

2019

PUBLIC HEALTH LAW
SUMMIT



Data Sharing to Improve Community Health

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Breakout two: Behavioral, mental health and primary health care

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Today's Roadmap



1. Legal Pathway Overview

Goal: Find and Support Pathways to Share Data



One bite
at a time



How do you analyze a data sharing issue?

- 
1. **Establish facts**
 - What
 - Who
 - Why
 2. **Identify law**
 3. **Apply law**
 4. **Establish & document terms for sharing**

This session focuses on:

1. **Identifying the law**
2. **Applying the law**
3. **Establishing and documenting terms for sharing**

***This session is designed for individuals who already have a fundamental understanding of data sharing.**

Data Protection and Disclosure Laws + frequent condition for receiving funds

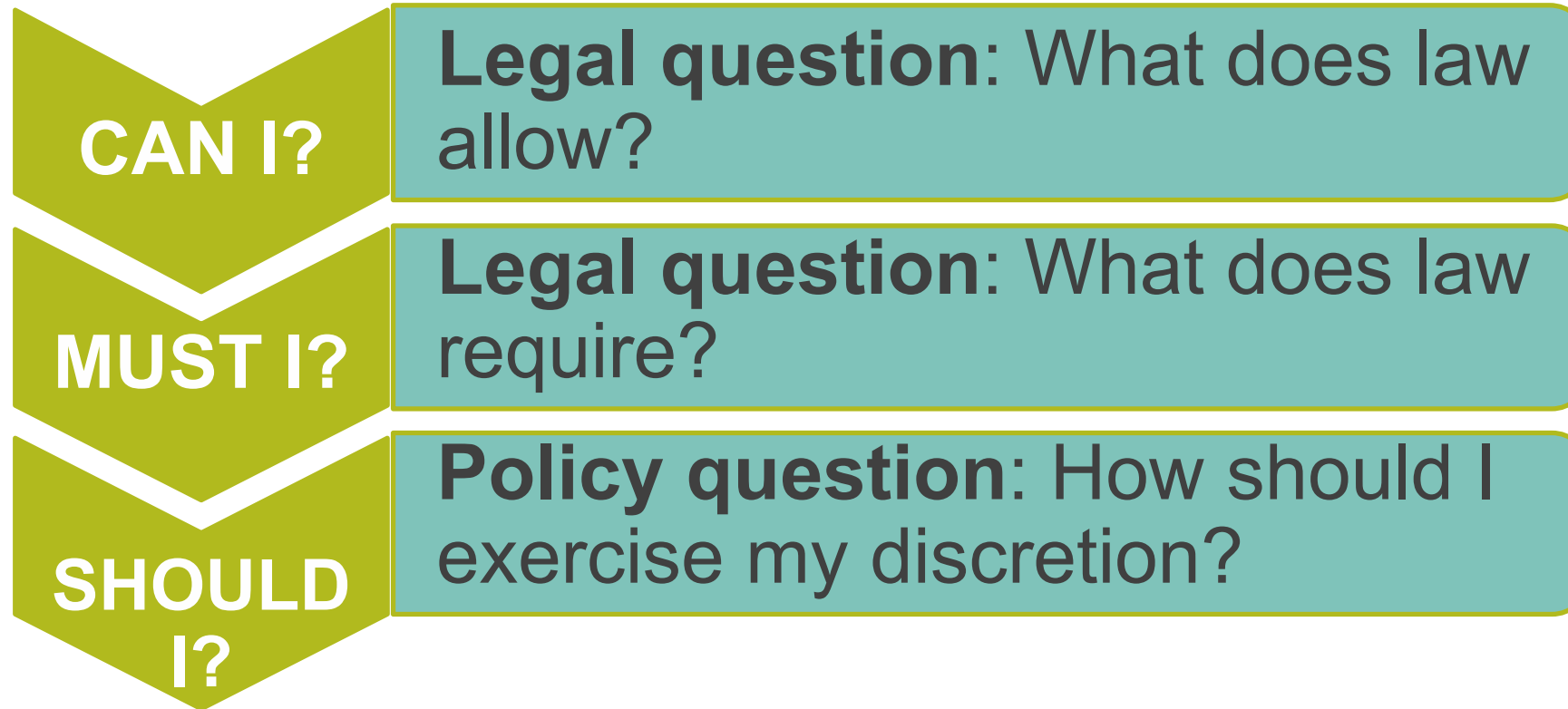
Federal

- **HIPAA**
- FERPA
- WIC
- Title X family planning
- Cancer registries
- **Substance abuse treatment**
- Federally supported research
- Social Security Act

State

- Health information
- **Mental Health**
- Disease surveillance
- Registries
- Vital records
- Screening
- Drug monitoring
- Medicaid
- Clinical services
- SSN

Apply the law



Establish and document terms for data sharing

- **Law may require specific terms**
- **Essential to data governance**
- **Designed to reduce risk and build trust**

2. HIPAA

What is HIPAA?

It's more than privacy . . .

- Electronic transactions
- Privacy
- Security
- Breach notification

What does HIPAA do?

- Requires appropriate safeguards to protect the privacy of personal health information
- Sets limits and conditions on uses and disclosures that may be made of such information without patient authorization
- Gives patients rights over their health information

To whom does HIPAA apply?

Regulated parties are HIPAA “covered entities,” which conduct covered transactions electronically:

- Certain (most) health care providers
- Health plans
- Health care clearinghouses
- Business Associates of a covered entity

Useful resource: OCR “Am I a covered entity?” tool

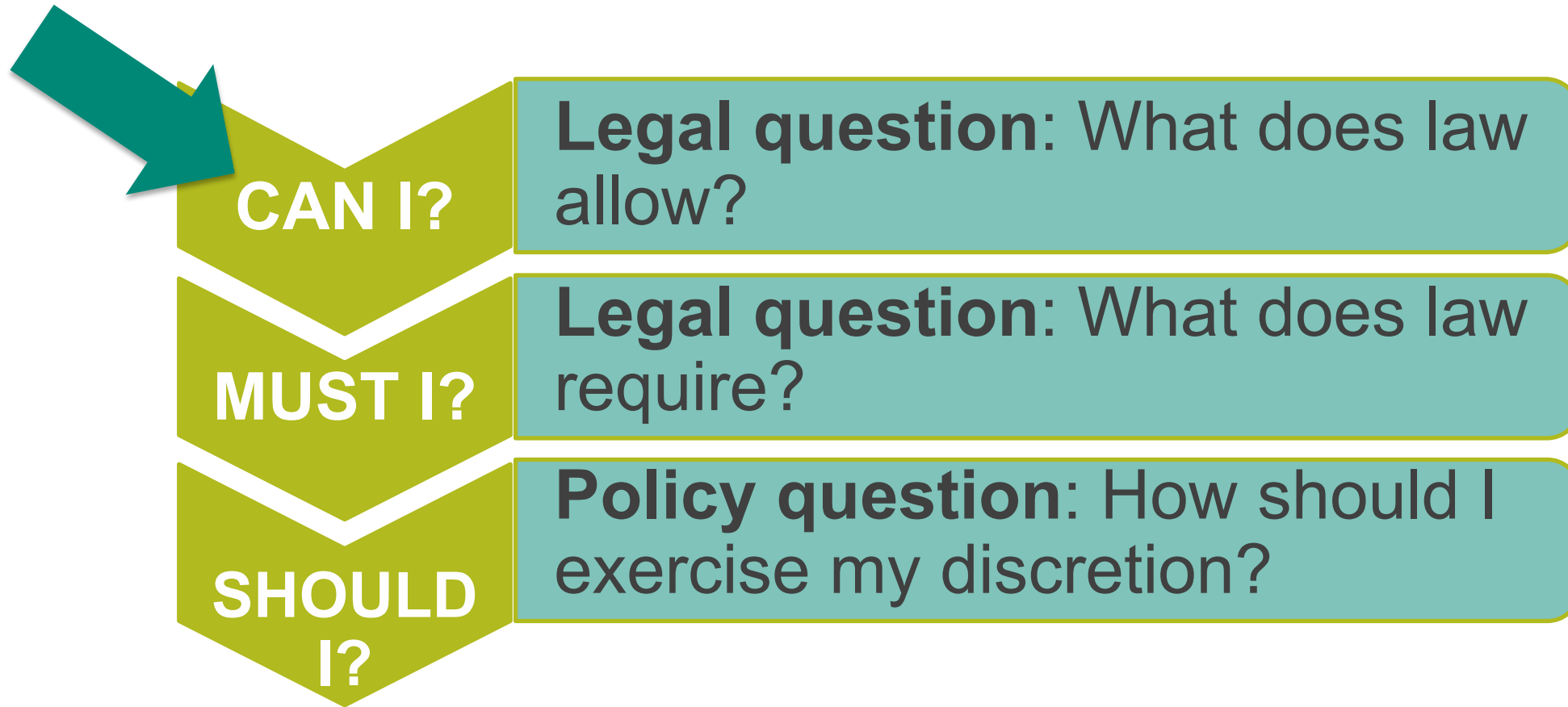
Protected Health Information

- Information, including demographic information:
 - In any form: written, electronic or oral
 - Relating to past, present or future
 - Physical or mental health status or condition
 - Provision of health care
 - Payment for provision of health care
- That identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual

Use and disclosure of PHI

- Use: The sharing, employment, application, utilization, examination, or analysis of PHI within the entity that maintains the PHI
- Disclosure: The release, transfer, provision of access to, or divulging in any manner of PHI outside the entity holding the PHI

Apply the law:



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

Minimum Necessary Rule

- Except for treatment purposes, must limit uses and disclosures of PHI to the minimum amount necessary to accomplish the intended purpose
 - Do not disclose more information than required
 - Do not access information you don't need

Permissible Disclosures

- Covered entities are prohibited from using or disclosing PHI unless required or allowed by HIPAA privacy rule
- The permissible disclosures are set forth in the Privacy Rule. The Rule also specifies conditions or limitations for each permitted disclosure.
- The following discussion addressed those most often raised in the context of data sharing for population or community health

Permissible Disclosures Include:

- » **To patient** (or legal representative, e.g. generally parent access to child's info) (**required disclosure!**)
- » **TPO**
 - Treatment: provision, coordination, management of care/related services including consults and referrals
 - Payment for health care – reimbursement for health care, coverage, all related activities
 - Health care operations

Permissible Disclosures Include:

- **Pursuant to an Authorization**
- **For Approved Research [45 CFR § 164.514(e)]**
- **Pursuant to a Limited Data Set Agreement [45 C.F.R. § 164.514(e)(2)]**
- **Required by law** – mandate contained in law that is enforceable in a court of law [45 C.F.R. § 164.512(a)]

Permissible Disclosures Include:

- **For Public Health Activities** [45 C.F.R. § 164.512(b)]
 - to public health authorities and their agents for authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability
 - e.g. public health surveillance, investigations, and interventions, including communicable disease exposure
 - to authorities for reporting child abuse or neglect; to FDA for reporting on regulated products; to employers where necessary for OSHA compliance

Analyzing a data sharing issue: Apply law



Does HIPAA ever *require* sharing of PHI?

Yes.

- **To patient** (or legal representative, e.g. generally parent access to child's info) or as directed by the patient or legal representative
- **To U.S. Secretary of Health and Human Services** during compliance investigation or enforcement proceedings

Note: sharing which is permitted by HIPAA may be compelled by another source of law

3. Mental Health Laws

HIPAA and Mental Health

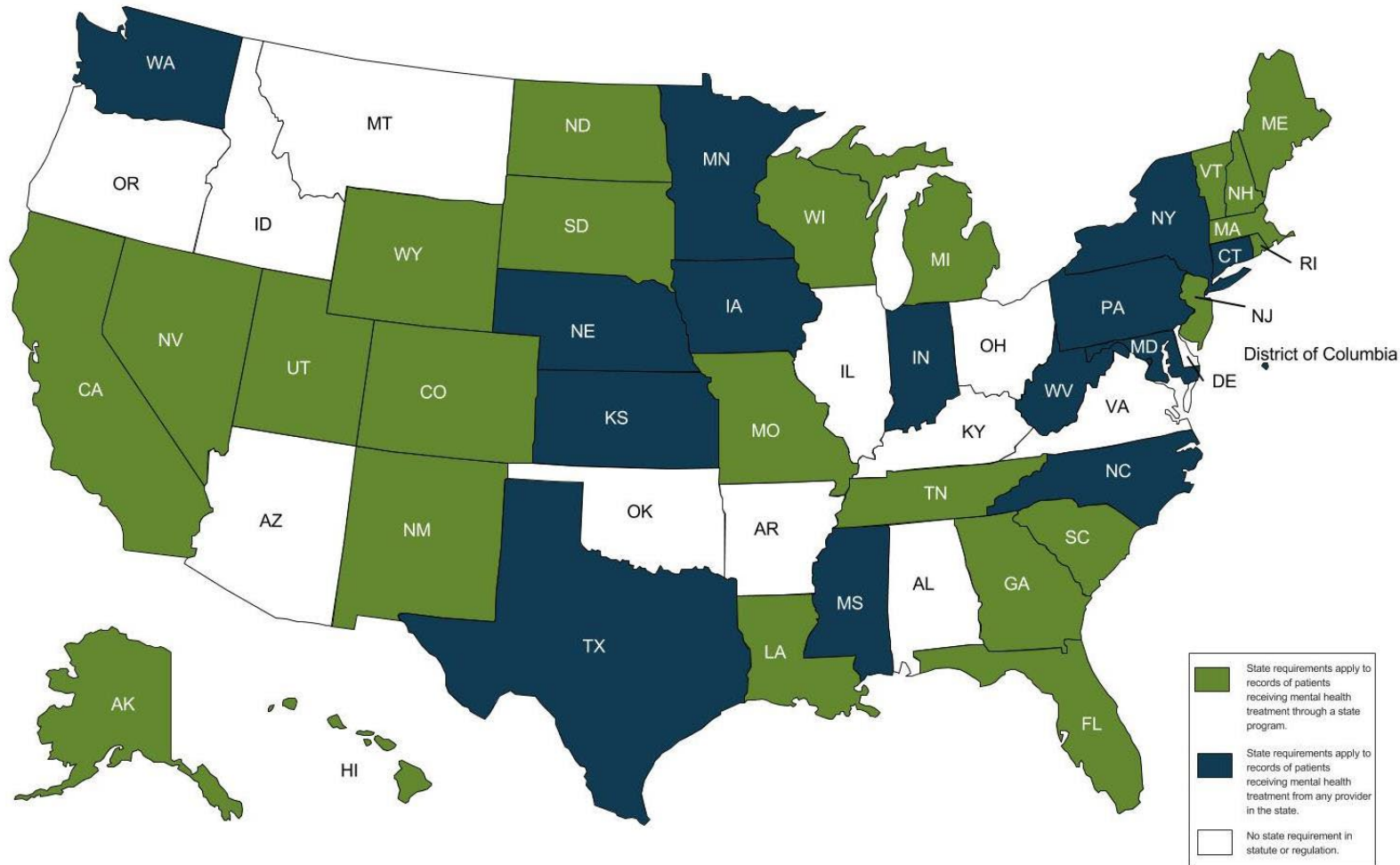
- Generally, HIPAA does not distinguish information about mental healthcare from other PHI.
- Only exception is psychotherapy notes, which
 - are “notes recorded by a health care provider who is a mental health professional documenting or analyzing the contents of a conversation during a private counseling session or a group, joint, or family counseling session and that are separate from the rest of the patient’s medical record” (*) and
 - do not include “any information about medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, or results of clinical tests; nor do they include summaries of diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date.” (*)
 - Particular authorization requirements for disclosure

State by State

- Challenge of defining what is meant by “mental health” information
- No national framework

Sources of State Requirements

- Generally applicable requirements
- Specific to type of service
- Professional licensure requirements and testimonial privileges



State Laws Requiring Authorization to Disclose Mental Health Information for TPO

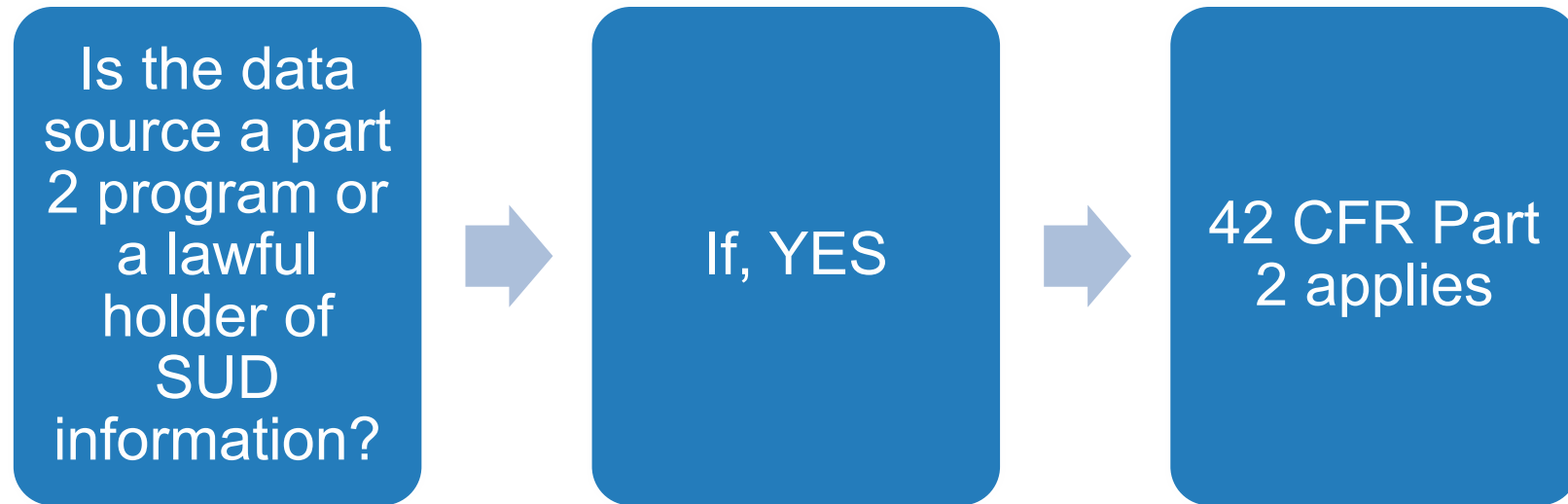
State Laws Requiring Authorization to Disclose Mental Health Information for Treatment, Payment, or Healthcare Operations. (2016, September). Retrieved from [https://www.healthit.gov/sites/default/files/State%20Mental%20Health%20Laws%20Map%202020Authorization%20Required%209-30-16 Final.pdf](https://www.healthit.gov/sites/default/files/State%20Mental%20Health%20Laws%20Map%202020Authorization%20Required%209-30-16%20Final.pdf)

Read the fine print ...

<input type="checkbox"/>	State requirements apply to records of patients receiving mental health treatment through a state program
<input type="checkbox"/>	State requirements apply to records of patients receiving mental health treatment from any provider in the state.
<input type="checkbox"/>	No state requirements in statute or regulation.

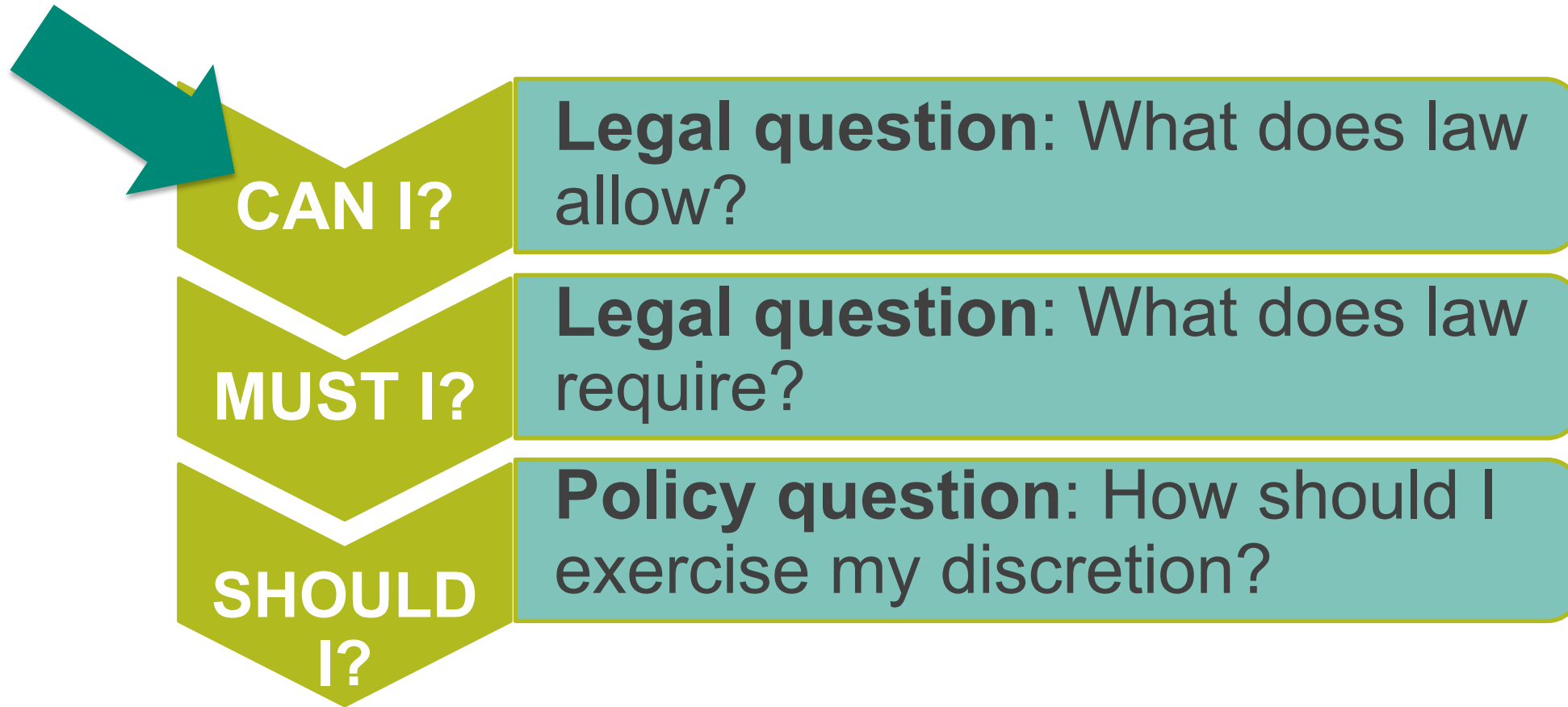
4. 42 CFR Part 2

Identify the Law: 42 CFR Part 2 = Data **Source** Law



- **What kind of information does this law cover?** Substance use disorder (SUD) identifiable patient records maintained in connection with the performance of a part 2 program. 42 CFR § 2.1.
- **What is a Part 2 program?** Any individual or entity that is federally assisted and holds itself out as providing, and provides, SUD diagnosis, treatment or referral for treatment **and** lawful holders of SUD information. 42 CFR §§ 2.11 and 2.12.

Apply the law:



Can I share?



Examples
follow...

Minimum necessary applies to all disclosures of SUD data. 42 CFR § 2.13(a).

Where is minimum necessary the only prerequisite for disclosure?

With an entity with direct administrative control over the part 2 program, that has a need to know for the diagnosis, treatment or referral for treatment. 42 CFR § 2.12(c)(3).

For medical emergencies. (1) SUD records may be disclosed to medical personnel in an emergency situation where prior consent cannot be obtained. (2) SUD records may be disclosed to the FDA for notification purposes regarding an error in the manufacture, labeling or sale of a product that threatens the health of an individual. 42 FR § 2.51.

For disclosing decedent's SUD records to vital statistics. All other disclosures that require consent may be executed by the deceased's personal representative. 42 CFR § 2.15.

For reporting suspected child abuse and neglect under state law to state or local authorities. This exception does not extend to use in civil or criminal proceedings arising therefrom. 42 CFR § 2.12(c)(6).

For what purposes can I disclose SUD data with minimum necessary *and* consent? Examples...

- **Generally, for treatment purposes.** 42 CFR §§ 2.2(b) and 2.33(a).
- **Required by law disclosures.** 42 CFR §§ 2.2(b) and 2.33(a). Additionally, state law that authorizes or compels any disclosure prohibited by part 2 is preempted. 42 CFR § 2.20.
- **Generally, to public health.** 42 CFR §§ 2.2(b) and 2.33(a).
- **About victims of abuse, neglect or domestic violence.** 42 CFR §§ 2.2(b) and 2.33(a).
- **Health oversight disclosures.** 42 CFR §§ 2.2(b) and 2.33(a).
- **Criminal Justice disclosure.** When participation in a part 2 program is a condition of the patient's diversion/parole/release, disclosure to the criminal justice system must only occur to those with a need to know; further, there are unique consent requirements. 42 CFR § 2.35.
- **For cadaveric organ, eye or tissue donation purposes.** 42 CFR §§ 2.2(b) and 2.33(a).
- **For Workers' compensation purposes.** 42 CFR §§ 2.2(b) and 2.33(a).
- **Re-disclosure of records.** 42 CFR §§ 2.2(b) and 2.32.

For what purposes can I disclose SUD data with minimum necessary *and* a signed agreement?

Audit and evaluation of a part 2 program. 42 CFR § 2.53.



Qualified service organizations that provide services to part 2 programs, such as legal or accounting services. 42 CFR §§ 2.11 and 2.12(c)(4).

For what purposes can I disclose SUD records with minimum necessary *and* consent *and* a signed agreement?

Payment or health care operations contractor.

A lawful holder of part 2 records who receives them for payment or health care operations activities under a written consent, may further disclose the records to contractors, subcontracts or legal representatives to carry out the lawful holder's payment or health care operations.

The lawful holder must have a written agreement in place with the contractor to safeguard the information in compliance with 42 CFR Part 2. 42 CFR § 2.33.

For what purposes can I disclose SUD records with minimum necessary *and* under a court order?

Judicial and administrative proceedings

In a criminal proceeding, it is permissible to disclose SUD records in response to a part 2 compliant court order where necessary to protect against an existing threat to life or of serious bodily injury, related to an investigation or prosecution of an extremely serious crime allegedly committed by the patient or connected with litigation or an administrative proceeding in which the patient testifies or offers other evidence. 42 CFR §§ 2.61 and 2.63.

In a civil proceeding, it is permissible where SUD records are needed as evidence. Part 2 only allows disclosure upon entry of a compliant order issued after notice and opportunity for response. 42 CFR § 2.64.

For what purposes can I disclose SUD records with minimum necessary *and* IRB approval?

Research, with:

- (1) **HIPAA compliant authorization**, if applicable or a waiver or alteration of authorization consistent with HIPAA; and/or
- (2) If subject to the **Common Rule**, demonstrates compliance or exemption qualification; or
- (3) If **neither** HIPAA nor the Common Rule applies, then research is not an option.

*Additionally, data linkage projects must be reviewed and approved by an IRB. The data repository must comply with specific security requirements regarding record destruction. Prohibition on re-disclosure. 42 CFR § 2.52.

Can I disclose de-identified SUD records?

Yes. Part 2 N/A to properly de-identified SUD information..

See, 42 CFR § 2.12(e)(3).

Requirements:

- Removal of patient identifying information which means the name, address, social security number, fingerprints and photograph
- Removal of direct and indirect identifiers. Does not include a randomly generated medical record number. 42 CFR § 2.11.

Evaluate the prohibitions

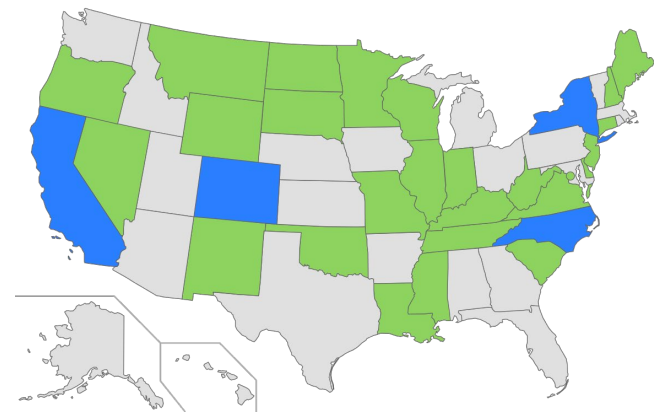
General prohibition on use or disclosure not specifically permitted by 42 CFR Part 2. 42 CFR § 2.13(a).

Prohibition on re-disclosure without consent or otherwise permitted by 42 CFR Part 2. Additionally, special notice must accompany re-disclosure. 42 CFR § 2.32.

Prohibition on disclosure for criminal charges. There is a prohibition on disclosure of SUD records to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient. 42 CFR § 2.12(a)(2).

Impact on State Law

- **If state law prohibits a disclosure permitted under 42 CFR Part 2, the state law prohibition on disclosure stands.**
- **Where 42 CFR Part 2 prohibits a disclosure, state law cannot authorize or compel it. 42 CFR § 2.20.**



Analyzing a data sharing issue: Apply law



Does 42 CFR Part 2 contain any mandatory disclosures?

- **No.** The regulations state that they “do not require disclosure under any circumstances.” 42 CFR § 2.2(b)(1).



Analyzing a data sharing issue: Apply law



Requirements for Data Sharing by Agreement

Sharing with a qualified service organization (QSO)

- Written agreement
- Acknowledging that the organization is fully bound to 42 CFR Part 2
- Will resist judicial proceedings to access identifiable SUD records, except as permitted by the regulation.
- 42 CFR § 2.11.

Sharing for audit and evaluation purposes

- With a health oversight agency – where the agency agrees not to re-disclose and makes the written commitments required by 42 CFR § 2.53(d). If the records are removed from the premises, the agency must agree to comply with 42 CFR § 2.53(b).
- With an outside auditor, the requirements for a QSO must be satisfied.
- 42 CFR § 2.53.

5. Small Group Legal Navigation

Navigating Law to Share Data

Network for Public Health Law Resources

- Checklist of Information Needed to Address Proposed Data Collection, Access and Sharing
- Data De-Identification Toolkit
- Federal Privacy Laws – snapshots + annotated compilation
- HIPAA Hybrid Status Toolkit

https://www.networkforphl.org/resources/topics_resources/health_information_and_data_sharing/

Navigating Law to Share Data

Resources continued

Legal Bibliography

- *Data Across Sectors for Health*
- *Network for Public Health Law*

<http://legalbib.communitycommons.org/>

Network for Public Health Law

The [Network for Public Health Law](#) is a national program partially funded by the Robert Wood Johnson Foundation to promote and support the use of law to solve public health problems. Our work includes providing legal technical assistance and training to assist attorneys and their client agencies in sharing meaningful data to improve the health of communities in compliance with applicable laws.

This presentation should not be considered legal advice or representation. For legal advice, please contact your attorney.

Thank you for participating!

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