

2009 HISPC Seminar Series

Health Information Security and Privacy Collaboration (HISPC)

State Access and Disclosure Law Project

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Health Information Security & Privacy
COLLABORATION



Before we begin...

- All participants are in audio broadcast mode—you must enable your computer speakers to listen to today's presentation.
- If you experience any difficulty with the audio, please notify the Webex Producer.
- 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.
- Please e-mail privacy.security@rti.org if you have any questions following this presentation.
- All HISPC materials can be found on the Web: <http://healthit.hhs.gov/HISPC>

HISPC Phase III



State Law Research: Four Projects

- Patient access to medical records
- Clinical Laboratories Improvement Amendments (CLIA) issue: Persons authorized to receive clinical laboratory results under state law
- Requirements for prescribing:
 - Transmitting prescriptions
 - Specifying “brand necessary” or “dispense as written” to override generic substitution or reimbursement cap requirements
- Disclosure of identifiable health information for treatment purposes

Patient Access to Medical Records Project



Patient Access to Medical Records

- General access rights
- Minors and access rights

General Medical Record Access

- Leveraged prior project for National Library of Medicine
- Focused on records held by
 - Doctors of medicine (MDs)
 - Hospitals
- Reviewed
 - Health information access laws
 - Licensing laws
 - Evidentiary codes
 - Probate codes
 - Statutes, regulations, attorney general opinions

General Access Issues

WILSON & BERKELEY
WORLDWIDE INFORMATION SERVICES

- Scope of access
- Response time
- Record retention periods
- Format of information provided
- Copying fees



Scope of Access

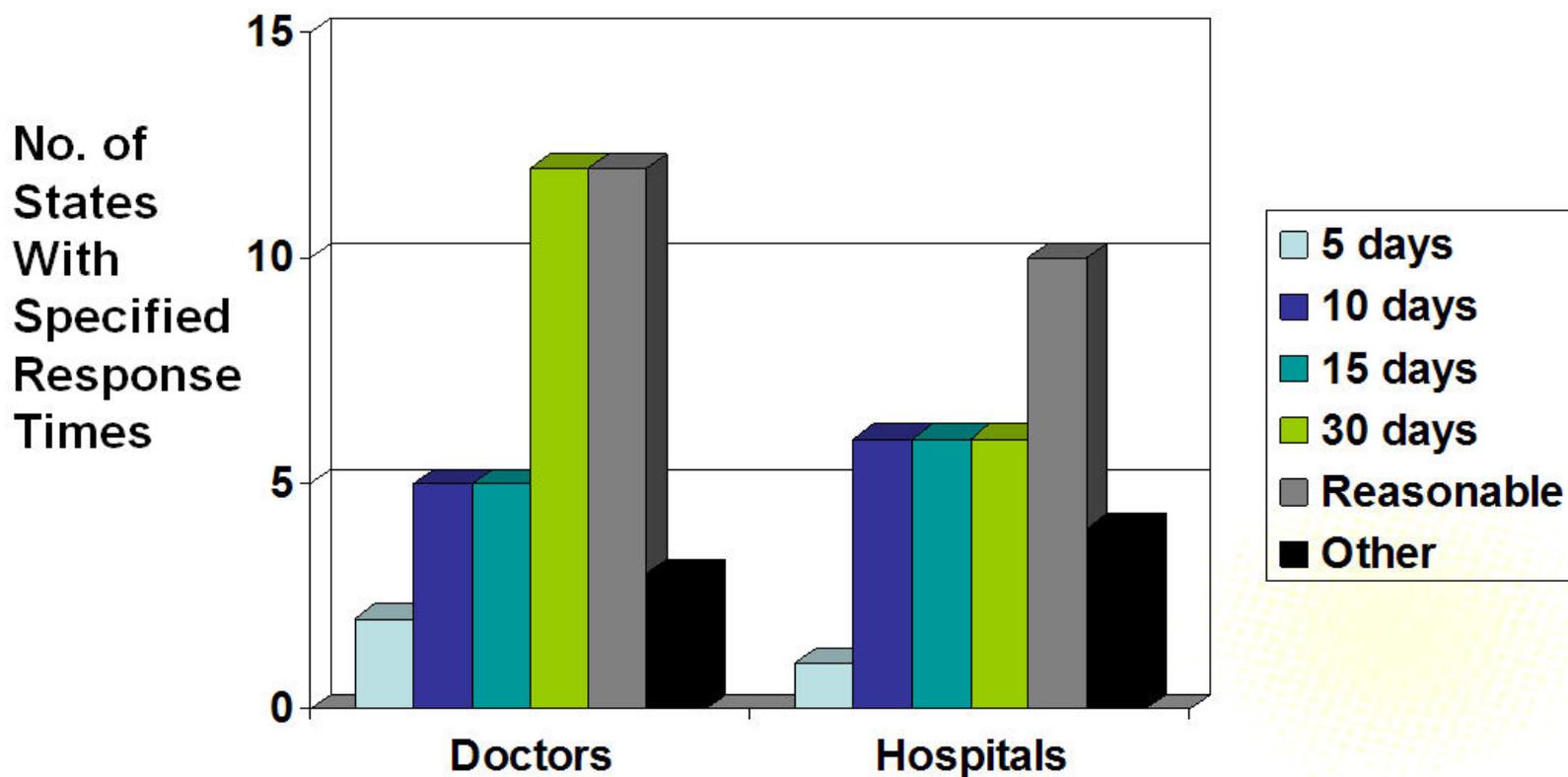
HEALTH INFORMATION SYSTEMS
SECURITY AND PRIVACY

State laws

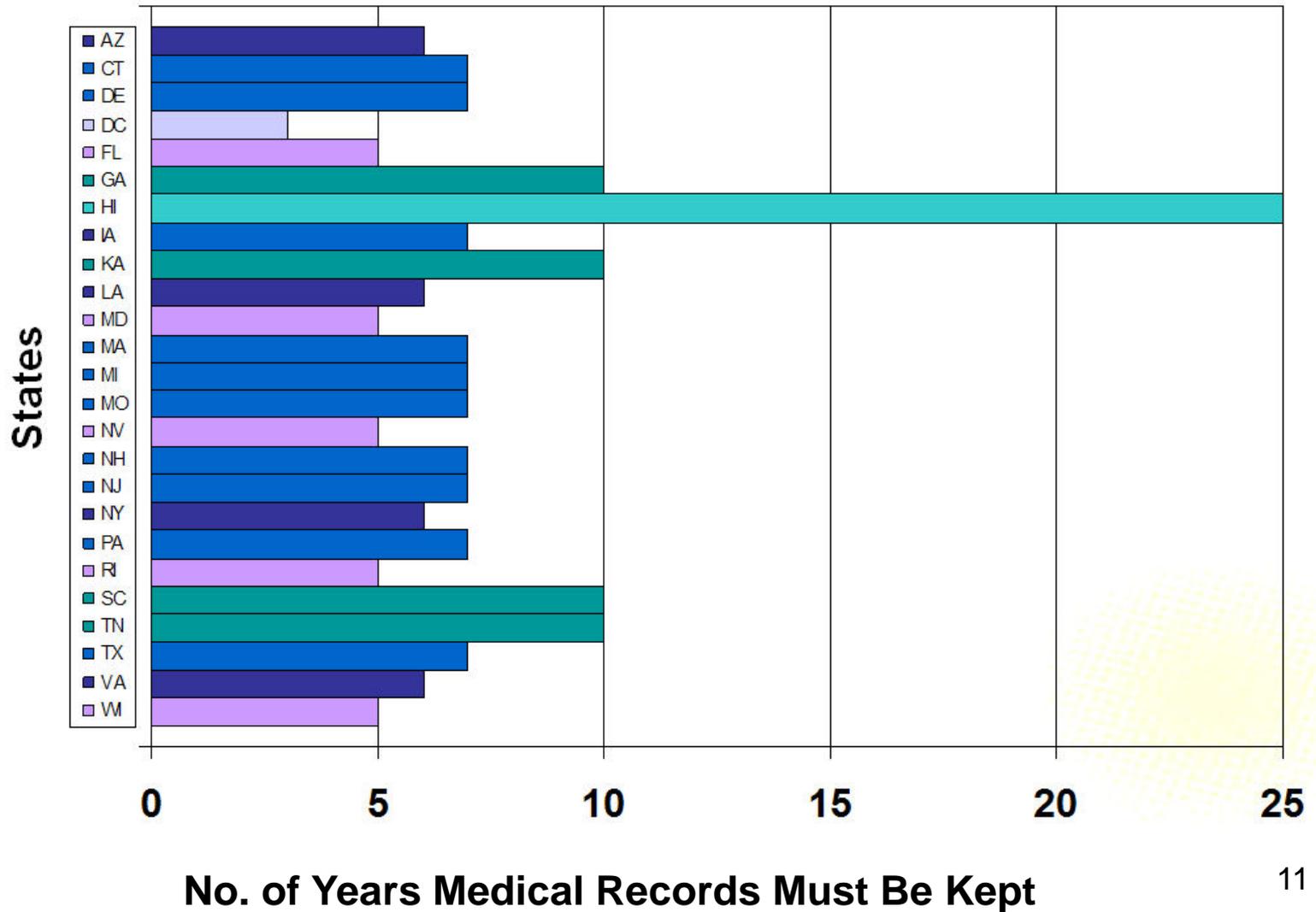
- Often fail to define “medical record” or scope of information covered by individual right of access
- Apparently interpreted as being limited to information created by that specific provider



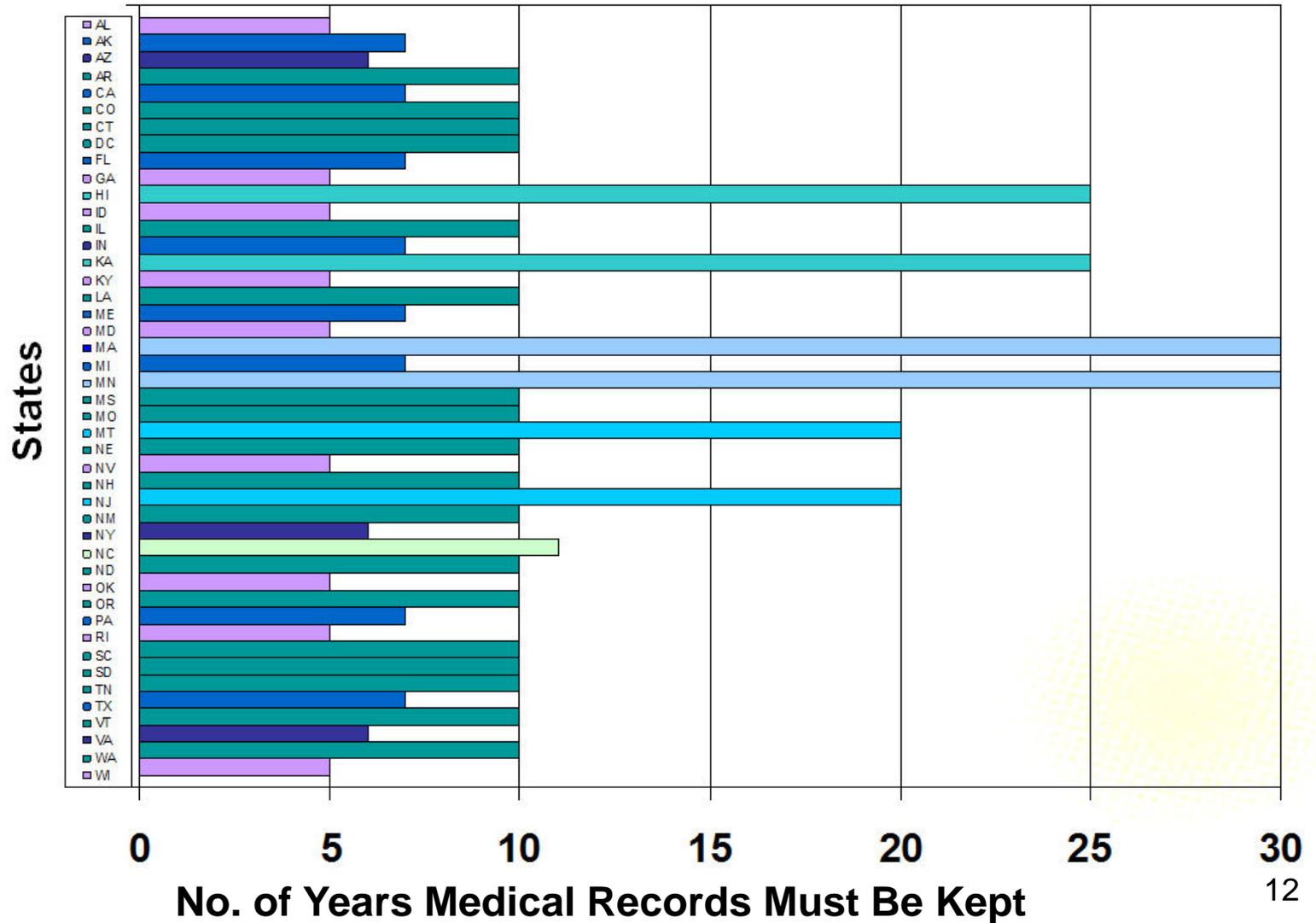
Timeframe for Responding to Access Requests



Medical Record Retention Requirements for Medical Doctors



Medical Record Retention Requirements for Hospitals



Record Retention Laws

- Tied to statutes of limitations for tort actions
- Time to shift to focus on assuring access for longitudinal care?

Copying Fees

- HIPAA generally defers to state law
- Difficult to parse out elements
- Fee for first page
 - Ranges from free to >\$40
- Fee for first 100 pages
 - Ranges from free to \$175
 - In 8 states > \$100
- HITECH Act (ARRA)*
 - Fees for electronically copying records limited to labor costs

* American Recovery and Reinvestment Act of 2009

Minors and Medical Records Access

- HIPAA generally defers to state law
- Central issue:
 - Who has the right of access to medical records of a minor?
- Related issue:
 - When must/may a provider notify the minor's parents of treatment or services received?

Minors: Preliminary Issues and Research

- Age of majority
- Other means of emancipation
- General ability of unemancipated minor to consent to care in own right
 - Life circumstances, e.g., marriage, living independently
- Statutes, regulations, attorney general opinions, related case law

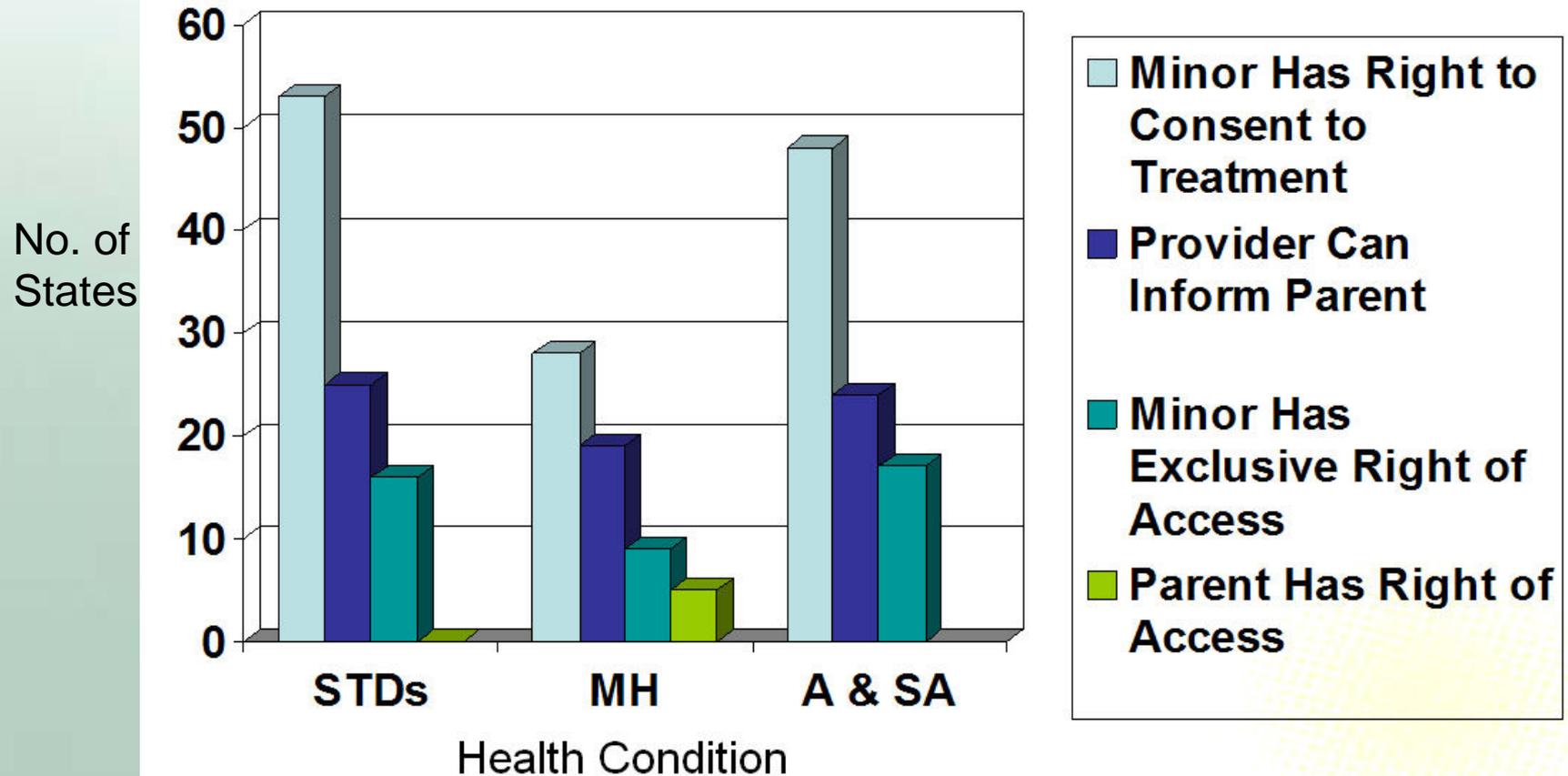
Minors and Right to Consent to Care

Researched and summarized laws addressing:

- Outpatient mental health
- Outpatient substance abuse
- STDs
- HIV

Due to limited resources, did *NOT* research/summarize laws regarding reproductive health

State Laws Granting Minors Right to Consent to Care and Providing Access to Related Records*



* Laws *expressly* addressing right of access

Access Project Deliverables

- Excel data collection chart for each state and territory (see App. B of Report)
- Excel combined charts with laws for all jurisdictions by
 - Doctors
 - Hospitals
- Report with summary findings

Tables in Report

- General Overview: State Medical Records Access Laws
- Response to Access Requests (MDs and Hospitals)
- Copying Fees (MDs and Hospitals)
- Medical Record Retention Laws (MDs and Hospitals)
- Minors' Right to Consent to Health Care without Parental Permission and Access/Disclosure of Related Health Information to Parents
- For each of above
 - Overview table (Measles chart, or Y/N, or short answer)
 - Text summary of state laws with citations

Medical Records Access Project

Questions?



State Laws on Reporting Clinical Laboratory Test Results



Federal Clinical Laboratories Improvement Amendments (CLIA)

- Test results must be released only to
 - Authorized persons
 - Individual responsible for using the test results
 - Requesting lab
- “Authorized person” means “an individual *authorized under State law* to order tests or receive test results, or both.”

State Law Issues

- Who is authorized to receive test results?
 - Providers?
 - Patients?
 - Others ?
 - Health plans
 - Health information organizations (HIOs)

State Laws Reviewed

- Clinical laboratory licensing and operating laws
- Standards for hospital laboratories in hospital licensure and operating laws
- State medical record access laws
- HIV/AIDS
 - Example of health condition-specific provisions

Deliverables

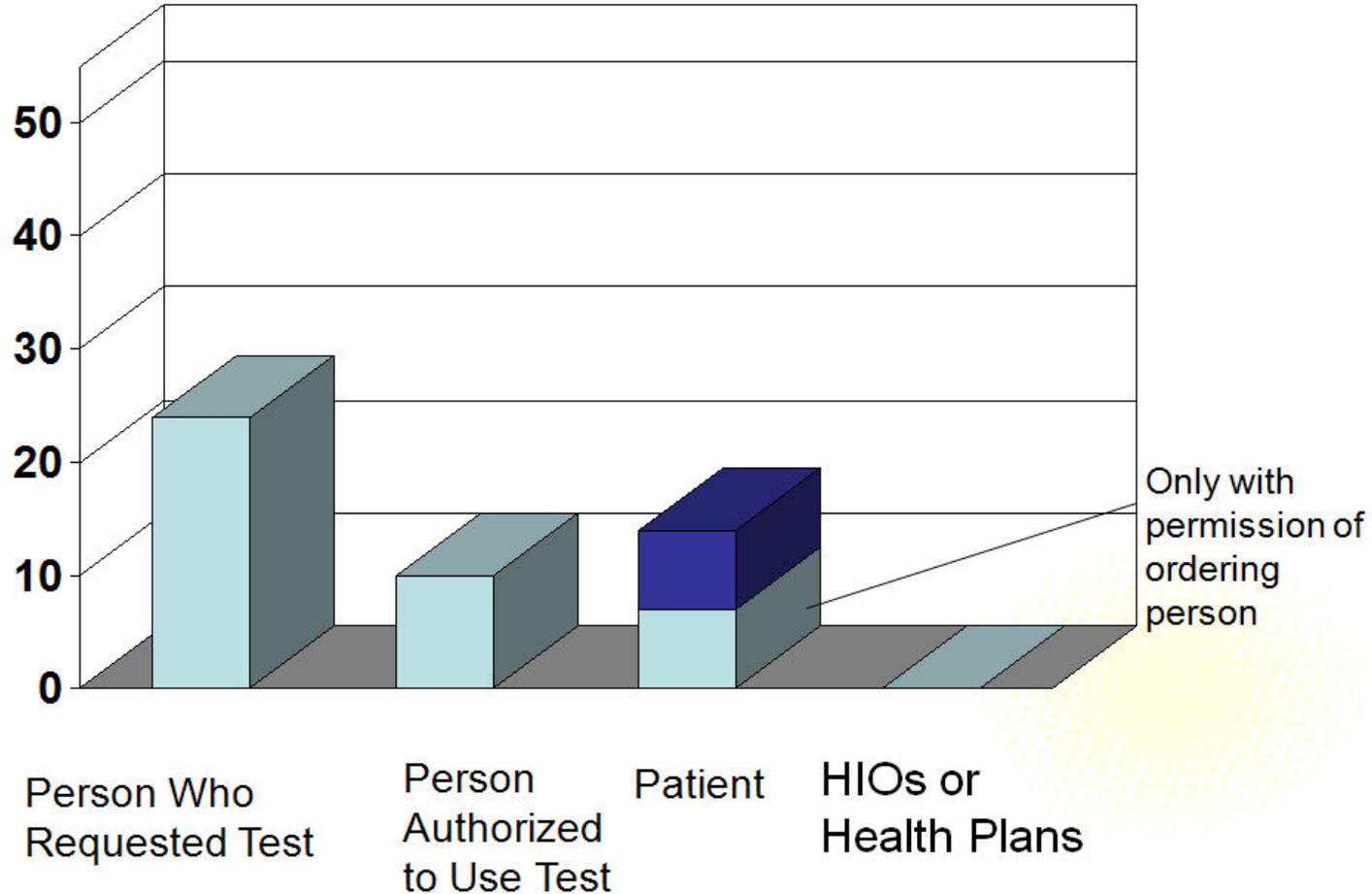
- Collated state statutes and regulations using a matrix reviewed by major stakeholder
- Entered into database
- Report

Findings: Overview

- Many state laws are silent as to who may receive laboratory test results
 - CLIA alone governs
- Clinical laboratory laws intertwined with practitioner licensing laws
 - May examine at request of and report results only to providers acting within scope of their license

States With Clinical Laboratory Licensing Laws that Expressly Authorize Release of Laboratory Test Results to Specified Categories of Persons

Number of States/
Territories



Clinical Laboratory Test Results Project

Questions?



State Prescribing Law Project



State Law Issues

- Laws governing means of transmitting prescriptions facilitate or hinder e-prescribing
- General overview
- Two issues of recent federal government action
 - Proposed regulations that will allow prescriptions for controlled substances to be transmitted electronically
 - Recent amendments to federal Medicaid regulations that allow electronic designation of “brand necessary”

Laws Reviewed

PHARMACY LITIGATION 2014-2015
SOCIETY OF PHARMACY LITIGATION EXPERTS

- Professions and occupations
 - Pharmacists/pharmacies
 - Medical doctors
- Food and drugs
 - Prescription drugs
 - Controlled substances
- Medicaid
 - Statutes and regulations
 - **Not** manuals
- Controlled substances
- Crime
- Public Health
- Consumer Protection



Noncontrolled Substance Prescriptions

- Vast majority of states expressly recognize validity of and permit e-prescribing
- Issues:
 - Intrastate inconsistency among statutes and regulations
 - Requirements for hard copies of electronic prescriptions and other paper records
 - Prohibitions/requirements for use of electronic data intermediaries
 - Individuals' ability to choose paper prescriptions

Controlled Substance Prescriptions: Transmission Restrictions

- Most reiterate verbatim current federal law restrictions on transmitting prescriptions for controlled substances.
 - Will require modification, if and when, DEA regulations are modified
- A few states expressly permit e-prescribing of controlled substances “when and as permitted by federal law,” an approach that will accommodate changes to federal regulations.

State Brand Necessary Prescriptions

- Generally applicable generic substitution laws
- Medicaid
 - Generic substitution
 - Reimbursement caps on name-brand prescription drugs

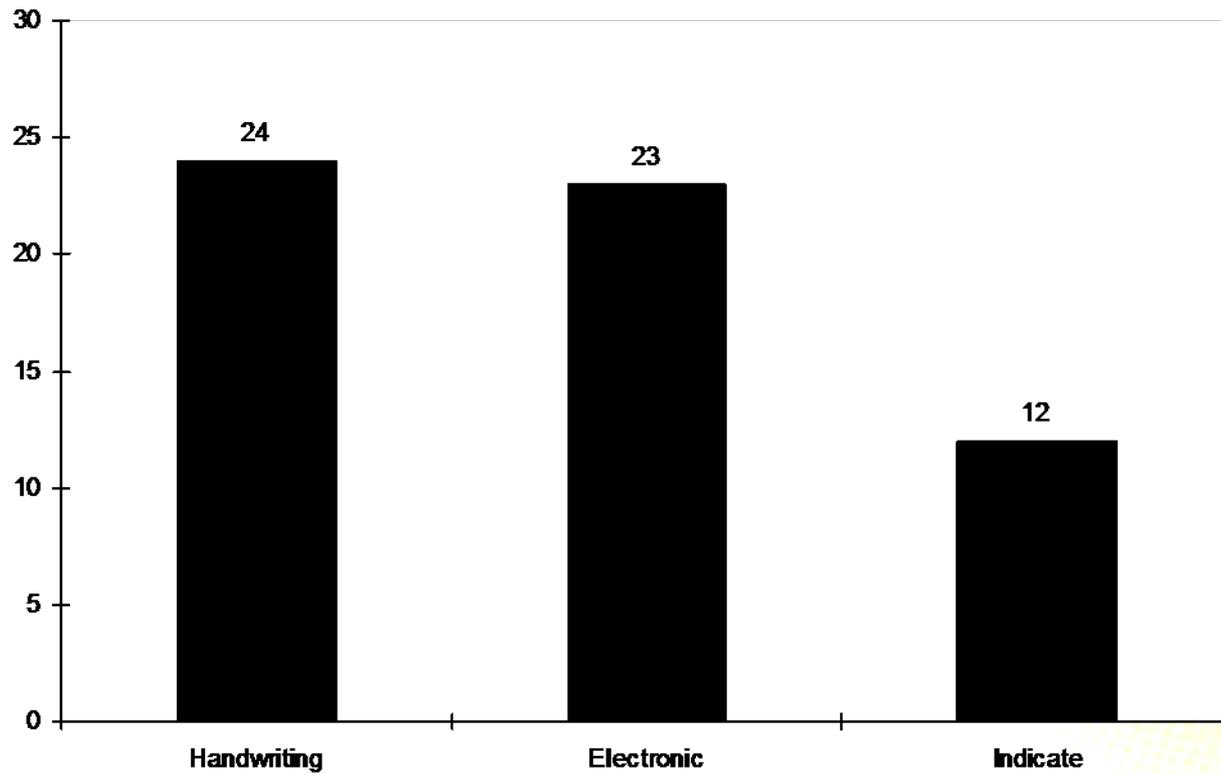
Brand Necessary

- Provider may override generic substitution and reimbursement restrictions by specifying:
 - Brand necessary
 - Brand medically necessary
 - Dispense as written (DAW)
 - No substitution
- Issue: What means or method must provider use to specify?

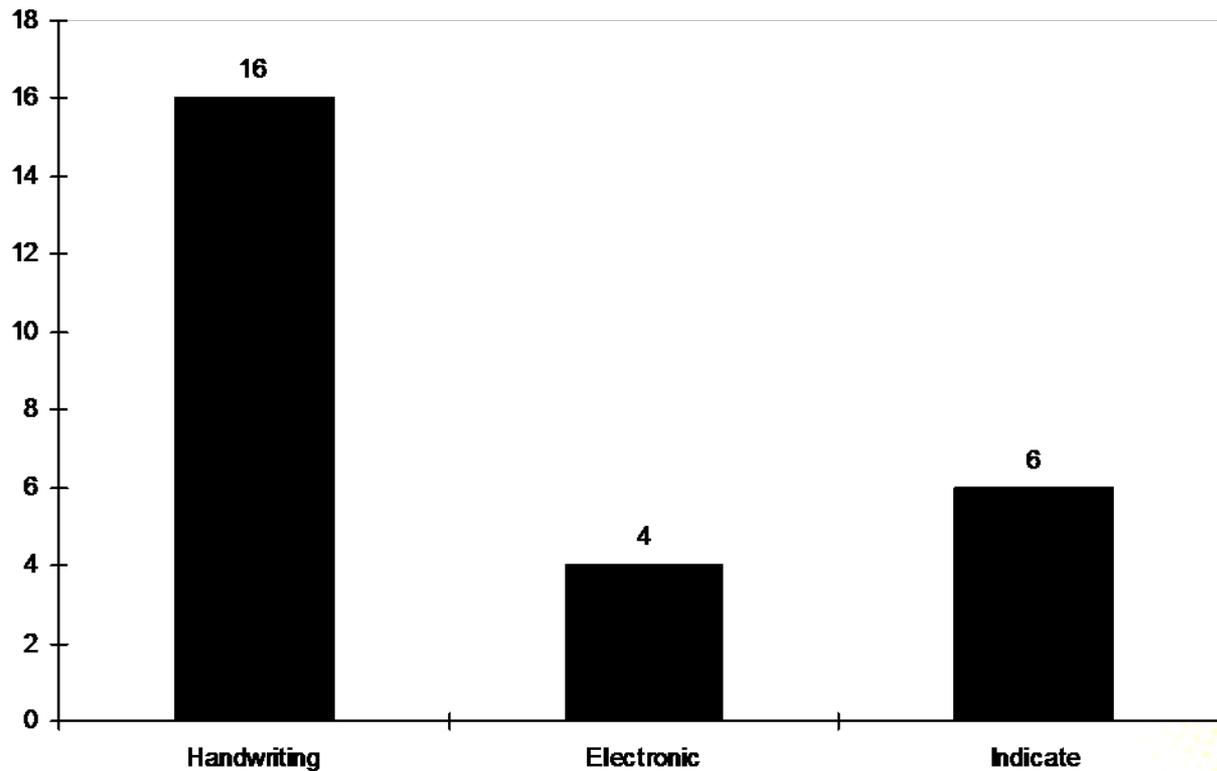
State Requirements for Brand Necessary

- Electronic
 - Facilitates e-prescribing
- Indicate
 - Could impede e-prescribing
- Handwriting
 - Impedes e-prescribing

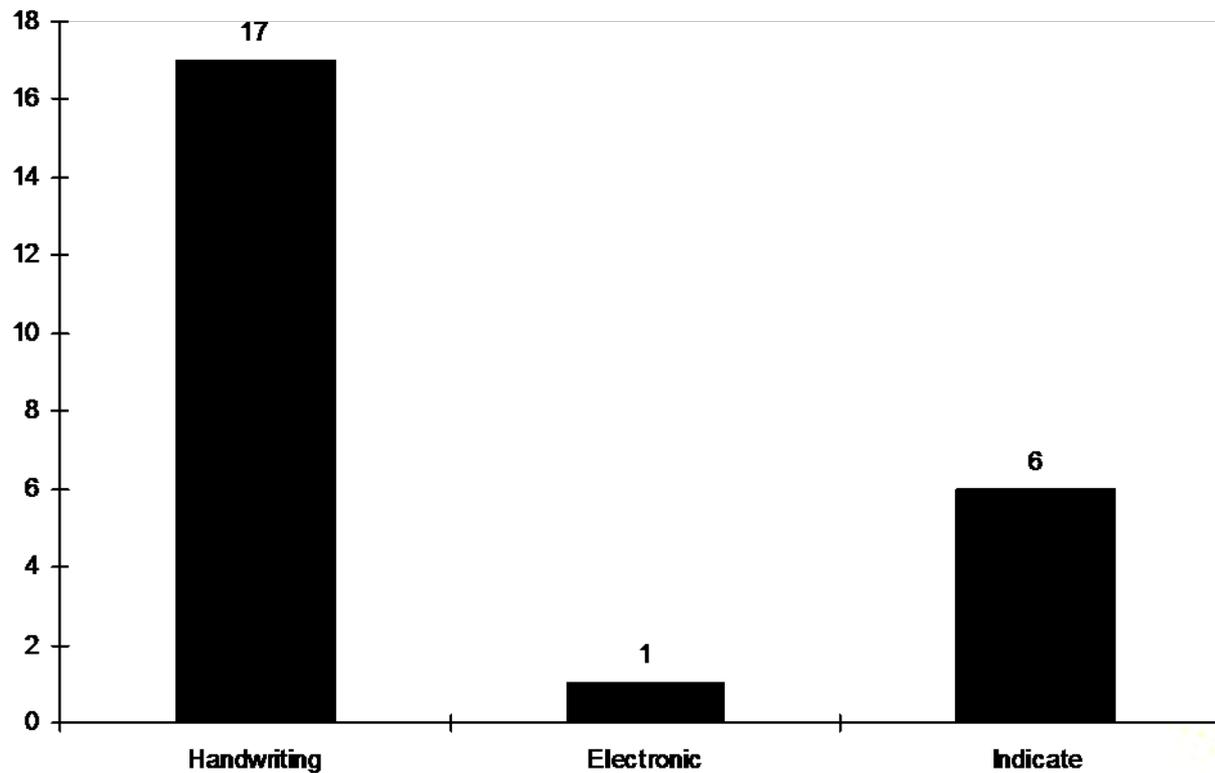
General State Brand Necessary Laws (non-Medicaid)



State Medicaid Generic Substitution: Brand Necessary Requirements



State Medicaid Reimbursement Caps: Brand Necessary Requirements



Report Tables

- Summaries of State Statutory and Regulatory Prescription Transmission and Retention Requirements for Noncontrolled and Controlled Substances That May Impact e-Prescribing
- Overview: Requirements for Specifying “Brand Necessary” in State Generic Substitution Statutes and Regulations (Non-Medicaid)
- Overview: “Brand Necessary” Requirements in State Medicaid Generic Substitution and Prescription Reimbursement Cap Laws
- Summaries of “Brand Necessary” Provisions in State Medicaid Generic Prescription Substitution and Prescription Reimbursement Cap Laws

Prescribing Laws Project

Questions?



State Disclosure Law Project



Issues

- May a health care provider disclose identifiable health information for treatment without the patient's permission?
- If so, under what circumstances?

If Permission Is Required

- Exceptions/restrictions?
 - Emergency exception separate inquiry
- Specific written format required?
- Duration?
- Limits on redisclosure?
 - Notice of limits required?

Goal

- Classify state laws into similar categories, if possible.



Laws Reviewed

- Major confidentiality statutes
- Provider-specific statutes
- Regulations
- Case law interpreting these statutes and regulations

Types of Health Information

- Clinical health information (general)
- Sensitive clinical health information
 - HIV/AIDS (test results/information)
 - Mental health
 - Substance abuse
 - Genetics (test/information)

Provider-specific Statutes

- Private practice physicians (MDs)
- Hospitals
- Pharmacists
- Outpatient substance abuse treatment facilities
- Inpatient mental health care providers

Other Resources

DEPARTMENT OF HEALTH & HUMAN SERVICES
NATIONAL SURVEILLANCE SYSTEM

- Coordinated with utilized HISPC Phase I materials
- Leveraged prior survey *State of Health Privacy*
- Publicly available state preemption analyses



Deliverables

DEPARTMENT OF LAW
SCHOOL OF LEGAL STUDIES

- Excel sheets
- Queriable database
 - Collated statutes and regulations
 - Analysis of pertinent questions



Categorizing State Laws



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Categories

- Y = May disclose without patient permission for treatment. No additional conditions.
- N = Provider may not disclose without patient permission for treatment.

Sometimes

May disclose without patient permission:

- S-SP = To specific categories of providers (e.g., mental health)
- S-CC = For continuity of care
 - Transfer
 - Referrals
 - Continued care
- S-E = For emergent treatment



Sometimes

- S-O = Disclosure generally permitted, but patient may opt out
- S-AP = Provider must first attempt to obtain permission



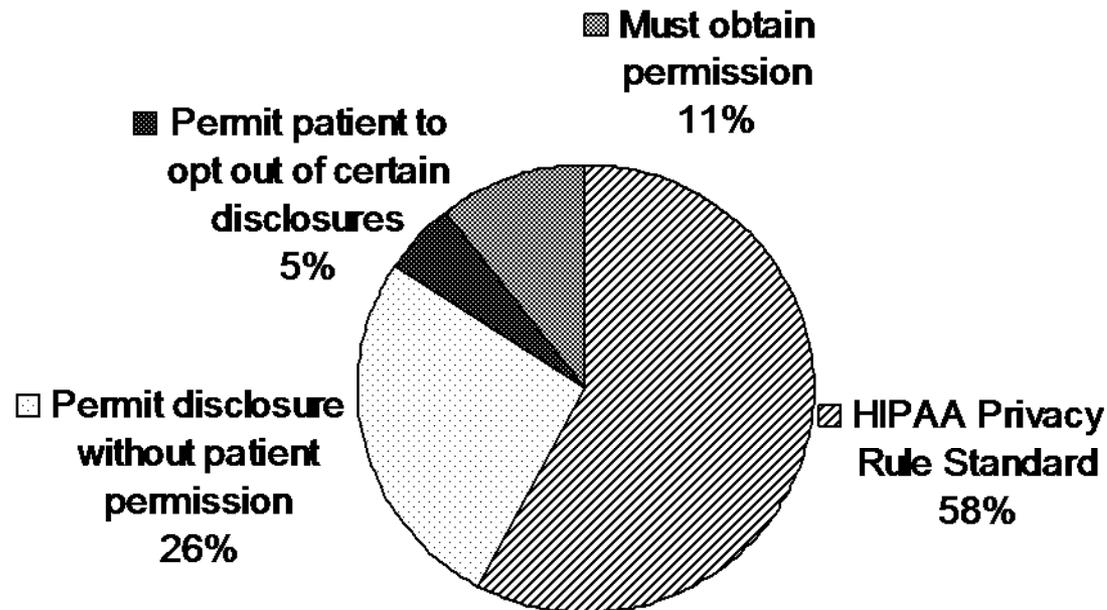
Sometimes

- **S-PJ = Professional judgment**
 - When, in the provider's professional judgment
 - When the provider determines
 - When the provider deems disclosure is appropriate or necessary for treatment.
- **S-NT = Necessary for treatment**
 - When necessary to protect health and well-being
 - When medically appropriate
 - Required for treatment

Unclear

- U= Unclear—variety of reasons
- UABL= Unclear because provision generally requires patient permission, but permits disclosure “as otherwise authorized by law”
 - Statutory construction principles
 - Promulgated pre-HIPAA—unclear if statute was intended to encompass HIPAA
 - Other provisions rendered meaningless if provision was interpreted as encompassing HIPAA

Hospitals—Standards for Disclosing General Clinical Information



▨ HIPAA Privacy Rule Standard

■ Permit patient to opt out of certain disclosures

□ Permit disclosure without patient permission

▩ Must obtain permission

Deliverables

- Excel sheets
- Report
- Queriable database
 - Collated statutes and regulations
 - Analysis of pertinent questions

Functionality

- Cross-jurisdiction collation of statutes and regulations addressing specific topics
- Intra-jurisdiction collation of statutes and regulations on disclosing health information for treatment

Disclosure Laws Project

Questions?



Thank You for Attending

- 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 July.

