

Health Information Security and Privacy Collaboration (HISPC) Multi-State Collaboration

Interstate Disclosure and Patient Consent Requirements

June 11, 2009

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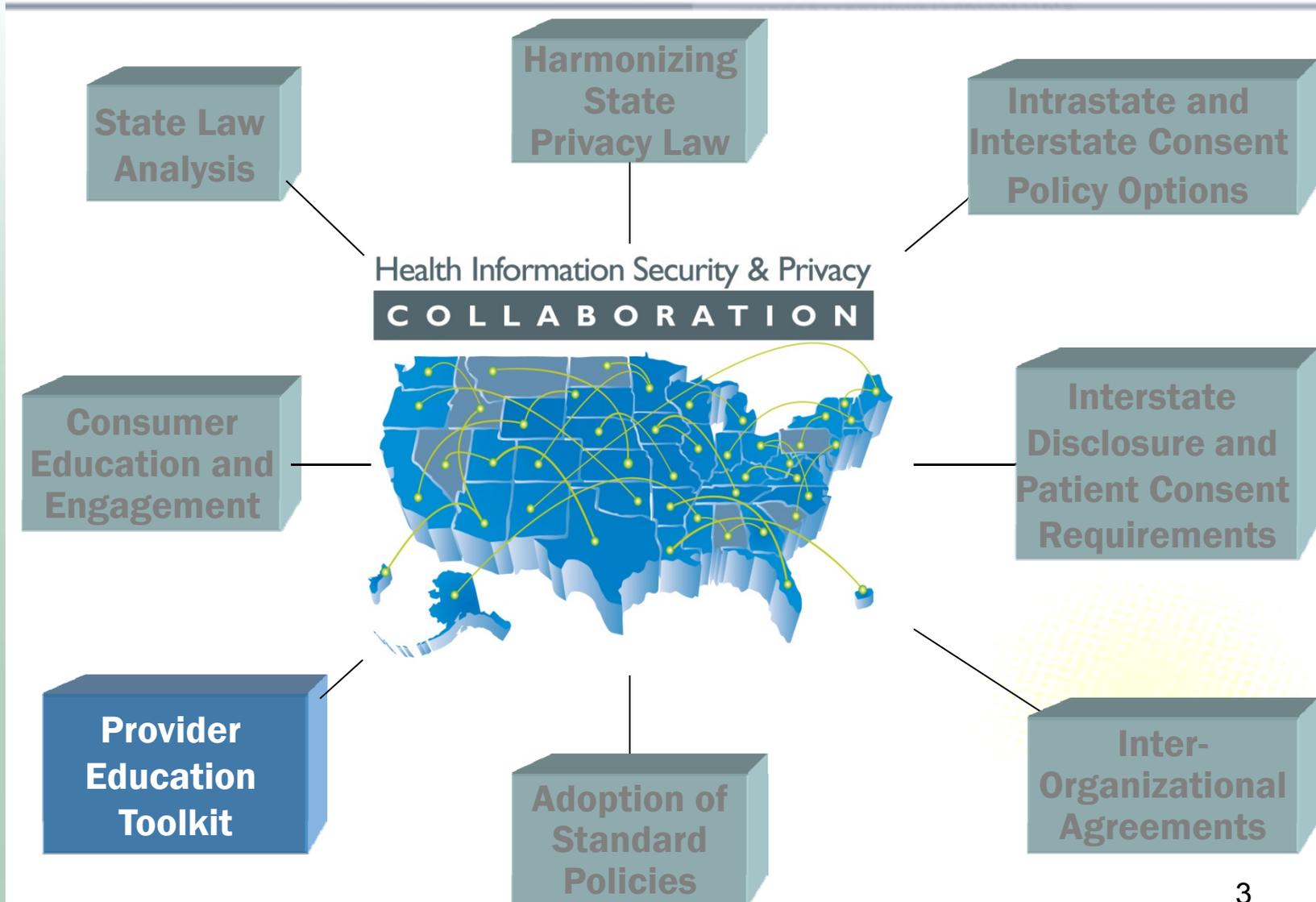
Health Information Security & Privacy
COLLABORATION



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- If you have a question during the presentation, please send it in the Q&A box in the bottom right corner. At the end of the presentations, there will be a question and answer period.
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- All HISPC materials can be found on the web: <http://healthit.hhs.gov/HISPC>

HISPC Phase III



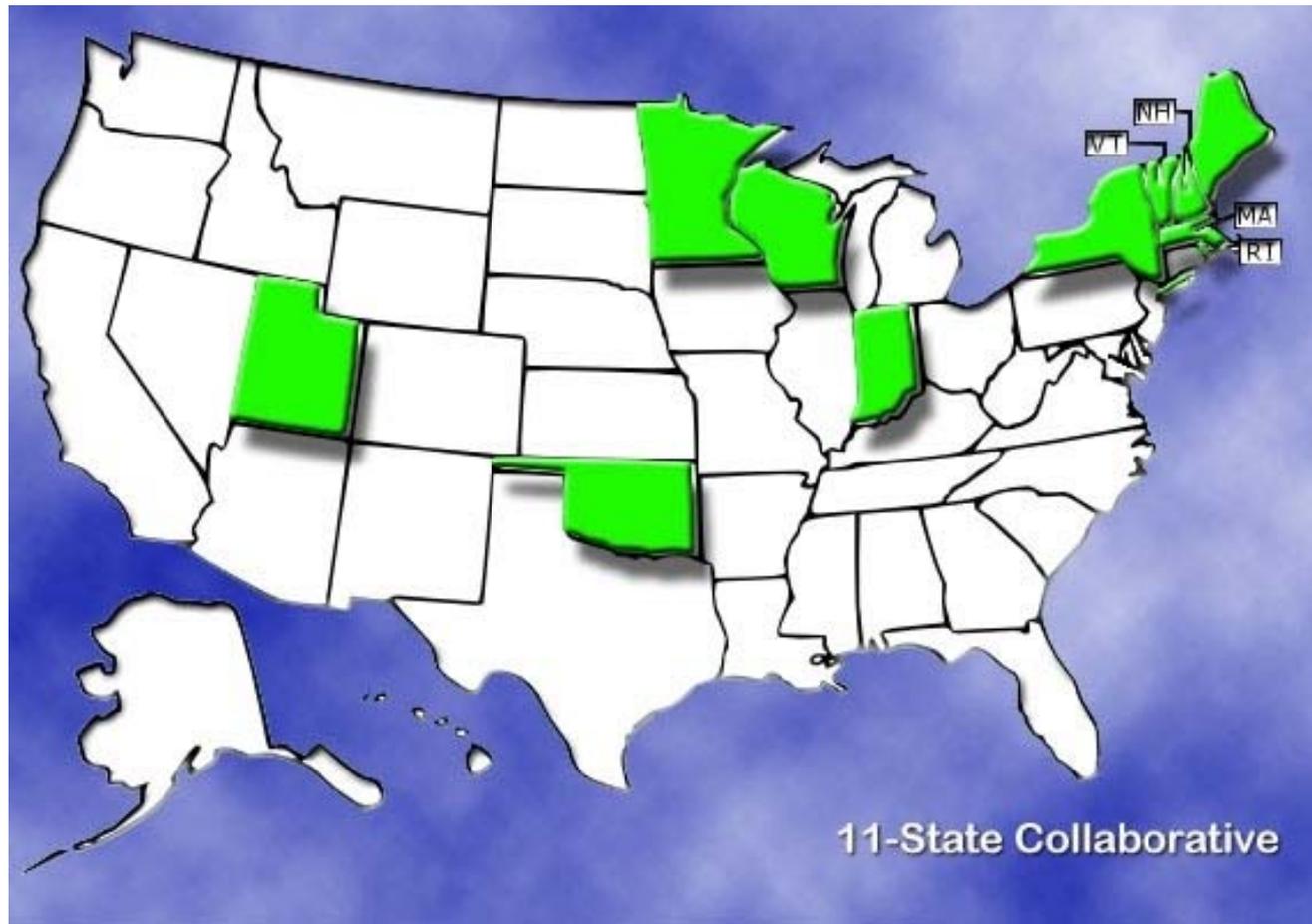
Agenda

- Project background
- About the templates
- Findings from 11 states

Learning Objectives

- Understand:
 - Consent Collaborative process
 - Interstate patient consent challenge
 - How consent templates address the challenge
 - How to use the consent templates
 - Interstate consent findings
 - Options for reducing interstate variability and establishing interstate consent requirements framework

Background



Problem

- HIPAA sets privacy floor
 - No patient authorization needed for treatment.
- States are free to legislate more restrictive laws.
- Result: varying privacy laws in states.
- How do we reconcile different approaches to enable interstate health information exchange?

Focus—Interstate

- Use of protected health information (PHI)
 - PHI held by physicians, hospitals, etc.
 - Certain PHI held by state government
- Situation:
 - Nonemergency treatment
 - Emergency treatment
- Is patient consent for disclosure required by state law?
 - If yes, what are the elements of the patient consent?

Process and Timeline

- Develop scenarios (April–May 2008)
- Develop and validate template (June–July 2008)
- Complete research (July–September 2008)
- Analyze results (October–December 2008)
- Develop report of findings (January–March 2009)

The Templates



Benefits of the Templates

- Offers an organized way to document state consent and disclosure laws.
- Provides clarity about state laws for disclosing PHI for specific data sources and data types.
- Provides a mechanism to identify conflicts in state law with regard to disclosure for the specified data source/type.

Limitations of the Templates

- Limited to the use of PHI for treatment
 - Doesn't include use of PHI for quality, public health, etc.
- Limited to certain types of PHI due to the scope of the project
 - For example, disclosure of reproductive health records not included
 - Policy not included
- Answers in the template represent a snapshot in time

Scenarios in the Templates

- Scenarios 1 and 2 in one template
 - Scenario 1: Disclosure of PHI in a nonemergency treatment situation
 - Scenario 2: Disclosure of PHI in an emergency treatment situation
- Scenario 3 in a separate template
 - Scenario 3: Disclosure of state-held PHI to providers treating the patient in either nonemergency or emergency treatment situation

Completing the Templates

- Process supports flexibility in approach
- Offers options for organizing and executing data collection:
 - Facilitated group session (e.g., stakeholders)
 - An individual respondent (e.g., Attorney General, health information lawyer)
 - A combination of the two

Alternative Uses of the Templates

- Could choose to complete only one part of the template or all parts
 - Could choose to complete only the first template for Scenarios 1 and 2 or only the template for Scenario 3
 - Could choose to complete only certain worksheet(s) in the matrix (e.g., Tab 4, Baseline Disclosure Requirements)
 - Could choose to complete only certain columns or rows in the matrix (e.g., only clinical data, rather than claims data held by private insurers)

Completing the Templates

- Facilitator (e.g., state project director) should be involved, at least initially, to help explain the template organization.
- Project Directors Guide is an instructional document designed to accompany the template.
- Process is expected to be at least two to three sessions:
 - one to explain the template organization and goals;
 - one after the individuals providing the responses have researched what the answers would be and completed the applicable template sections; and
 - an optional one for a group to validate the responses (i.e., Legal Working Group).

Template Organization

- Excel spreadsheet with several tabs:
 - Tab 1: Intro, Scope, Assumption, & Directions
 - Tab 2: Definitions & Exclusions
 - Tab 3: Open-ended general consent questions
 - Tab 4: Scenario and matrix of yes/no type questions based on type of PHI and source of PHI
 - Tab 5: Detailed questions contingent on matrix response
 - Tab 6: Legal citations contingent on matrix response
 - Tab 7: Specific questions if consent is required
 - Tab 8–12: Scenarios 1 & 2 template only: emergency treatment
- Optional health information organization (HIO) template

Before You Begin Collecting Information

- Review template instructions and the template content in its entirety.
- Ensure everyone involved fully understands the Assumptions, Definitions, and Scenarios (Tabs 1 & 2).
- Determine the mode of information collection most suitable to your situation.

Completing Consent Scenarios 1 & 2 Template

Tab 3

General consent questions—intent is to capture state's overall approach and key drivers in state's health information disclosure laws, regardless of treatment situation/setting.

- Nine high-level questions
- High-level regulatory overview

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	A	B	C
1		GENERAL QUESTIONS FOR SCENARIOS 1 AND 2	
2			
3	DIRECTIONS		
4		1. Complete the questions below with respect to your state law.	
5		2. These questions are intended to capture general information and key drivers in your state's health information disclosure laws, regardless of treatment situation or setting. Please consider both emergency and non-emergency treatment situations when completing these questions.	
6		3. Please keep your answers on this chart brief and at a high level. Responses are intended to give the reader an overview. The other worksheets you are required to complete will provide a chance to give a more detailed explanation of specific laws.	
7		4. Use as much room as you need. The boxes below automatically wrap text that is entered directly into this worksheet.	
8			
9		Your State Name:	INDIANA
10	QUESTIONS AND RESPONSES		
11	Q #	GENERAL QUESTIONS ABOUT STATE HEALTH INFORMATION DISCLOSURE LAWS	
12	Question 1	Does your state regulate the disclosure of PHI by where the data are created? If so, please explain.	
13	Response to Q1	<i>Generally, no. There is a general medical records statute. Most types of PHI are covered there, regardless of where it is created. One exception seems to be the pharmacist statute which could arguably apply a different standard to the disclosure of PHI. In addition, PHI created at a managed care organization is regulated under a different statutory scheme.</i>	
14	Question 2	Does your state regulate the disclosure of PHI by who holds the data (e.g., healthcare providers, healthcare practitioners, health plans, healthcare facilities or other category)? If yes, please explain. Please provide any applicable statutory definitions of these terms.	
15	Response to Q2	<i>See answer as for Q1. The general medical records statute covers a broad range of entities and individuals (see Q8 below for full definition of "provider" for this statute), but most all of them are some type of health care provider (whether individual or entity, and including mental health care providers). From an entity standpoint, there is another statutory scheme for health maintenance organizations.</i>	

3. General Questions / 4. 1A-Baseline (non-emergency) / 5. 1B-Details / 6. 1C-Citations / 7. 1D-Conser

Ready

Tab 4. 1A Baseline

WORKSHEET 1A: BASELINE DISCLOSURE REQUIREMENTS

Your State Name:

Purpose of this Worksheet:
 To capture a categorized view of when disclosure requirements exist under state law for the

Scenario #1 (Treatment – Non-Emergency): **Scenario Description**

Adult person from your state seeks non-emergency treatment from a healthcare provider in another state (e.g., doctor's office, a healthcare treatment facility such as a hospital center). What is required by your state to allow the disclosure of any and all PHI on this patient held by the "PHI Sources" below to the healthcare provider in the other state?

Directions:

- Please make sure you have reviewed the worksheet entitled "Definitions for Worksheet 1A-2A" prior to beginning this Worksheet 1A, because it provides a greater description of the rows and column labels below and specifies what is outside the scope of this project.
- Complete a copy of this Worksheet 1A indicating where consent or other disclosure requirement is mandated for disclosure in the Scenario above. If using this worksheet please note that this worksheet is formatted to print on LEGAL SIZE PAPER. For each cell below, choose from the drop down box selections of:

KEY:

- "Yes" means consent or other disclosure requirement is mandated
- "No" means consent or other disclosure requirement is NOT mandated
- "Sometimes" means consent or other disclosure requirement is mandated in some cases for this type of PHI from this type of PHI Source
- "Unclear" means the state law is unclear as to whether consent or other disclosure requirement is mandated
- "n/a" means not applicable for the particular source and/or type of PHI

Page 1

...s", "Sometimes", or "Unclear" in a cell below, use the Worksheet 1B-Details to specify the details for those cells. Please note that additional explanation is required if there is an additional disclosure requirement other than or in addition to patient consent.

...ure to complete the Worksheet 1C-Citation which is cross-referenced to the applicable Cell Reference Numbers in this Worksheet 1A.

...s" or "Sometimes" in a cell below, then you will need to answer questions about any consent that may be required in the Worksheet 1D-ConsentQs. Go to Worksheet 1D and follow the instructions there.

...columns labeled "Other" to the Worksheet 1A chart below to accommodate additional types of PHI or additional sources of PHI. If you do so, please label the columns and include the definition in Worksheet 1B: Details. If not all Other columns/rows are used, please leave them blank.

Questions | 4. 1A-Baseline (non-emergency) | 5. 1B-Details | 6. 1C-Citation | <

Answer key:
Yes
No
Sometimes
Unclear
n/a

Tab 4. 1A Baseline

Tab 2: Definitions further describes data types and sources

Rows: Types of PHI

Indiana: Emergency Treatment Scenario			Question: Is consent required for disclosure?													
WORKSHEET 1A: BASELINE DISCLOSURE REQUIREMENTS			SOURCES OF PHI													
CELL REFERENCE #			A	B	C	D	E	F	G	H	I	J	K			
TYPES OF PHI	Patient ID & demographic info	1	no	no	no	no	no	no	no	no	no	no	unclear	no	no	
	Medication history	2	no	no	no	no	no	no	no	no	no	no	unclear	no	no	
	Lab test order and results	3	no	no	no	no	no	no	no	no	no	no	unclear	no	no	
	Clinical notes/reports	4	no	no	no	no	no	no	no	no	no	no	unclear	no	no	
	Diagnosis or procedure info	5	no	no	no	no	no	no	no	no	no	no	unclear	no	no	
	Allergies/adverse reactions	6	no	no												no
	Claims data (other than med history)	7	no	no												no
	HIV test - id of person taking test	8	unclear	unclear												no
	HIV test results	9	unclear	unclear												no
	Medications used for HIV	10	unclear	unclear												no
	Diagnosis for HIV/AIDS	11	unclear	unclear												no
	Other indication of HIV/AIDS status	12	unclear	unclear												no
	Other STDs	13	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	no	no
	Mental health records	14	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	no	no
	Substance abuse	15	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	unclear	no	no

Columns: Source of PHI

Is consent required under state law for disclosure?
 Responses are Yes, Sometimes, or Unclear Go To Tab 5. 1B Details; Tab 6. 1C Legal Citations; Tab 7. 1D Consent Questions

Tab 5. 1B Details

Further Explanation provides additional details for matrix responses.

Excerpts from the actual statute/regulation/rule in quotation marks help clarify an explanation but the excerpt alone will not be sufficient as it is subject to multiple interpretations.

Additional details for matrix responses 11 to 171
And so on...

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WORKSHEET 1B: FURTHER EXPLANATION

Your State Name: INDIANA

4 To capture details of the state law(s) for the particular cells from Worksheet

5

6 Directions:

1. For any cells on Worksheet 1A that you entered "Yes", and where there is an additional disclosure requirement other than or in addition to patient consent, please explain here.
2. For any cells on Worksheet 1A that you entered "Sometimes", or "Unclear", please complete a further explanation below. You may also enter further explanation for other cells as well, if desired for clarity.
3. Please use excerpts from the actual statute/regulation/rule in quotation marks in your explanation.
4. To make completing this chart faster, feel free to reference multiple Cell Ref #s from Worksheet 1A in the left column below.
5. Use as much room as you need. The boxes below automatically wrap text.
6. See a brief example of this Worksheet B on the worksheet entitled "Example of B"

Your State Name: INDIANA

Worksheet 1A Cell Ref #	FURTHER EXPLANATION
11 to 171	This series of cells addresses a pharmacist's ability to disclose PHI without consent. Indiana law definition of "provider" includes pharmacists. (See Indiana Code 16-18-2-295). Thus, Indiana's general medical records statute (Indiana Code 16-39-1-1 <i>et seq.</i>) applies to pharmacists. Indiana's general medical records statute which permits the disclosure of health information (including medication history) for treatment purposes without patient consent under the interoperable exchange of records statute at Indiana Code Section 16-39-5-1. However, Indiana's pharmacist licensure provisions state that "[a] pharmacist shall hold in strictest confidence all prescriptions, drug orders, records, and patient information. He may divulge such information only when it is in the best interest of the patient or when requested by the board or its representatives or by a law enforcement officer charged with the enforcement of laws pertaining to drugs or devices or the practice of pharmacy." (See Indiana Code Section 25-26-13-15). This statute may cause ambiguity in pharmacists' use of prescription information, particularly because the "best interest of the patient" standard is vague. This phrase has not been interpreted in re
8A to 13K	These cells refer to PHI related to HIV/AIDS and to STDs. Indiana's general medical records statute (at 16-39-1-1 <i>et seq.</i>) allows for the interoperable exchange of records without a patient's consent. It specifically states at Indiana Code 16-39-5-1 that, "[t]his article does not prohibit a provider from obtaining a patient's health records from another provider without the patient's consent if the health records are needed to provide health care services to the patient. However, Indiana Code 16-39-1-1(b) states that the general medical records statute "applies to all health records, except: (1) records regarding communicable diseases, which are governed by IC 16-41-8-1...." Indiana Code 16-
14A to 14K	Indiana's law for mental health records permits the disclosure of a patient's mental health records without the patient's consent under certain circumstances. Those reasons are at Indiana Code Section 16-39-2-6. Disclosure without patient consent is allowed "(1) To individuals who meet the following conditions: (A) Are employed by: (i) the provider at the same facility or agency; (ii) a managed care provider ...; or (iii) a health care provider or mental health care provider, if the mental health records are needed to provide health care or mental health services to the patient. (B) Are involved in the planning, provision, and monitoring of services...." Indiana Code Section 16-
15A to 15I	Indiana's general medical records statute states that it does not apply to "records regarding alcohol and other drug abuse patient records, which are governed by 42 CFR Part 2". This reference creates some ambiguity because 42 CFR Part 2 only applies to drug and alcohol

3. General Questions 4. 1A-Baseline (non-emergency) 5. 1B-Details

Tab 6. 1C Citations

Indiana: Emergency Treatment Scenario Question: Is consent required for disclosure?

SOURCES OF PHI SOURCES OF PHI

WORKSHEET 1A: BASELINE DISCLOSURE REQUIREMENTS	Other Outpatient Facility (non-mental health and non-substance or alcohol abuse)	Substance or alcohol abuse (non-mental health) - Outpatient or Inpatient Facility	Mental Health Facility - Outpatient (including provider licensing laws)	Health Facility - Inpatient	Other Outpatient Facility (non-mental health)	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 org)
	no	no	no	no	no	no	no	no	unclear	no	no

For each cell in matrix with a response Yes, Sometimes, Unclear

Legal citation for 1I-17I and so on...

STATE LAW REFERENCE INFORMATION

Cell Ref #	Citation	Link to URL	Derives from (click to see drop down list)	Location
1I-17I	Indiana Code 16-18-2-295 Indiana Code 16-39-5 Indiana Code 25-26-13-15	http://www.in.gov/legislative/ic/code/title16/ar18/ch2.html http://www.in.gov/legislative/ic/code/title16/ar39/ch5.html http://www.in.gov/legislative/ic/code/title25/ar26/ch13.html	state law statute	health/general medical records health/general medical records licensing/pharmacist & pharmacy
8A to 13K	Indiana Code 16-39-1-1 Indiana Code 16-39-5-1 Indiana Code 16-41-8-1	http://www.in.gov/legislative/ic/code/title16/ar39/ch1.html http://www.in.gov/legislative/ic/code/title16/ar39/ch5.html	state law statute	health/general medical records
14A-14K	Indiana Code 16-39-2-6	http://www.in.gov/legislative/ic/code/title16/ar39/ch5.html		health/general medical records
15A to 15I	Indiana Code Section 16-39-1-1			health/general medical records
16I to 16J	Indiana Code Section 27-8-26-1 et seq.	http://www.in.gov/legislative/ic/code/title27/ar8/ch26.html	state law statute	insurance

Links to statutes captured for further analysis

Tab 7. 1D Consent Questions

This form is used to detail consent requirements. For each response given on Tab 4. 1 A Baseline of "Yes," "Sometimes," or "Unclear," a separate **Consent Questions** sheet is completed to understand the specific elements of the patient consent stated in statute/administrative rule.

As a result, this form may need to be reproduced multiple times.

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A3 This consent requirement applies to the following CELL REF #s from Worksheet 1A (in the shaded space below, please list all applicable cells as described in the directions):

WORKSHEET 1D: CONSENT QUESTIONS

Your State Name: **INDIANA**

This consent requirement applies to the following CELL REF #s from Worksheet 1A (in the shaded space below, please list all applicable cells as described in the directions):

Cells: I1 to I17 (PHI held by a pharmacist) and 8A to 13K (communicable disease/HIV/AIDS PHI)
To the extent that a consent would be required for a pharmacist to disclose PHI (see Tab 5 for explanation of why this may or may not be necessary), or for communicable disease/HIV/AIDS PHI to be disclosed (again, see Tab 5 which fleshes out the ambiguity), the patient would have to give the consent. However, the statute does not provide any detail as to the content of the consent. Presumably, the elements of a patient consent under Indiana Code Section 16-39-1-4 would be sufficient. Below, we make that assumption and discuss the consent requirements of Indiana Code Section 16-39-1-4.

Purpose of this Worksheet:
To document the specific details about the consent required under your state law in order to permit the disclosure of the patient's PHI.

Directions:

1. You will only use this Worksheet if you answered "Yes" or "Sometimes" or "Unclear" to one or more cells on Worksheet 1A and patient consent is required to enable the disclosure.
2. If you have more than one type of consent under your state law, then you will need to make a copy of this Worksheet 1D. Rename each new Worksheet 1D to something like 1D-Consent1, 1D-Consent2, 1D-Consent3. [Thus, if you would answer any of the questions below differently for a different cell in Worksheet 1A, you will need more than one Worksheet 1D.]
3. List all Cell Ref #s from Worksheet 1A that your answers on this worksheet apply to in the box indicated
4. See a brief example of this Worksheet 1D on the worksheet entitled "Example of D".

Your State Name: **INDIANA**

QUESTIONS AND RESPONSES

Q #	QUESTIONS ABOUT PATIENT CONSENT REQUIREMENTS
Question 1	Who must give consent to the disclosure (e.g., patient, doctor)? It is not necessary to go into detail about who can give consent on behalf of the patient. This question is only meant to capture whether someone other than the patient or his/her representative has to give consent to disclose the PHI.
Response to Q1	To the extent that a consent would be required for a pharmacist to disclose PHI or for communicable disease/HIV/AIDS PHI to be disclosed, the patient would have to give the consent. However, the statute does not provide any detail as to the content of the consent. Presumably, the elements of a patient consent under Indiana Code Section 16-39-1-4 would be sufficient.
Question 2	What form must the consent take (e.g., in writing, electronic, oral, implied)? Please be specific. <i>The patient's consent must be written. It is not clear whether an electronic communication would constitute a "written" consent. See</i>

Ready

4. 1A-Baseline (non-emergency) / 5. 1B-Details / 6. 1C-Citations / 7. 1D-Consent I / 7a. 1D-Consent II

Tab 8. Questions for Scenario 2 ONLY

	A	B	C
1	SPECIFIC QUESTIONS FOR SCENARIO 2 ONLY		
2		Your State Name:	
3	Scenario 2 (Emergency Treatment): An adult person from your state is seen by a healthcare 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 Worksheet A to the healthcare provider in the other state?		
4			
5			
6	Directions:		
7			
8			
9			
10			
11			
12			
13			
14			
15			
16	Your State Name: 0		
17			
18	QUESTIONS AND RESPONSES		
19	Q #	SPECIFIC QUESTIONS ABOUT SCENARIO 2 ONLY	
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			

Are consent requirements disclosing PHI for emergency treatment different from nonemergent?

If yes, complete a similar matrix for emergent disclosure requirements Tab 9. 2A- Baseline and steps for completing the Details, Citation and Consent questions.

If no, the template is complete.

Completing Consent Scenario 3 Template

Your State Name: **Indiana**

Scenario 3:
Disclosure of
state-held PHI
for treatment

Columns:
Type of Provider
Seeking Access
to State-Held PHI

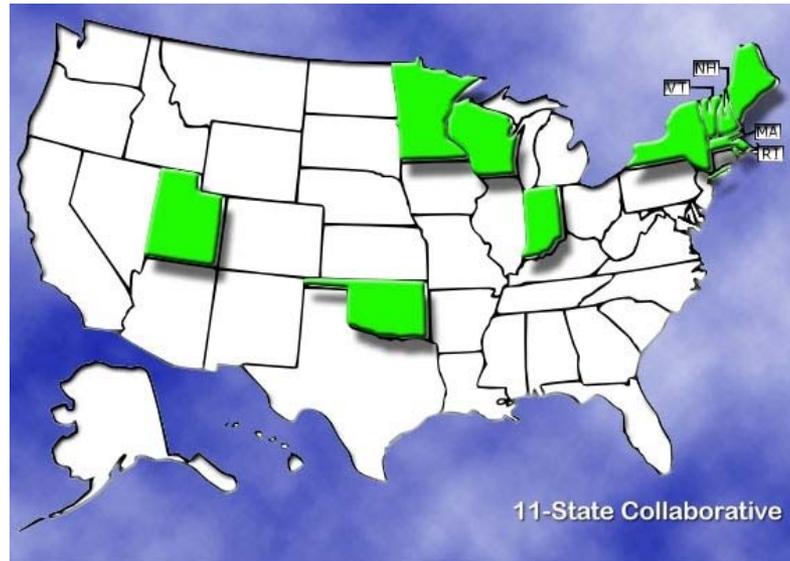
WORKSHEET 3A: BASELINE DISCLOSURE REQUIREMENTS		TYPE OF PROVIDER SEEKING ACCESS TO PUBLIC HEALTH PH							
		Hospital	Other Inpatient or outpatient facility	Physician	Non-physician provider	Pharmacist			
CELL REF #		A	B	C	D	E	F	G	
TYPES OF PUBLIC HEALTH PH	Immunizations	1	yes	yes	yes	yes	yes		
			1A	1B	1C	1D	1E	1F	1G
	Medication history from PMP	2	yes	yes	yes	yes	yes		
			2A	2B	2C	2D	2E	2F	2G
	Newborn screen - metabolic	3	unclear	unclear	unclear	unclear	unclear		
			3A	3B	3C	3D	3E	3F	3G
	Newborn screen - hearing	4	unclear	unclear	unclear	unclear	unclear		
			4A	4B	4C	4D	4E	4F	4G
	Lead results	5	n/a	n/a	n/a	n/a	n/a		
			5A	5B	5C	5D	5E	5F	5G
	HIV results	6	unclear	unclear	unclear	unclear	unclear		
		6A	6B	6C	6D	6E	6F	6G	
STD results/registries	7	unclear	unclear	unclear	unclear	unclear			
		7A	7B	7C	7D	7E	7F	7G	
Communicable	8	unclear	unclear	unclear	unclear	unclear			
		8A	8B	8C	8D	8E	8F	8G	
		9	n/a	n/a	yes	n/a	n/a		
		9A	9B	9C	9D	9E	9F	9G	
		10	n/a	n/a	n/a	n/a	n/a		
		10A	10B	10C	10D	10E	10F	10G	
		11	n/a	n/a	n/a	n/a	n/a		
		11A	11B	11C	11D	11E	11F	11G	

Rows:
Types of State-Held PHI

Templates: Summary and Lessons Learned

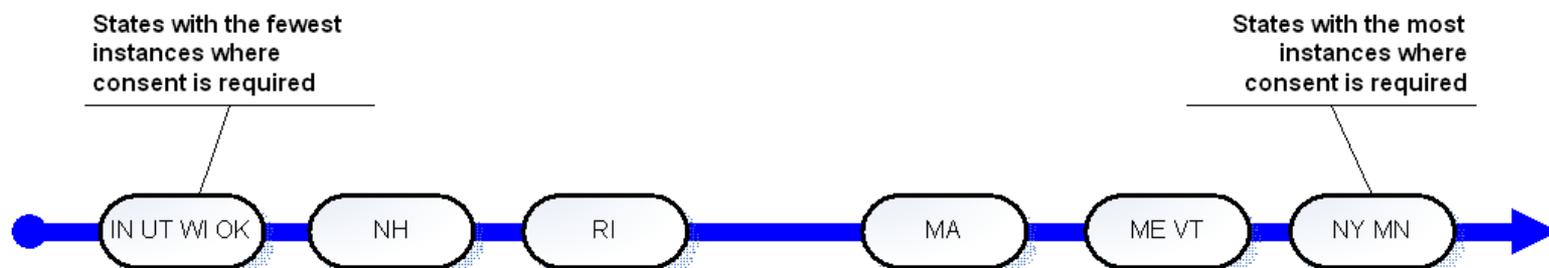
- Valuable tool for organizing and reconciling interstate consent requirements
- Valuable tool for in-state/interstate education
- Valuable process to help identify key areas of conflict and/or ambiguity in current laws
- Subject to limitations
- Do not simplify all state requirements to simple Yes/No answers
- Do not eliminate need for interpretation

Findings from 11 States



Findings: Wide spectrum of state law approaches

- Nonemergency Treatment



- Emergency Treatment



Note that reference to “the fewest” and “the most” requirements may not reflect the level of restrictions placed on disclosure, but rather may simply reveal a level of completeness or complexity in terms of a state’s laws and how they are structured.

Goal of the Project

- Goal: Establish a model for identifying and resolving consent and disclosure requirements across states.
- Objective: To collect information to allow 11 states to compare state consent and disclosure laws, specifically with regard to interstate exchange.

Challenges of the Project

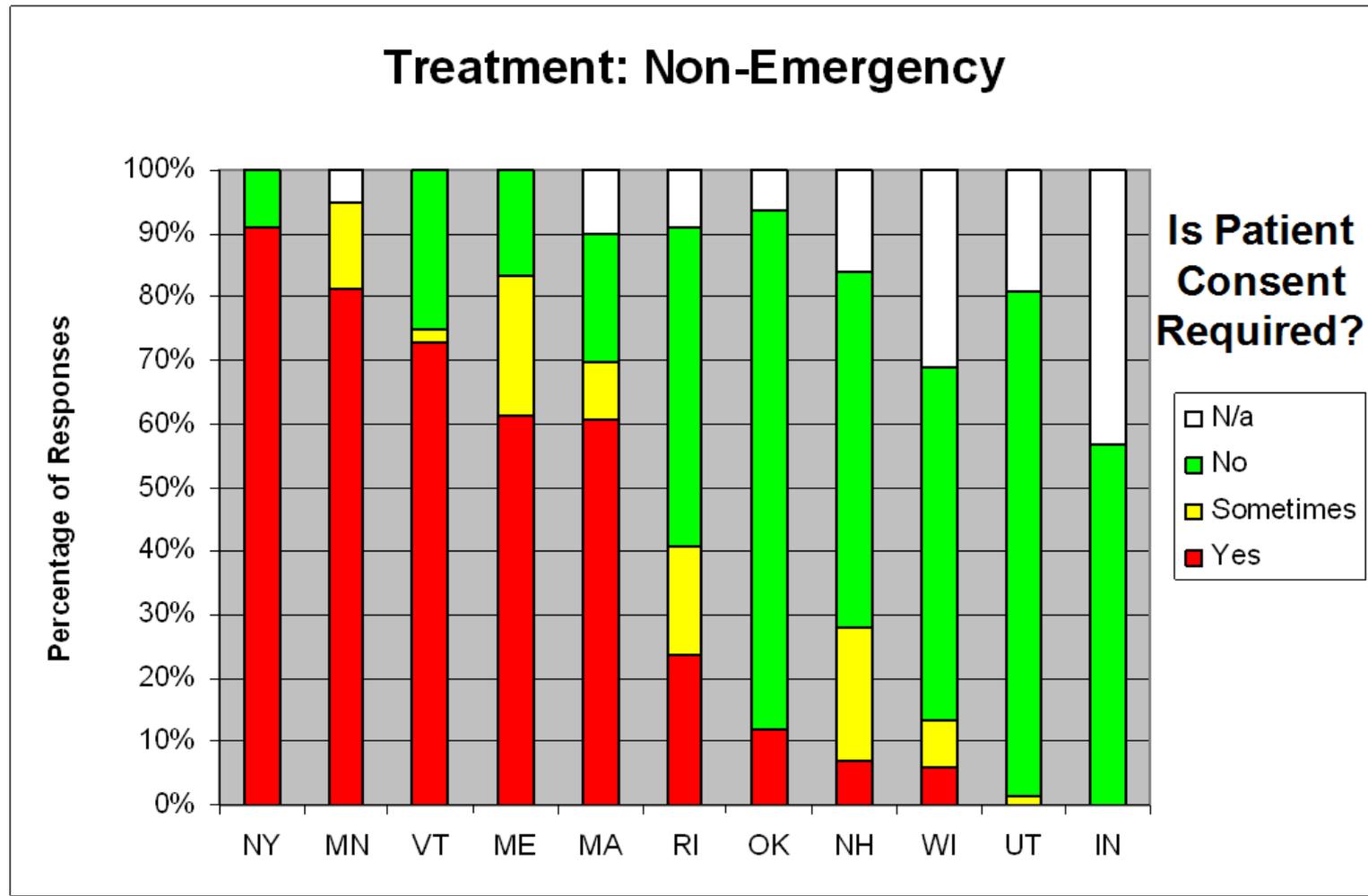
- Answer to question of disclosure often spread out over many statutes
 - General medical records statute
 - Statutes covering specific types of PHI, such as
 - HIV tests
 - mental health records
 - substance abuse treatment records
 - Professional licensing statutes
 - Statutes covering the activities of a facility
 - Specific statutes dealing with an HIO-type service

Challenges of the Project

- Some statutes are very complex
 - Exceptions within exceptions
 - Complicated descriptions of PHI covered
 - Very specific types of facilities or providers
 - Some provisions are not consistent
 - Most statutes do not differentiate between access by in-state vs. out-of-state health care provider
- Plain reading of state law
 - Still subject to interpretation (ambiguous)
 - Some provide subjective decisions
 - “best interest of the patient”

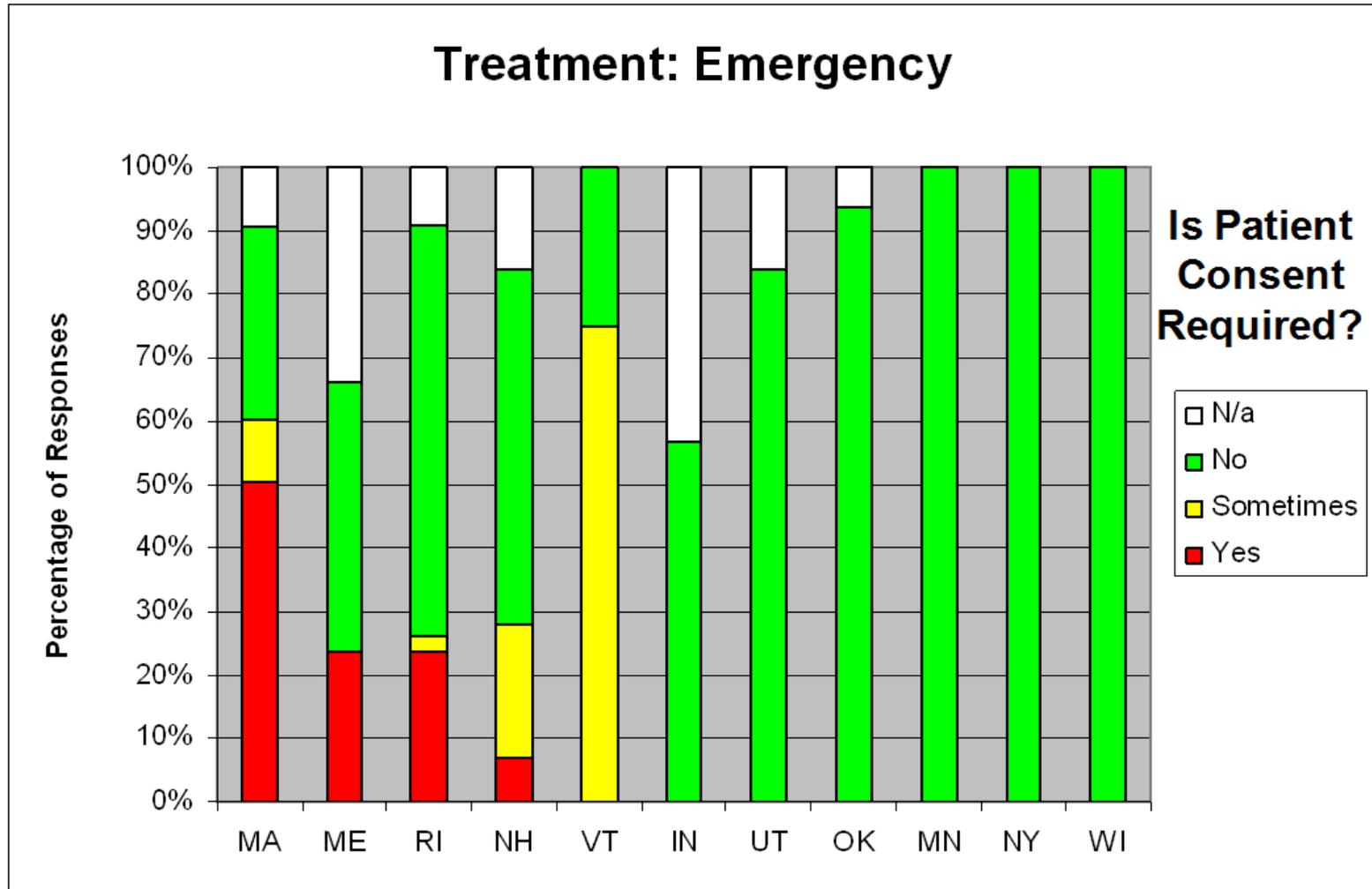
Findings By State

WILSON & JACOBS, 2004
WORLDWIDE MEDICAL SERVICES



Findings By State

WILSON, J. L. (2004). THE
WORLD EMERGENCY TREATMENT



Key Take Away Points from Graphs

- No consistent patterns across states' laws.
- Although several states permitted disclosure without consent for emergencies, the definition of emergency varied.
- Some states did not allow any disclosure even in emergency.
- Some require additional acts after emergency disclosure without consent.

Findings: Consent Specifics in Statute

- Specific elements of consent varied.
- Some states did not specify details of what should be included in the consent.
- Others set out lists of requirements and specific statements that must be included.
- Most required consent in writing; some permitted oral authorization in certain cases; other statutes did not specify.

Findings: Consent Specifics in Statute

- Some limit duration of the consent; others do not specify a limit.
- In some states, there was more than one consent form, depending on the type of PHI.
- A few states had forms officially approved by the state.

Options for Progress to Support Interstate Disclosure of PHI



Critical Reality

- Approaches to achieve widespread interstate electronic health information exchange must first address limitations created by differences in state laws.
- Not feasible to develop rules to reflect plain reading of state law because laws are
 - complicated,
 - frequently ambiguous,
 - frequently subjective, and
 - state policy may be more restrictive or may implement a specific interpretation of state law.

Options for Progress

- Options represent diverse vantage points from 11 participating states.
- Range of options for further consideration.
- Options are organized based on whether they are driven by
 1. A single, nationwide approach
 2. A state-based approach
 3. A current day approach (the option assumes variation in state law and attempts to manage them)

Option Set #1: Nationwide Approach

- 1A: Amend federal privacy laws so that they preempt state laws, thus establishing one common, nationwide set of rules.
- 1B: Amend federal privacy laws only to specifically permit HIO-to-HIO exchange of PHI for treatment purposes (in context of NHIN).

Option Set #1: Benefits and Challenges

- Consistent, nationwide approach; however, Option 1B does not address in-state and could create a double consent standard.
- A stronger consent law could impact provider workflow and costs.
- Changing laws impacts current HIE activities and business models.
- Federal law change can be a slow process.

Option Set #2: State-Driven Approach

- 2A: Groups of “trading partner” states develop a plan for resolving differences in law and possibly creating a state-level master data sharing agreement. Could have a national entity play a role in coordination.

Option Set #2: State-Driven Approach

- 2B: Amend state privacy laws and/or develop model laws.
- 2C: Propose a framework for HIO policy development that will target HIE with the fewest barriers and permit sharing with the greatest number of states.

Option Set #2: Benefits and Challenges

- Incremental progress may be achieved by targeting high-value, focused types of HIE within regions that would benefit directly from reconciling state privacy approaches.
- Legislative processes are unpredictable and could result in more variation, not less.
- Amending state laws does not address issues of interpretation.
- A model law takes ~3 years to develop and may be difficult to implement without harmonizing statutes.

Option Set #3: Current Day Approach of Managing within Existing State Law Framework

- 3A: Document in a simple, structured, and standardized way each state's official position on when disclosure of PHI for treatment requires consent, and if so, the elements of the consent.
 - Make these state-approved profiles available to the public as an online resource (reference guide on disclosure rules and elements of consent).

Option #3B

- As an expansion of work in Option 3A:
 - Build out the rules database capability to enable automating disclosure decisions by facilitating reconciliation of consent requirements and generating compliant consent forms on request.
 - Engine could be incorporated into interstate HIE networks and/or NHIN.

Option Set #3: Benefits and Challenges

- Don't need to amend current laws.
- Not all states have to have the same disclosure laws to share PHI.
- Can make recipient aware of restrictions on further disclosure (and the PHI transmitted for this use can be flagged and/or segregated by the recipient if further redisclosure for treatment is not permitted without additional patient consent).

Option Set #3: Benefits and Challenges

- Documenting the states' positions in structured categories provide the common terminology and standardized rule sets that
 - enable a state to easily understand what the position of another state is (reduces complexity),
 - provide common lexicon that can be used in interstate (or nationwide) data sharing agreements to outline how interstate disclosure would be handled, and
 - enable the automated reconciliation of different consent forms.

Option Set #3: Benefits and Challenges (cont'd)

- Need state and federal support/approval to garner interest.
- Each state to determine the most appropriate mechanism/legal jurisdictions through which to issue its official position/profile.
- Process must be established for approving and updating state profile, and entity responsible for hosting rules database.
- Option 3B would require development of interface and messaging standards.
- Requires maintenance and updates as state laws and positions shift.

Conclusions

- No silver bullet.
- Any changes must take into account impact to existing HIE activities.
- Much work to reconcile state laws remains.
- Even if state law permits disclosure of PHI, local business practice/policy may be more restrictive.
- Combined approach to work with HIOs and other stakeholders is necessary.
- Efforts are now underway to assess the feasibility of states' "official position."

Questions



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Interstate Disclosure & Patient Consent Requirements

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Thank You for Attending

HEALTH INFORMATION SYSTEMS
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- Please visit <http://healthit.hhs.gov/HISPC> for full access to all of the products discussed today as well as information about the other HISPC collaborative products.
- Additional materials are being posted as they become available throughout the month of June.

