

Introduction to Public Health Law

for Birth Defects Surveillance Programs

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Network for Public Health Law – Mid-States Region

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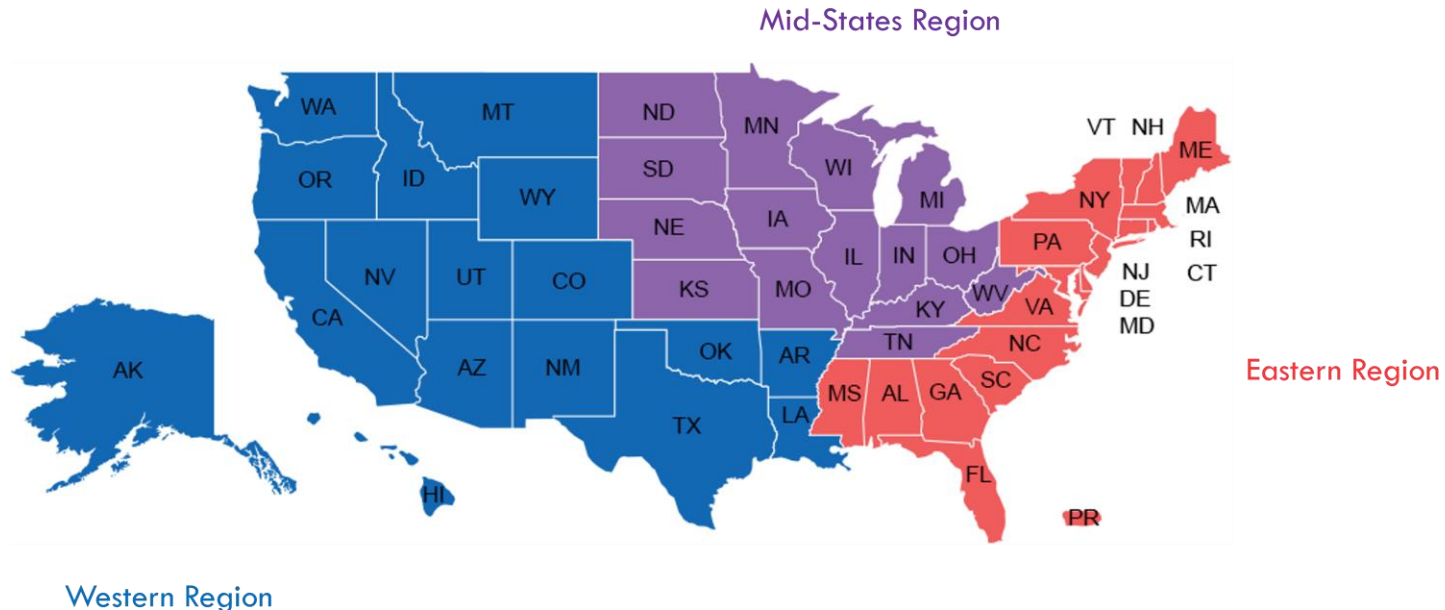
Colleen Healy Boufides, JD, Co-Director

With thanks to Denise Chrysler and Peter Jacobson

The Network for Public Health Law

Contact the Network to:

- Get practical legal assistance on a variety of public health topics
- Find helpful resources from webinars and trainings to fact sheets and legal briefs
- Connect with a community of experts and users of public health law



The Fine Print



This presentation is for informational purposes only. It is not intended as a legal position or advice from the presenters or their employers.

For legal advice, attendees should consult with their own counsel.

Outline

- **Public Health Law Basics**
- **Public Health Data Sharing Basics**
- **Working with Legal Counsel**
- **Q&A + Discussion**



The Network
for Public Health Law

Ideas. Experience. Practical answers.

Public Health Law Basics

Key Concepts

Overview: I

- **Law as foundation for public health action**
- **Tension between protecting community's health and intruding into personal liberties (e.g., stay-at-home orders)**
- **Public health law as cumulative body of constitutional doctrine, statutes, administrative regulations, executive orders, case law**

Policy Context

- **Social compact as basis for public health laws**
- **Public health as collective endeavor in age of individualism**
- **Public distrust of government/scientific denialism (vaccine protesters)**
- **Steady decline in public health workforce/investment**
- **Lack of public support/public health voice**
- **Political accountability**

Concepts: Federalism

- **States and federal government as co-equal units**
 - **Some powers explicitly federal (defense, nuclear power)**
 - **All powers not specifically federal are reserved for the states (public health)**
 - **Cooperative federalism (environment)**
- **Historical tension for control over policy**

“[T]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people...”

U.S. Constitution, 10th Amendment

Concepts: Preemption

- Higher level of government can preempt (block) actions of lower level
 - Congress can reserve power to the federal government
 - State government can override local municipalities

Concepts: Governance

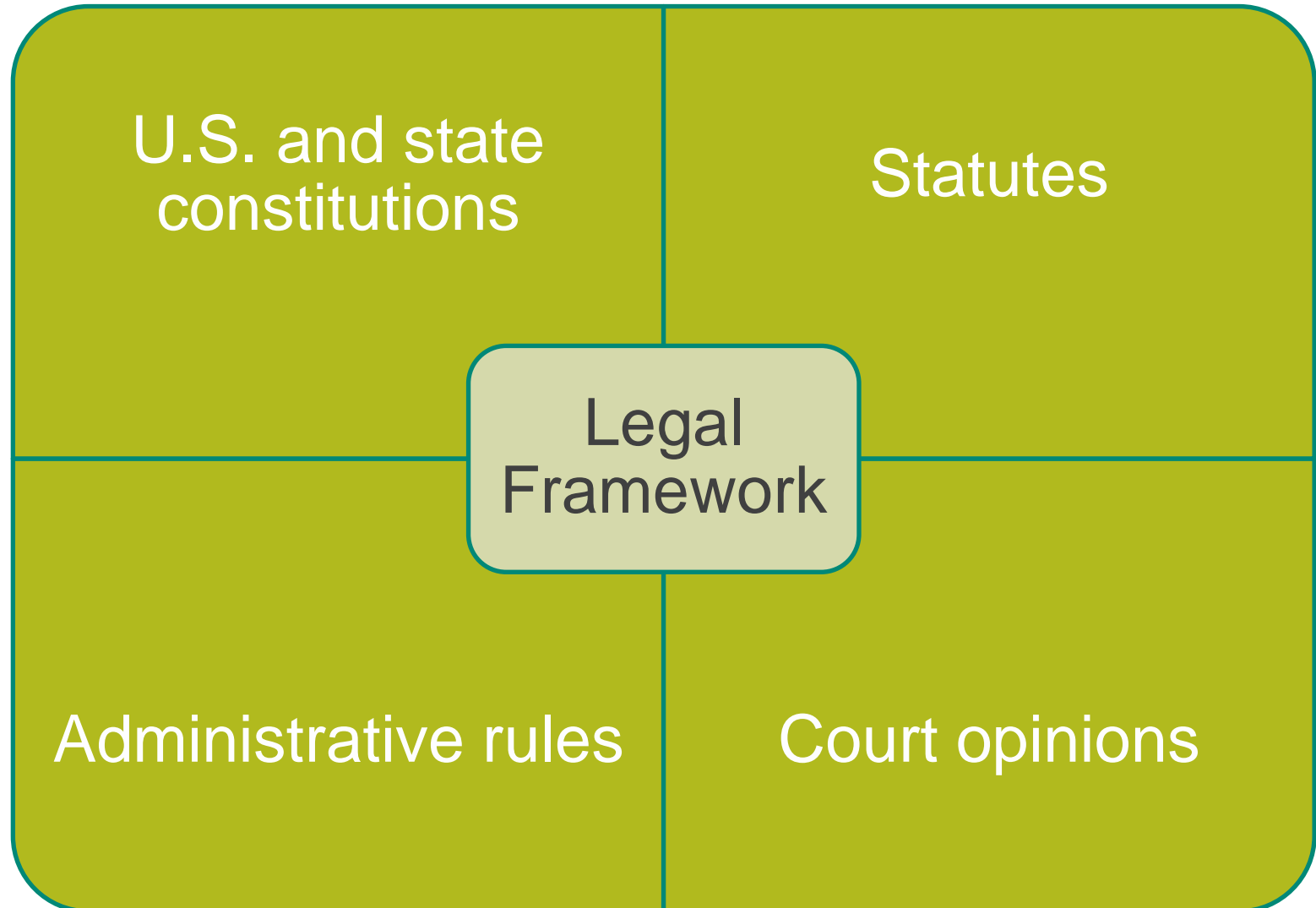
- **Separation of powers**
- **Checks and balances**
- **Political accountability**

State Agencies

- **Functions**
 - Issuing regulations
 - Enforcement
 - Issuing policy guidance
- **Public hearings**
 - Generating community support
 - Identifying opposing arguments
 - Timelines
- **Judicial standards of review**

Sources of Public Health Authority

4 Sources of Public Health Authority



Sources of Public Health Authority

- State sovereignty—10th Amendment
- Police powers
- State Public Health Code
- Common law (*parens patriae*)

Police Powers: II

- **Broad delegation of authority to administrative agencies**
- **Broad discretion accorded to agency (e.g., whether/when to notify public of Legionella outbreak)**
- **Must follow administrative procedures**
- **Regulations must be within scope of legislation**

Limitations on Public Health Authority

Limitations on Public Health Authority

Police Powers ≠ Police State

Jurisdictional

Separation (branches)

Allocation (levels)

Assignment (agencies)

Territorial

Statutory

Preemption

Limitations on Public Health Authority

Police Powers ≠ Police State

Constitutional

Liberty

Due Process

Protection Against Search & Seizure

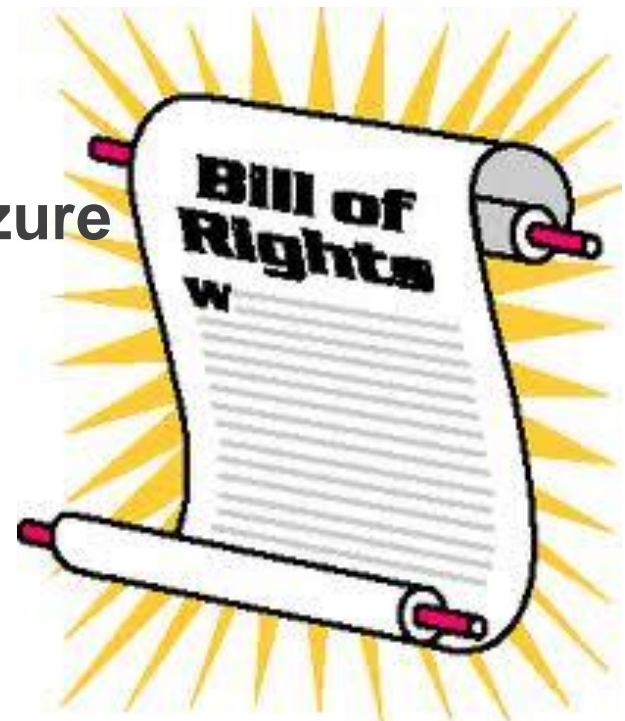
Equal Protection

Right to Privacy

Freedom of Association

Freedom of Religion

Just Compensation



Public Health Data Collection

Collection & use of data

- » **Public health has broad authority to collect data to prevent and control disease and protect public health (1977 S. Ct opinion, Whalen v Roe)**
- » **Established by state law**
- » **Corresponding duty to protect information**
- » **HIPAA should not impede public health data collection functions (45 CFR 164.512(b))**

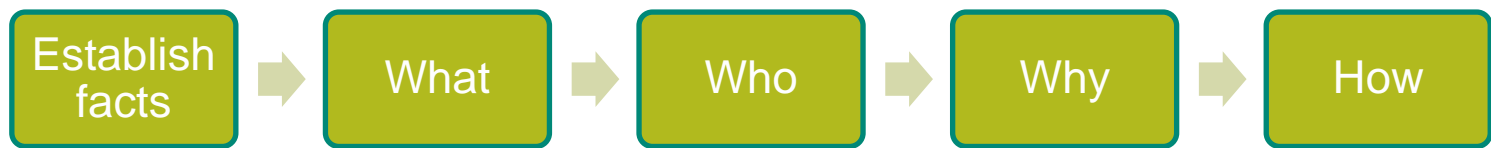
Authority for Birth Defects Surveillance Programs

- » **Specific authority to collect birth defects data**
 - » e.g. Minn. Stat. § 144.2215-2219 (establishes the Minnesota Birth Defects Surveillance System)
- » **General authority**
 - » e.g., Wash. Rev. Code § 43.20.050 (grants broad rulemaking authority to the state board of health); Board of Health adopted Wash. Admin. Code § 246-101 et seq. (Notifiable conditions)

Data Sharing Basics

The What, Who, Why and How

Analyzing a data sharing issue



The **WHAT**

» **What do you want to accomplish?**

» **What is your level of focus?**

- **Individual** (e.g. case management; care coordination; crisis intervention)
- **Systems** (e.g. assessment and improvement; of individual organization or public health, human services or health services delivery systems)
- **Population health** (e.g. public health or community interventions)

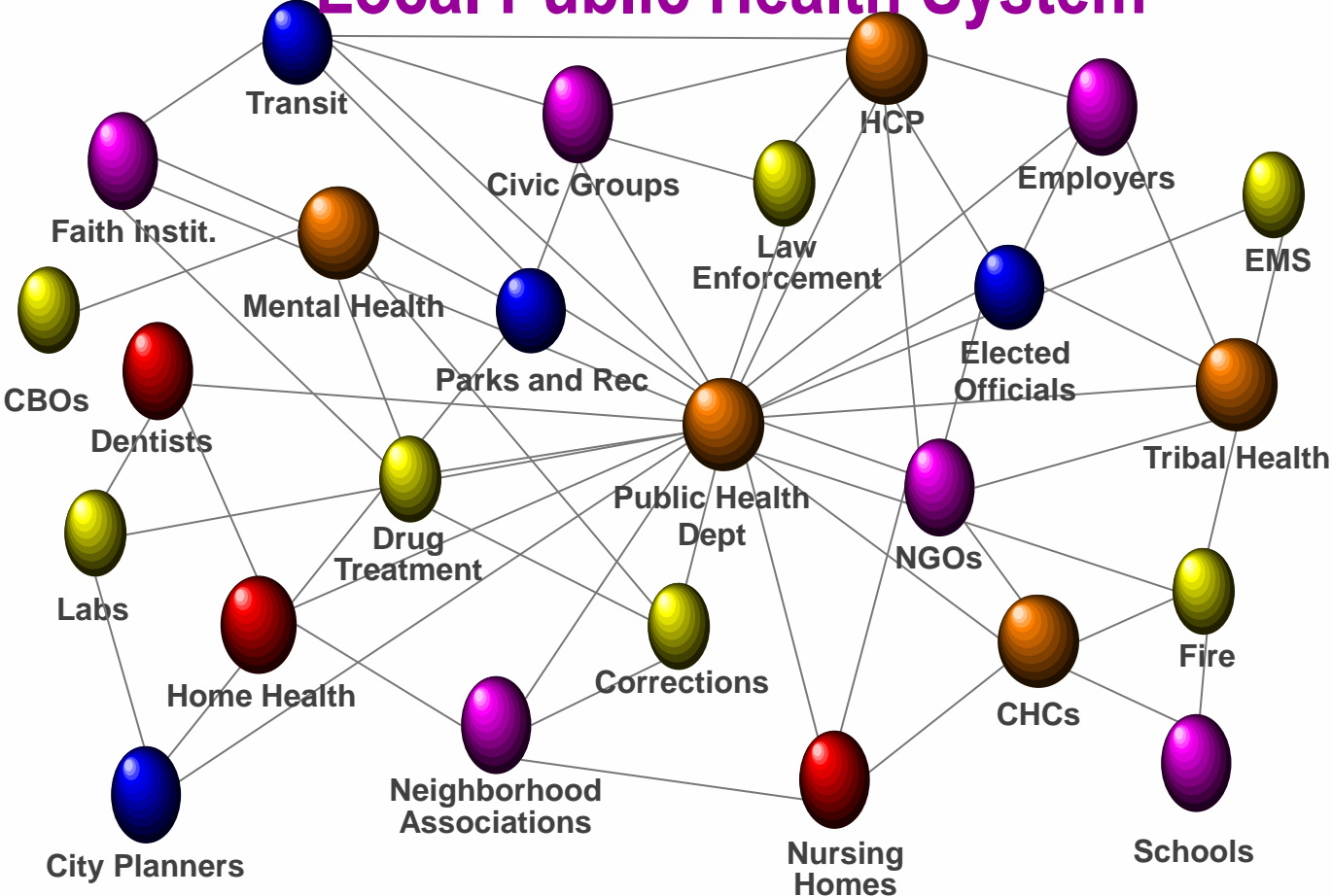
The **WHAT**

» **What data do you need to accomplish your goal?**

- Data Type
 - Data Source
 - Data elements
 - Minimum necessary? If you collect it, you protect it!
 - **Primary vs. secondary data use**
 - Secondary use \neq second class
- . . . But secondary use and disclosure must be permitted

The WHO

Local Public Health System



Acknowledgment: NACCHO Jellybean Diagram

The WHO

Documenting relationships

- » Establish general terms of the relationship, secure commitment, e.g. partnership agreement, charter, or master data sharing agreement
- » Enter a data sharing/use agreement for a specific project
- » Reflect on-going initiative with master data sharing agreement – appendices to cover specific projects

The **WHY**

- » Why are you sharing these data with these partners?
- » Be specific
- » Permissible and prohibited disclosures often depend on purpose

The HOW: Identifying applicable law

Identify laws that apply to each

» Data type

» Data source

May include general and/or specific laws:

- Health information
- Public health data and reporting
- Medical records
- Education records
- Data Practices
- Privacy
- Security
- Breach notification
- Identity theft protection acts
- Patient rights
- Health professional or facility licensing, certification
- Insurance laws
- Consumer protection laws
- Health information exchange
- Social Security No. protection
- Sunshine/Freedom of information

The HOW: Complying with law

Apply law

- » What does law allow?
- » What prerequisites, conditions, limitations apply

Balance: Maximize benefits, minimize risks

- » Data management and statistical controls to provide the most meaningful data possible while protecting privacy

The HOW: Establish and document terms of sharing

» **Data sharing agreements & MOUs**

Set out

- » legal authority;
- » terms for sharing;

Provide for monitoring and accountability for compliance with terms;

Demonstrate that proposed data sharing is legal under all applicable laws

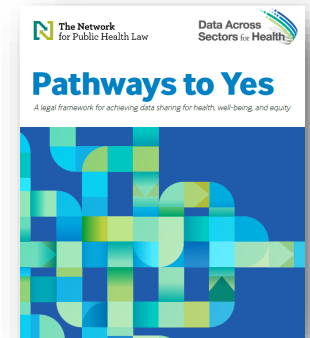
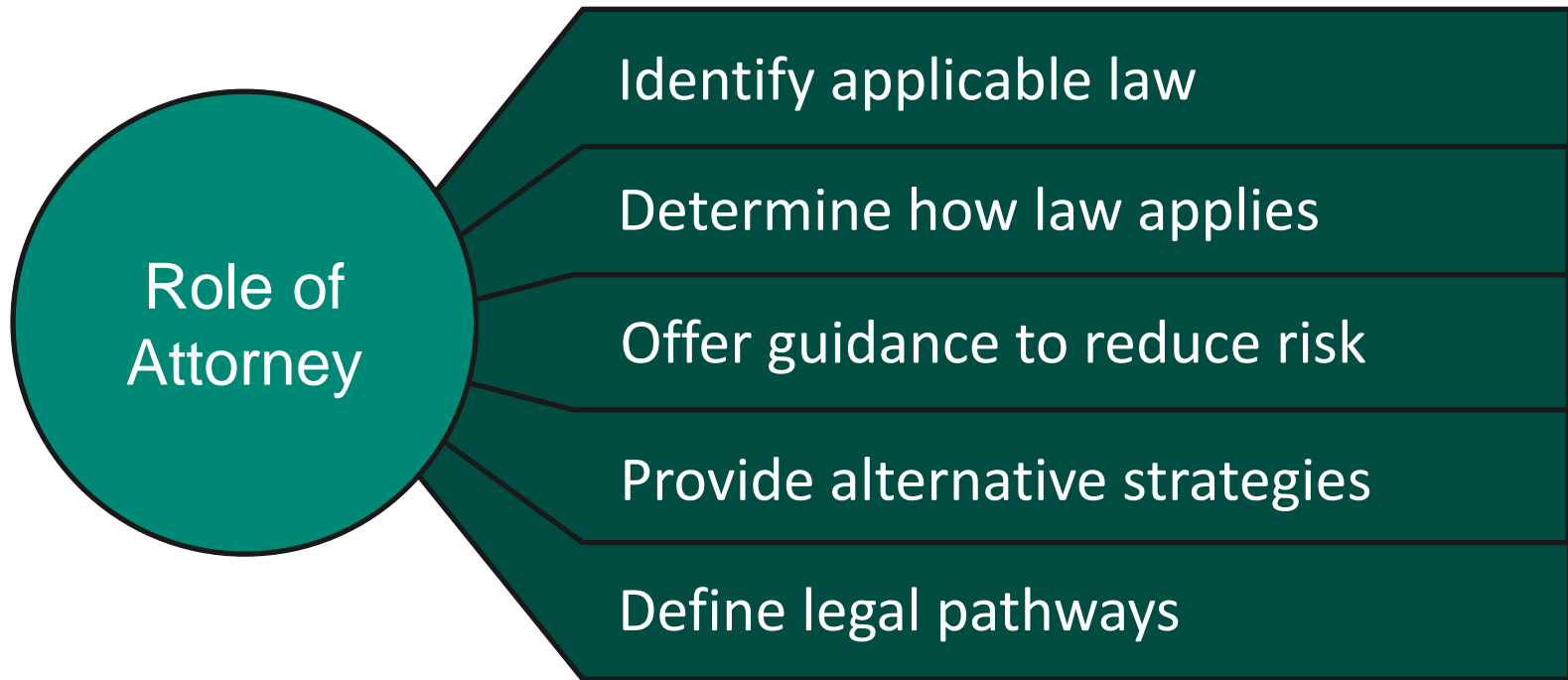
» **Service provider agreements**

e.g. business associate agreements, qualified service provider agreements, service level agreements

Establish business relationship;

Terms for receiving, using and protecting data needed to provide services

What is the role of the
attorney?



Working with Your Attorney

Bring attorney on board during the initial phase

Add the attorney to the team, share ownership

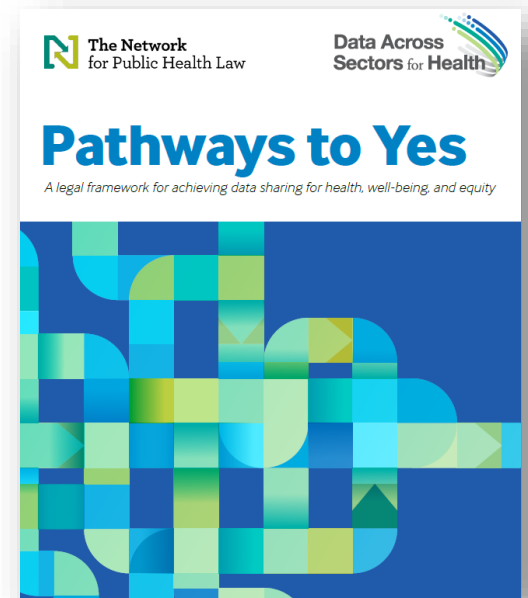
Attorneys trained to avoid risk

Give time for attorney to get up to speed

Sidestep the “yes/no” question: Present goals and desired outcomes

Foster trust and personal connections

Adapted from:



NPHL as a Resource www.networkforphl.org

Legal technical assistance

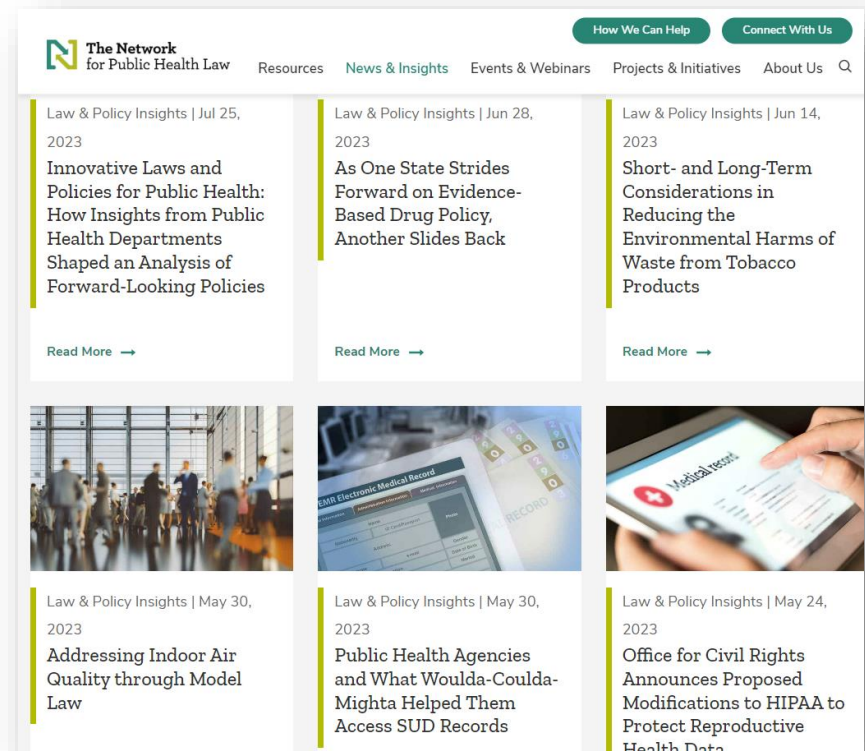
Resources

*Fact sheets, insights,
blogs*

Trainings

Webinars

Peer groups



Lightning Round: HIPAA

Public health in population health role

- » **Health care providers are crucial source of health information needed to protect and improve the public's health**
- » **Most health care providers are covered by HIPAA**
- » **Providers may question or deny access to information**

What does HIPAA cover?

HIPAA Privacy Rule applies to Covered Entities and covers:

» Use and disclosure of *protected health information (PHI)*

Use – The sharing, employment, application, utilization, examination, or analysis of PHI within the entity that maintains the PHI

Disclose – The release, transfer, provision of access to, or divulging in any manner of PHI outside the entity holding the PHI

What does HIPAA require? Privacy: Basic rules

- » **Covered entities are prohibited from using or disclosing PHI unless required or allowed by HIPAA privacy rule**
- » **Rule provides numerous exceptions that permit disclosure**
- » **If another law provides greater privacy protection or greater rights to individual concerning his/her health information, must comply with the other law**

HIPAA exceptions that allow disclosure to public health departments

- » **“Required by law” – mandate contained in law that is enforceable in a court of law**
 - Law includes statutes, administrative rules, executive orders (such as under Emergency Management Law), court-ordered subpoenas, etc.
- » **“Public health” – to public health authorities and their authorized agents for public health purposes, including but not limited to public health surveillance, investigations, and interventions**

Select Network Resources

- [Pathways to Yes](#): A legal framework for achieving data sharing for health, well-being, and equity (Oct. 2022)
- [Legal Handbook](#) for Establishing A Public Health Registry for Establishing a Public Health Registry (June 2022)
- [IZ Gateway Project](#) - Cross-jurisdictional immunization data sharing
- [Summary](#) of State Laws that Facilitate Data Sharing Among State Agencies (Oct. 2019)
- [Checklist](#) of Information Needed to Address Proposed Data Collection, Access and Sharing (Oct. 2019)
- [Equity Assessment Framework](#) for Public Health Laws and Policies (Dec. 2020)
- [How We Can Help](#) - overview of the types of assistance the Network provides

Thank you!

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