts, Minnesota, New Hampshire, Vermont, and Wisconsin) have requirements for PHI disclosure based on the type of provider to whom PHI is disclosed. Minnesota, Vermont, and Wisconsin have specific provider definitions.

3.5.4 Different Treatment Scenarios: Emergency vs. Nonemergency

- Ten of 11 states (all but Utah) differentiate between emergency and nonemergency treatment, but only one state, Minnesota, actually provides a definition of emergency in the context of treatment. Interestingly, for state government agencies, only 6 of 11 states differentiate between emergency and nonemergency treatment.
- For states requiring consent, many had some “break-the-glass” exceptions permitting PHI to be shared without consent in situations like emergencies. However, states had varying thresholds for whether there was an exception in cases of emergency. In some instances the state law did not allow disclosure without consent even in a medical emergency (HIV test results in Maine⁹ and Massachusetts¹⁰).
- Regarding “break-the-glass” exceptions, several statutes that required consent from the participating Collaborative states were examined and compared to the emergency exception found in 42 C.F.R. Pt. 2 (federal law on disclosure of certain PHI from federally funded substance abuse treatment programs)¹¹ and the emergency exception found in Family Educational Rights and Privacy Act (FERPA) (federal law on disclosure of education records from federally funded institutions, which definition includes student health records).¹² The language in statutes related to disclosure of PHI in emergencies was examined and the following points are noted:

Some statutes do not require an emergency to permit exclusions to disclosure restrictions, but have the lesser standard that is “in the best interest of the patient” (e.g., pharmacists in Indiana).¹³ Other examples of this language include the following:

- “for the purpose of treating a condition which poses an immediate threat to the health of any individual, and which requires immediate medical intervention” (42 CFR Pt. 2);¹⁴
- “in connection with an emergency if knowledge of the information is necessary to protect the health or safety of the student or other individuals” (FERPA);¹⁵
- “is necessary in order to protect the health of the person” (New Hampshire);¹⁶

⁹ 5 M.R.S.A. § 19203.

¹⁰ Mass. Gen. Laws ch. 111 s. 70F.

¹¹ 42 C.F.R. § 2.51.

¹² See 34 C.F.R. §§ 99.31(a)(10) and 99.36.

¹³ Indiana Code 25-26-13-15.

¹⁴ 42 C.F.R. § 2.51.

¹⁵ 34 C.F.R. §§ 99.31(a)(10) and 99.36.

- “medically necessary care which is immediately needed to preserve life, prevent serious impairment to bodily functions, organs, or parts, or prevent placing the physical or mental health of the patient in serious jeopardy” (Minnesota).¹⁷

3.5.5 Different Consent Processes and Forms

- In all 11 states, in cases when consent is required for disclosure, the patient (or guardian or legally authorized representative) must give consent for the release of the patient’s PHI by any facility/source or for any type of PHI.
- In most cases, the form of the consent must be expressed in writing (although Massachusetts, Maine, New York, and Utah allow for oral authorization in some cases) or point out that the form that the consent must take has not been specified.
- While it is not readily clear in every state, the term “written form” includes both digital and facsimile.
- Five of the 11 states (New Hampshire, New York, Rhode Island, Utah, and Vermont) have no limit or no mention of a limit to the duration of consent.
- In 6 of the 11 states (Massachusetts, Minnesota, New York, Oklahoma, Vermont, and Wisconsin) the consent allows the patient to limit the disclosure of information to a specific person or entity.

3.5.6 Differences in Requirements for Minimum Necessary

The *minimum necessary* standard in the HIPAA Privacy Rule requires covered entities (entities subject to HIPAA) to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.¹⁸ While the *minimum necessary* standard does not apply to disclosures to a health care provider for treatment under HIPAA, several state statutes imposed a *minimum necessary*-type limitation on disclosures for treatment for certain types of PHI. As is evident in **Table 3-2** below, states’ definition of *minimum necessary* and as compared to federal law are somewhat consistent (HIPAA and 42 CFR Pt. 2).

¹⁶ NH Rev Stat Ann 141-F:8.

¹⁷ Minn. Stat. 144.291, subd. 2 (f).

¹⁸ 45 C.F.R. § 164.502(b).

Table 3-2. Sample Language Pertaining to *Minimum Necessary* Disclosure Requirements

Statute	Sample Language
Maine ¹⁹ : general clinical statute	"may not disclose information in excess of information reasonably required for the purpose for which it is disclosed"
Massachusetts ²⁰ : mental health statute	"shall be limited to the minimum information necessary to achieve the purpose of the exception"
New Hampshire ²¹ : mental health statute	"but only specific information necessary to the relief of the emergency may be released without the client's consent"
New York ²² : mental health statute	"shall be limited to that information necessary in light of the reason for such disclosure"
Wisconsin ²³ : substance abuse statute	"shall be limited to that part of the records necessary to meet the medical emergency"
Federal law on substance abuse treatment records of federally funded facilities (42 C.F.R. Pt. 2) ²⁴	"to medical personnel, who have a need for information about a patient"
Federal law HIPAA (does not apply to disclosures for treatment, but is useful for the definition of minimum necessary) ²⁵	"make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request"

3.5.7 Special Classes of PHI

As mentioned previously, many states' disclosure laws have developed so that different laws apply to different types of PHI. This is typically the case with very sensitive information for which a greater level of privacy is needed. Understanding these types of PHI and the differences associated with the disclosure of information is critical to implementing HIE across state lines. The following sections provide findings from the exploration of state statutes pertaining to specific PHI types including HIV/AIDS, mental health treatment, substance abuse treatment, and medication history.

HIV/AIDS

In comparing the 11 states' approaches to disclosure of HIV-related PHI, the Collaborative noted the following:

¹⁹ Me. Rev. Stat. Ann. tit. 22, § 1711-C(10)(B).

²⁰ 104 Mass. Code Regs. 27.17(h).

²¹ N.H. Code Admin. R. Ann. He-M 309.05(f)(10).

²² N.Y. Mental Hyg. Law § 33.13 (f).

²³ Wis. Stat. Ann. § 51.30(4)(b)(8).

²⁴ 42 C.F.R. § 2.51.

²⁵ 45 C.F.R. § 164.502(b).

- Some HIV statutes only cover HIV test results, while other states have HIV statutes that apply to any HIV-related information.
- Some statutes seem to apply the restrictions only to state government (public health department) as the holder reporting HIV test results, and would not apply the statute restrictions to private labs, hospitals, or physicians holding the test results.
- Some states require a specific consent for release of HIV records while others do not specify, assuming a general consent form would be sufficient.
- No statutes specifically mention medications for HIV.

Table 3-3 summarizes sample language describing what PHI is covered by HIV statutes.

Table 3-3. Examples of PHI covered in HIV Statutes

HIV Statute	Example
Indiana ²⁶	"medical or epidemiological information involving a communicable disease" [which includes HIV/AIDS and other STDs]
Maine first statute (covering HIV test results) ²⁷	"results of an HIV test"
Maine second statute (covering disclosure of HIV information as part of a medical record) ²⁸	"any HIV infection status information contained in the medical record," but <i>HIV infection status</i> is defined as "HIV test results" ²⁹
Massachusetts ³⁰	"'HTLV-III test' shall mean a licensed screening antibody test for the human T-cell lymphotropic virus type III"
New Hampshire ³¹	"HIV test results" ³²
New York ³³	"confidential HIV-related information"
Oklahoma ³⁴	"...all information and records which identify any person who has participated in a public health investigation or who may have any communicable or noncommunicable disease which is required to be reported...." [that includes HIV infection]
Rhode Island ³⁵	"results of an individual's HIV test" [note: Rhode Island specifically excludes HIV tests from the STD statute]

²⁶ Indiana Code 16-41-8-1.

²⁷ 5 MRSA §19203.

²⁸ 5 MRSA §19203-D.

²⁹ 5 MRSA §19201(9).

³⁰ Mass. Gen. Laws ch. 111 s. 70F.

³¹ NH Rev Stat Ann 141-F:8.

³² Note that while the statute only mentions HIV test results, the New Hampshire team stated that given the focus of HIV confidentiality in New Hampshire statutes, it would be reasonable to conclude that other PHI that would be indicative of a positive HIV test should not be disclosed either.

³³ NY Public Health Law 2782(1)(b).

³⁴ Okla. Stat. tit. 63, § 1-502.2 (A).

³⁵ Rhode Island Gen. Law 23-6-17.

Mental Health Treatment

State laws on mental health treatment information were some of the most complex and varied of all the types of PHI studied. For example:

- The types of records covered were not consistent.
- Rules on disclosure of mental health records were sometimes spread out over several statutes in a state (e.g., sometimes by specific type of facility or in the professional licensing regulations).
- Statutes vary in whom it covers. Examples include:
 - Oklahoma³⁶: “All mental health and drug or alcohol abuse treatment information”;
 - Utah statute on state facilities³⁷: “Utah State Hospital or other facility that provides mental health services under contract with the division, a local mental health authority, or organization that contracts with a local mental health authority”;
 - Utah statute³⁸ regulating mental health therapists, which includes: APRN, MD, social worker, professional counselor, marriage and family therapist; and
 - New York³⁹: All facilities providing mental health services.

Substance Abuse Treatment

Records containing PHI held by certain federally funded substance abuse treatment programs are specially protected under federal law, 42 C.F.R. Pt. 2. Specialized written consent is required for disclosure of those records, with a limited exception for a medical emergency defined in the rule.⁴⁰ The rule also places certain limits on even the disclosure that a patient is physically at the facility for treatment.⁴¹ Our Collaborative examined whether the 11 participating states have laws that impose restrictions greater than the federal law. The findings revealed:

- States often reference 42 C.F.R. Pt. 2, but many are not clear whether their state law applies the rigorous consent requirements and emergency exception to facilities that do not fall under the 42 C.F.R. Pt. 2 (e.g., a facility that is not federally funded, such as a private pay treatment program, would not be subject to 42 C.F.R. Pt. 2).
- A few states have separate categories within substance abuse (e.g., alcoholism⁴²).

³⁶ Okla. Stat. tit. 43A, § 1-109 (A)(1) and Okla. Admin. Code § 450:15-3-20.1 (a).

³⁷ Utah Code Ann. § 62A-15-602 (9).

³⁸ Utah Code Ann. § 58-60-114.

³⁹ N.Y. Mental Hyg. Law §33.13 (e) (2008) (extending the application of the statute to mental health facilities not operated by the Office of Mental Health).

⁴⁰ 42 C.F.R. § 2.51.

⁴¹ 42 C.F.R. 2.13 (c)(1).

⁴² Rhode Island Gen. Law 23-1.10-13.

- The fact that the patient was even treated at the facility may also be restricted from being disclosed without consent, similar to 42 C.F.R. Pt. 2 provisions (e.g., Maine⁴³, New York⁴⁴, Wisconsin⁴⁵).

In summary, the wealth of data collected and analyzed demonstrates that states have a wide range of approaches to handling the disclosure of PHI for treatment purposes both in an emergency and in routine care. Additionally, the ability to disclose PHI from state government agencies (e.g., public health) to providers is also handled in a variety of ways. While some trends were identified, generally more differences than similarities exist among state laws. These facts challenge us as a nation to develop effective ways to promote HIE across state lines. After careful review of the data and numerous discussions among Collaborative members, all participants agreed that a range of strategies would likely be needed to reduce these variations. Therefore, the Collaborative developed a variety of options for consideration, which are discussed in the next section.

⁴³ Me. Rev. Stat. Ann. tit. 5, § 20047(1).

⁴⁴ N.Y. Mental Hyg. Law § 22.05 (b).

⁴⁵ Wis. Stat. Ann. § 51.30(1) (b).

4. IMPLICATIONS OF FINDINGS AND OPTIONS FOR PROGRESS

4.1 Overview

After extensive examination of 11 states' PHI disclosure laws, the Collaborative has clearly demonstrated the intricacies and complexities amongst state legal environments. This complexity contributes to the challenge of undertaking nationwide health information exchange (HIE) on the scale envisioned to support transformational health reform. While variations in state laws and regulations pertaining to the disclosure of protected health information (PHI) have been confirmed in this and other work, findings from the Collaborative's current analyses provide specific insights into the diversity of state-level privacy approaches. Indeed, differences in states' laws go beyond simple variability. These differences drive business practices across the health care industry and have perpetuated various "consent cultures" that define the context for HIE and impact the range of acceptable approaches for advancing interstate electronic HIE in any given state. Furthermore, differences in state legal and regulatory environments are but one factor in our rate of progress toward nationwide interoperable HIE capability; the scope of HIE activities under development, health IT adoption rates, actual technological capacity, consumer support, and other indicators of progress also vary significantly across states participating in the Collaborative. All of these factors are, and will continue to be, a reality within which implementation of a national health IT and HIE strategy will occur. Considering these dynamics, it is clear that state-level engagement in interstate HIE, both regional and nationwide, faces significant challenges until the basic legal, political, market, and technology components to support HIE exist within individual states and they are able to achieve their own local goals for improving health and health care.

States are moving at different rates and with different priorities in addressing state law barriers to HIE. A number of states have adopted laws specifically aimed at facilitating electronic HIE, while others have laws originally intended for a paper-based system that lack a comprehensive and consistent approach to current as well as emerging health care information policies, practices, standards, and technologies. Many states have formed or are forming organized state-level HIE initiatives involving diverse private sector and government participation to guide statewide and regional HIE development and ensure its alignment with public policy goals. In several states, state-level HIE initiatives are in the planning stages; while in others, regional and/or statewide HIE is operational and has driven improvements in health care and reduction in costs. Given these varying stages of state HIE development and diverse approaches to privacy protections, states have different needs and different viewpoints on how best to accomplish interstate HIE.

A heightened sense of urgency was injected into the HIE dynamic when on February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (the

stimulus bill). A portion of the bill created the Health Information Technology for Economic and Clinical Health Act (the HITECH Act). The HITECH Act affects certain changes in, and expansions of, HIPAA privacy and security provisions, and charges the Secretary of the U.S. Department of Health and Human Services (HHS) with issuing new clarifying guidance and promulgating regulations in specific areas. The timing of the bill and forthcoming guidance did not permit the Collaborative to analyze the specific implications of the bill on the work of the Collaborative.

The states in the Collaborative represent a diverse cross-section of stages of HIE development as well as a wide-ranging spectrum of privacy approaches in state law. With the HITECH Act as additional impetus for advances in HIE, it is even more critical to give careful consideration to the current HIE landscape, with all its inherent dynamics, since it is the basis upon which progress will be made. The vantage points of the Collaborative participants are grounded in the realities of this complex HIE environment and, in acknowledgment of differences, the group offers numerous views on potential paths forward. The breadth of these views is represented in the options presented in this Section 4.

4.2 Presentation of Options

In the current HIE environment characterized by differences in state PHI disclosure laws, varying rates of progress, and a national HIE agenda driven forward under the stimulus bill, both federal and state-driven activities to advance HIE will likely continue. If state and federal leaders can articulate a coordinated plan for realizing continuity in the legal and regulatory infrastructure to support nationwide HIE capabilities, it will take many years to implement. However, the use of policy, contracts, interstate compact, and technology options are relatively more expedient, flexible mechanisms that may bolster progress in interstate HIE in the near to medium term.

Amidst the continuing backdrop of variations in laws and regulations, the Collaborative offers a range of options to support incremental movement toward a common solution to nationwide electronic HIE to address variation in consent. The specific options described in this report represent a collection of diverse approaches that the Collaborative discussed. The options were developed in response to a set of critical realities that emerged from the review of state laws and regulations pertaining to interstate disclosure of PHI for treatment purposes. The options are intended to simplify the current complexity of varying state approaches to privacy and enable and accelerate realization of the benefits of HIE at interstate and national levels. These options have implications for key HIE stakeholders, including health policy and lawmakers, health care organizations and clinicians, statewide and regional health information organizations, and health IT vendors and service providers.

The options presented below outline progress that can be made to address reconciliation of state disclosure and consent laws and articulate potential next steps that will support the goals of protecting patient privacy and confidentiality, while enabling the acceleration and expansion of interstate electronic HIE. Options are organized based on whether they are driven by: (1) a single, nationwide approach; (2) a state-based approach or; (3) a current-day approach, meaning the options assume variations in state law and attempt to address and manage them.

This collection of options, especially when viewed in the context of the full range of HISPC Phase III projects, is intended to stimulate discussion and, ultimately, promote decisive action by ONC, states, and organizations. This Collaborative supports leveraging such work as new starting points from which to plan, design, and implement feasible and practical approaches to enable appropriate privacy and confidentiality protections so that nationwide electronic HIE can be realized.

4.2.1 Option Set 1: Nationwide Approach

As supported by the results of the Collaborative's analysis, the critical reality is that states have complex, often ambiguous state laws governing when PHI can be disclosed with and without consent. In addition, when consent is required, states have different standards for what elements are required in a consent form. Certainly, the most direct option for reducing and/or eliminating the differences between state law requirements is to establish and implement a nationwide HIE regulatory framework that would preempt or take precedence over state laws that may conflict with the national framework. Federal preemption could be narrowly targeted or more broadly applied. This option could be accomplished in several ways to achieve nationwide consistency in privacy approaches:

Option 1A: Federal privacy laws could be amended so they preempt state laws, thus establishing one common, nationwide set of rules for disclosure and consent. This would entail delineating when consent is required, and then establishing one standard consent/authorization form (or electronic equivalent) that states would be required to use (e.g., a form could include a provision for participation in an HIO and disclosure of PHI via the HIO to authorized requestors in other states). Whether changes to federal privacy laws should require consent more often or less often is a more difficult and contentious issue, especially when considering how changes may impact disclosure and consent practices relative to current state laws.

Option 1B: A more narrow, targeted federal approach is to enact new federal law(s) to specifically permit HIO-to-HIO exchange of PHI (e.g., in the context of the Nationwide Health Information Network-NHIN) for treatment purposes according to defined consent requirements, if certain conditions are met. The initial focus on treatment purposes as a disclosure parameter is intended to demonstrate feasibility and to encourage provider and consumer acceptance of the legal and technical mechanisms to support privacy protections

in network-to-network exchanges. Further, a narrowly defined implementation of disclosure laws specific to NHIN exchanges is responsive to public demand that privacy protections keep pace with HIE technology. This approach is also consistent with the wisdom behind incremental implementation strategies that have been adopted by newly established HIOs. For example, such new federal law(s) could be limited to only state-approved or state-designated HIOs and other HIOs that participate in NHIN and are compliant with specific standards and certification criteria. This new federal law would preempt state disclosure/consent law and provide a safe harbor for certified or accredited HIOs involved in exchange of PHI with other certified HIOs for treatment purposes. The goal of such a law would be to standardize consent requirements for HIE at the HIO-to-HIO level to allow the flow of PHI to requesting providers using HIOs requiring “less consent” to and from HIOs requiring “more consent” across the NHIN for treatment purposes. For example, such a law could be structured so as not to preclude an HIO from requiring (by law or policy) consumer consent to participate in that HIO, (i.e., with participation meaning some combination of: (a) the transmission of that consumer’s PHI to or through the HIO; and/or (b) accumulation of that consumer’s PHI in the HIO; and/or (c) disclosure of that consumer’s PHI to authorized persons who access the HIO for their treatment) with the understanding that this consent could permit the disclosure and redisclosure of information through the certified HIO to the treating providers of that consumer only if the requesting providers were using certified HIOs. The law could be structured to allow patients to participate in a primary HIO and have a choice as to whether they want to allow their PHI to be disclosed to providers using other certified HIOs. The law may stipulate that any other uses of the PHI requested from other HIOs could require additional consent for disclosure by the HIO.

Benefits and Challenges of Implementing Option Set 1

The primary benefit of implementing changes to consent and disclosure laws using a nationwide approach, such as federal preemption of state laws, is that a consistent approach to privacy protections for HIE could be realized immediately. Potential beneficiaries would depend on the extent of federal preemption relative to current state law, i.e., the extent to which changes to disclosure requirements in new federal laws differed from a given state’s laws. In a “strengthening federal law” scenario, consumers may indeed be the primary beneficiaries, while some in the health care industry would face the burden of increased compliance requirements. Detailed analysis is needed to understand the impact of strong privacy protections on consumer support for accelerated HIE and determine what impact stronger disclosure laws and consent requirements could have on provider workflow and the advancement of electronic HIE.

There are also challenges associated with federal action. Enacting legislation or promulgating regulations has historically been a slow process. In addition, while federal preemption could potentially significantly reduce variation across state laws, it could,

conversely, increase variation in practice, as seen in the varying interpretations and misunderstandings of HIPAA when initially enacted.

Changing disclosure and consent laws at the federal level could have dramatic impacts on current HIE practices, technology, and business models. Any change in federal law, whether perceived as positive or negative, would create disruption.

For example, PHI that had already been collected and used under certain authority may no longer be permitted to be used, or would be subject to new consent requirements, if the new law imposes the requirement of obtaining patient consent where one had not existed before. The same concern exists where an organization involved in HIE had been using a consent form for collecting and using PHI that may now not meet the requirements of a new federal consent form. Addressing administrative and technical details will increase the burden of work for organizations required to comply.

With respect specifically to Option 1B, if the HIO consent requirements under federal law are different than those provided for in a given state law, this could create a ‘double’ consent requirement if the law was not clearly defined or it could create consent requirements where none currently exist. It should be noted that some states, such as Rhode Island and Minnesota, are already enacting separate laws that pertain only to HIOs; therefore, there is a precedent for differences in consent if the HIE mechanism uses an HIO. Because some HIOs permit consumers to specifically identify who can access their records, a preemptive law that allows HIO-to-HIO sharing must consider exclusions to disclosure or risk deterring some consumers from wanting to participate at all.

4.2.2 Option Set 2: State-Driven Approach

The variations in state law approaches to the requirement of consent for disclosure of PHI affect all states, but particularly states with border towns or other medical trading areas that cross state lines. The options below take a more state-driven approach and suggest methods to reconcile state privacy laws as a national priority for health reform.

Option 2A: Consider approaching changes in state health information disclosure laws on a “trading partner” basis where groups of contiguous states or medical markets develop a plan for resolving differences. Ideas for plan development include consideration of creating interstate data sharing agreements or state-level master data sharing agreements that reflect common contract terms for HIE between entities within and among participating states. Eventually, these agreements could be aggregated into a single agreement governed by an appropriate “designated entity.”

In addition, consider developing/assigning a federally designated organization to coordinate and support this “trading partner” approach. Explore roles for this national entity varying from facilitative (ensuring lessons learned and success accomplished on state and regional

levels is documented and communicated nationwide); to authoritative (holding "master exchange contracts" with each state or state-designated HIO entity).

Option 2B: Target amending state privacy laws and/or developing model laws for disclosure to reduce variation in specific types of disclosures. Some areas to focus on include:

- i. Structure laws to address the "reason for disclosure," e.g., treatment, rather than having different disclosure rules based on who holds the data.
- ii. Allow a medication history exception to restrictions on the disclosure of sensitive data (i.e., HIV and mental health), thus allowing medication history to be shared without consent.
- iii. Establish one definition for emergency and allow disclosure of PHI without consent in emergencies.
- iv. Allow use of a one-time consent for disclosure of PHI held in repositories or routed through HIOs (instead of consent for every use, as mandated by some states).
- v. Investigate variations between states' approach to disclosure of Medicaid PHI. Conduct a project focused specifically on state Medicaid programs to document variations and commonalities between state programs regarding disclosure of patient data for treatment (and other) purposes. This analysis would have to entail multiple levels, i.e., a business practice and policy level and a legal level. Then focus on the next step of coming up with a common approach to reconcile variations between state approaches. Another option would be to request guidance from CMS on how states should interpret federal Medicaid law.
- vi. Pursue other state-held PHI sources (e.g., prescription monitoring programs, public health lab, registry data) and alignment of state laws and policies for disclosure.

Option 2C: Develop interstate HIE use cases that allow sharing of defined types of PHI with the greatest number of states based on a uniform consent requirement. This option is derived from the Collaborative's finding that on average, about half of the 11 states permit the disclosure of certain types of data without consent for nonemergency treatment. Building on HIE scenarios in which disclosures may be permitted in a higher proportion of states, perform a broader analysis of disclosure and consent requirements and document the likely disclosure outcomes that would result under specific HIE use cases. From such analyses, propose a framework for HIE policy development that will help HIOs develop policies that allow information sharing among organizations in the most number of states. For example, a detailed use case could be constructed in which diagnoses, procedures, and medication history were to be exchanged without consent to determine which, of all state laws, would permit specific PHI holders to participate in HIE. Similar analyses using different PHI types and PHI holders may provide additional insights into segments of HIE that have

the fewest barriers and, therefore, may help shape HIE priorities based on what types of exchanges are most feasible.

Benefits and Challenges of Implementing Option Set 2

Incremental progress may potentially be achieved by targeting high value, focused types of HIE, such as the disclosure rules for medication history and building consensus. The process of revising state law to remove variations that inhibit exchange with other states could be tied to clearly defined interstate HIE objectives and processes that result from building HIO trading partner arrangements between states.

Focusing on a trading partner approach would support resolving differences in regions that would benefit more directly from reconciling state privacy approaches. Model laws have worked well in some industries (e.g., Uniform Commercial Code, the Uniform Electronic Transactions Act, and the new Uniform Probate Code). These efforts are time consuming, but can yield good results.

Despite these benefits, the legislative processes are unpredictable, and attempting to develop common disclosure and consent standards across all states through the legislative process would likely more variations. It is unlikely that amending state laws would fully resolve the current variation between states that was identified through the research, because variations in interpretation of said laws may still continue from state to state.

Relative to Option 2B, national reference guidelines would be required for reasons of disclosure, to avoid inconsistencies in how each state defines them.

A draft model law for disclosure and consent rules may be difficult to implement in states, and must take into account the proliferation of disclosure and consent provisions across many statutes (e.g., some PHI-specific laws such as HIV, professional licensing statutes, regulations specifically for certain facilities, etc.). For a model law to reduce variation between states, it would have to preempt other state laws that may also prescribe certain disclosure rules or activities. Model laws typically take at least 3 years to develop, according to sources at NCCUSL.⁴⁶ State law approaches vary greatly, which may extend this timeframe estimate even more. In addition, the states are free to adopt and modify the model law, which would most likely allow some differences to persist.

4.2.3 Option Set 3: Current-Day Approach of Managing Within Existing State Law Framework

States' laws addressing when disclosure of PHI requires patient consent are often complex, ambiguous, and not easily understood. A simple way to understand these requirements is essential to enable treating health care providers to disclose PHI in compliance with any legal restrictions. This option seeks to work within the current framework of state laws,

⁴⁶ The National Conference of Commissioners on Uniform State Laws (<http://www.nccusl.org/>).

preserving the states' ability to govern and regulate local health care delivery and specifically how health data are shared and protected within a given state. The option presented below describes an approach to perform ongoing reconciliation of differences in state laws to enable interstate sharing of PHI at the point of care with less disruption to current HIE activities, systems, and business models within the states.

Option 3A: Document in a simple, structured and standardized way each state's official position on when disclosure of PHI for treatment can be made without consent, and if consent is required, what the elements of the consent are. If successful, this consent position can be used to facilitate examination of and reductions in variations in consent requirements and, ultimately drive electronic HIE solutions to actively manage persistent variations in consent requirements. More specifically:

- i. The steps to initiate development of the concept are:
 - a. Create a standardized rules structure in which to document state positions in simple, objective terms (e.g., in terms that can eventually be utilized for disclosure decisions in an electronic system). *[Note: this would not be merely documenting the state's current complex and often ambiguous laws, but rather simplifying the representation of the state's laws and policies on the disclosure of specific PHI for treatment purposes.]*
 - b. Engage states to officially confirm that the state's profile satisfies the state's legal, regulatory and policy requirements for the following rules: (1) Rules for when consent is or is not required for disclosure of PHI⁴⁷ for treatment, using the structured categories; and (2) when consent is required, rules describing mandatory elements in the state's consent form(s).
 - c. Each state would define its authoritative process to certify that its profile meets applicable state legal and policy requirements (e.g., state Attorney General opinion, state health department guidance, issuing Interpretive Guidelines).
 - d. Each state would designate an appropriate point of contact to be responsible for communicating official state approval of its profile and providing updates to the database on any changes in the state's position (e.g., to reflect changes in state law).

The next step in the process is to make the state-approved information in each state's profile available as an online resource (e.g., reference guide). This would ultimately be a rules database containing certified disclosure and consent rules for all 50 states. The rules database could be released as soon as states begin to approve their profiles. There are many ways to make this rules database available to the public.

- Provide a website with a searchable database to enable a search by state, or by situation. The website could also provide aggregated reports across states.
- Release the rules database as a downloadable file. However, a mechanism for incorporating updates to the information would have to be made clear.

⁴⁷ Note this would include PHI from various sources, including state-held sources such as state Medicaid PHI.

The rules database in Phase 2 could have some simple, automated capabilities, such as a consent form generator. This could be simply printing a blank PDF, or it could be more sophisticated, such as enabling the user to input the information into the form and then print it. An even more advanced approach could be to generate a consent form that met the requirements of more than one state (e.g., if the patient had PHI from multiple states, one consent form meeting all those states' requirements could be generated).

Option 3B: As an expansion of the work in Option 3A, engage technical vendors to build the rules database capability so that it may be incorporated as a functioning consent and disclosure management component into interstate HIE networks (and/or NHIN) to enable such HIE systems to access the rules database real-time to automate disclosure decisions, facilitate reconciliation of consent requirements, and enable generation of compliant consent forms, upon request, for the disclosure situation. Pursuing this option will require the development of a system interface from the rules database to HIE systems and messaging standards for disclosing and receiving systems. These messages would use the rules database to pass the parameters necessary to make the disclosure decision. The rules database would serve as an intermediary and/or part of the nationwide infrastructure to enable HIE in compliance with state law and policy on disclosure and patient consent requirements. This option would obviously take more planning and the development of standards for communicating with the rules database; however, pilot testing could begin with a small number of states participating.

Over time, other rules and consent policies can be added to the rules database, such as:

- state disclosure rules for uses other than treatment (e.g., quality improvement, post-marketing surveillance of FDA-approved drugs, research);
- rules for disclosure of state-held PHI (e.g., Medicaid, state controlled substance prescription monitoring program, immunizations);
- HIO policy disclosure rules; and
- rules for access of PHI by patients.

Benefits and Challenges of Implementing Option Set 3

The suggested rules structure provides a standardized way to represent, in objective terms, what the legal, regulatory, and policy position for a given state about disclosure of PHI. This official state position would serve as a common basis upon which stakeholders can easily understand another state's position, compare consent requirements among different states, and discuss ways to reconcile such requirements to enable HIE. The rules structure would not simply be documenting the current complexities of state laws, but rather would simplify the rules for disclosure, with a goal of implementing those rules in an electronic system to enable interstate HIE to occur expediently. Finally, the rules concept would facilitate interstate HIE without requiring states to change their approach to privacy protections.

Information in the rules database provides a common lexicon to be used in interstate (or nationwide) data sharing agreements by outlining how interstate disclosure would be handled (e.g., PHI coming from one state may be limited to the one instance for which it was disclosed, such as an emergency, and thus must be segregated and not used by the receiving state's HIO for any future uses). The structured information in the database in Option 3A lays the groundwork for automation of disclosure decisions and electronic reconciliation of consent requirements (Option 3B is one approach to utilize such a database). Given the complexities of today's HIE environment, many diverse consent documentation requirements could be satisfied using the rules database as a single mechanism to create legally compliant consent forms for specific HIE scenarios.

This approach also offers the flexibility to align with new federal developments. The HITECH Act establishes a new federal health IT Policy Committee and charges it with considering "technologies that protect the privacy of health information and promote security in a qualified electronic health record in accordance with applicable law, and for the use and disclosure of limited data sets of such information."⁴⁸ Option 3 supports achievement of this effort.

For this approach to be successful, the federal government would need to approve and support the approach to garner enough interest to launch the concept. Similarly, this option would ideally require cooperation and coordination across as many states as possible.

Each state would have to determine the most appropriate mechanism through which to issue its official position that would meet the state's legal, regulatory, and policy requirements for disclosure of PHI to a health care provider for treatment of the patient. In addition, a process would have to be established for recording the state's position in the rules database and having the state review it prior to public release. If the state's position and its use in the course of HIE disclosure is challenged, to the extent that judgments and interpretations of state laws are codified in an official state position on consent, there may be questions about the legality of the position and the authority of the approving entity relative to the actual prevailing laws. Such risk should be assessed and a mechanism to reliably address it is needed.

This solution would also require an entity to host and maintain the online rules database and work with states to update it as laws and state positions change. One possibility would be to house this database at ONC, which would also support NHIN efforts. Financial sustainability would also need to be addressed, as would liability and other responsibilities. To the extent that organizational policies can be more stringent than both laws and the official state consent profile as envisioned in this option, organizations with more stringent policies may not want to participate in HIE efforts in which the state's profile dictates consent and disclosure rules unless such additional policies can also be accommodated in

⁴⁸ § 3002(b)(2)(i).

the rules engine. Option 3B, as envisioned above, would require the development of an interface to the rules database, and the development of messaging standards for communicating with the rules database (e.g., between disclosing and receiving systems). Any use of the rules database within NHIN or other interstate HIE networks would have to be clearly delineated and technical barriers overcome.

4.3 Conclusion

The detailed analyses and focused work of the Interstate Disclosure and Patient Consent Requirements Collaborative has illuminated the specific nature of variations in state laws pertaining to the disclosure of PHI and related consent requirements. There are industry demands for safer, higher quality, and more efficient health care delivery, coupled with ambitious federal goals for accelerating the use of health IT to support the proliferation of secure HIE networks. In response to these needs, the Collaborative's findings suggest the problem of variation in state disclosure laws and regulations is extensive and in some areas problematic and worthy of decisive action.

The total dynamic created by our need for significant improvements in health care quality, safety, and affordability, coupled with a fragmented legal and regulatory structure, differing rates of health IT adoption, and rising consumerism, point to the need for interventions that both enable HIE and demonstrate a commitment to protect consumer privacy and the confidentiality of health information. If we are to realize HIE at an NHIN scale, the most likely path forward must go far to solve the problem of variation in state disclosure laws, either by eliminating variation or, conversely, managing variation to neutralize its impact on HIE. The three option sets described in this report represent a range of approaches carefully constructed for serious consideration, each with benefits and challenges. The Collaborative intends and hopes that after careful evaluation, some combination of these options could serve as significant departure points and yield meaningful progress to reduce barriers to interstate HIE and accelerate the realization of NHIN to help transform our health care system.