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Ideas. Experience. Practical answers.

HIPAA and 42 CFR PART 2: *Take 2*

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CSTE Linkage to Care Surveillance Community of Practice Group
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About the Network for Public Health Law

We believe in the power of public health law and policy to improve lives and make our communities safer, healthier, stronger and more equitable. We know that understanding, navigating and using law and policy can transform our communities so we work to help public health leaders, policymakers, researchers, educators, Advocates and health care providers do just that.

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At no cost, the Network provides public health legal support:

- **Legal technical assistance**
- **Training and resources**
- **Opportunities to build connections**
- **Visit *www.networkforphl.org***
- **Join the Network! (it's free)**

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.

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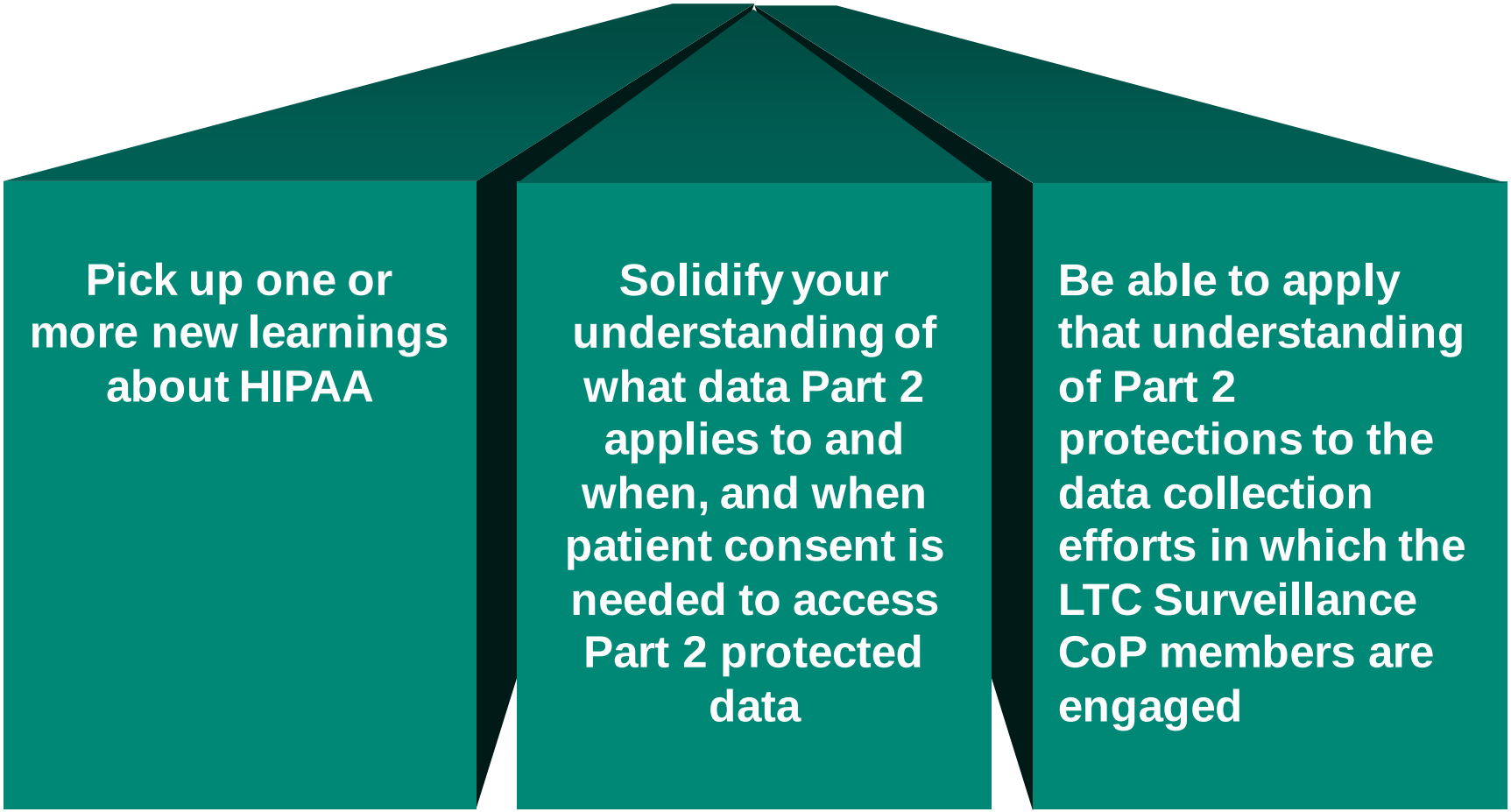

Today's Objectives

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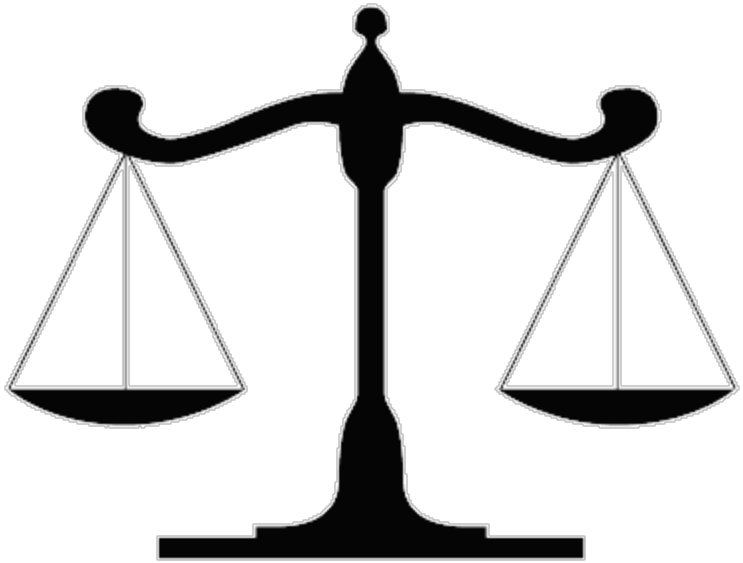
Health privacy laws are designed to balance

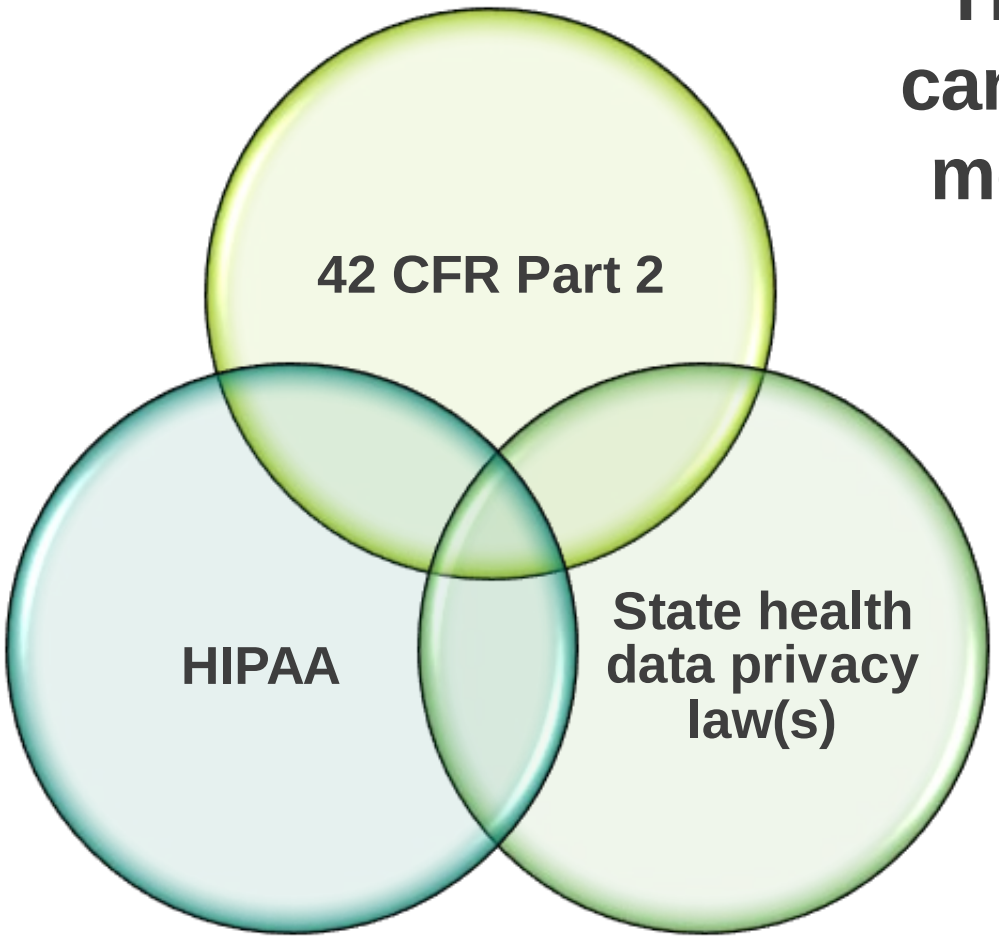


the sharing of health information

with

protecting the privacy of the person whose health information it is

Health information can be protected by more than one law.



Health Information Legal Privacy Protections

HIPAA Distilled

Sets minimum national standards for privacy and security

Gives patients rights regarding their health information

Applies to most health care providers and to health plans ("covered entities")

Covered entities are prohibited from using or disclosing identifiable health information unless required or allowed by HIPAA Privacy Rule

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Part 2 Distilled

Offers additional protection for substance use disorder treatment records.

Additional protections were intended to protect against stigma and prevent discrimination in legal matters.

The protections stick with the health information forever with one exception.

Not all SUD treatment providers are covered by Part 2 and not all SUD records are protected by it.

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What is Protected by HIPAA?

Any "Individually Identifiable Health Information" (IIHI):

- Created or received by **a health care provider, health plan, or health care clearinghouse**
- Relating to the **past, present of future physical or mental health or condition** of an individual (including information related to payment for health care)
- **Transmitted** in any form or medium—paper, electronic (email, fax, computer systems) and verbal communications

Referred to as **"Protected Health Information" (PHI).**

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What is Protected by Part 2?

Part 2 covers information identifying, directly or indirectly, any person having, diagnosed with, or referred for treatment of a substance use disorder.

- Current patients
- Former patients
- Individuals who have applied for services
- Deceased patients

Referred to as **"Patient Identifying Information" (PII).**

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Examples of identifying information

- Name
- Date of Birth
- Address
- Social Security #
- Medicaid #
- Fingerprints
- Driver's license #
- Photograph

- Diagnosis
- Program status
- Test results
- Co-occurring conditions
- Treatment Info
- Medications
- Or any other information that would lead you to identify the patient

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Who must abide by HIPAA?

"**Covered entities"**

- Health care providers
- Health (insurance) plans
- Health care clearinghouses (ex., health information exchanges)

"Business Associates" of covered entities that handle the CE's patients' Protected Health Information

"Subcontractors" of those Business Associates who handle the CE's patients' Protected Health Information

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Who must abide by Part 2?

Part 2 requirements apply to Part 2 "Programs", for which there is a two-pronged test:

1. **"Federally assisted"**
   - management by a federal office or agency
   - receipt of any federal funding
   - program has tax exempt status

2. **Meets the definition of a "Program"**

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What is a Part 2 Program?

Program Definition	Example(s)
a.) An **individual or entity** other than a general medical facility that holds itself out as providing SUD services	• Free-standing SUD clinic • SUD Residential Program
b) An **identified unit** within a General Medical Facility that **holds itself out** as providing SUD services	• Outpatient SUD program affiliated with a hospital • Identified SUD unit of community health center
c) Medical staff or other personnel whose **primary function** is providing SUD services and who is identified as such a provider	• Identified SUD specialist in an FQHC or ED whose primary function is providing SUD services

Note: Does not apply to entire hospitals, trauma centers, or other general medical facilities, or an ER provider who refers person to ICU for overdose (if not an identified SUD specialist). See SAMHSA fact sheet Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?

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Duration of Protection

HIPAA: Protections may not travel with the information that is disclosed to a non-HIPAA data recipient.

The protections travel with the information from the Part 2 Program to whoever receives the information; they are termed "Lawful Holders".

- A "**lawful holder**" is any individual or entity that receives information from a Part 2 program with patient consent or by a Part 2 consent exception.
- Lawful holders may only re-disclose records *as permitted by Part 2.*

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The one exception when Part 2 data loses its protected status is the **Exception for Verbal Disclosures.**

Part 2 information **shared *verbally* with a non-Part 2 provider for treatment** loses its Part 2 protections - even if the non-Part 2 provider documents that information in writing.

- Initial patient consent still required for the disclosure
- Non-Part 2 provider can enter the information received orally into patient's file - no requirement to segment or flag
- **Part 2 information disclosed verbally must still comply with HIPAA requirements** (minimum necessary, etc.)

NEW **as of 2020**

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HIPAA and Part 2 permit disclosure of de-identified data

Two methods to de-identify under both laws:

1) **Expert Determination**
2) **Safe Harbor**

See, *OCR Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*

De-Identification – Expert Determination

- Person with appropriate knowledge and experience
- Applies statistical or scientific principles
- Determines very small risk that anticipated recipient could identify individual
- May use mitigation strategies to reduce risk
- Documents methods and results of analysis

De-Identification – Safe Harbor

- HIPAA lists 18 identifiers that must be removed, and includes the
  - » name; address, including street address city, county, zip code and equivalent geocodes; all dates, including birth, death, date of service, admission, discharge, etc.; social security number; medical record number, photographic images; etc.
- Of the individual and of relatives, employers, or household members of the individual
- Very small risk that anticipated recipient could identify individual

Limited Data Set under HIPAA

(does not apply to Part 2)

- PHI from which direct identifiers have been removed (dates, demographic identifiers allowed)
- May be used and disclosed for research, health care operations, and public health purposes
- Provided that there is a data use agreement with specified safeguards

Authorization/Consent

HIPAA and Part 2 permit disclosure of identifiable information if patient gives written permission

The General Rule: *Written* patient authorization (HIPAA) or *written* patient consent (Part 2) required before any disclosure can be made *unless the applicable law requires or allows disclosure*

NOTE: HIPAA authorizations DO NOT satisfy the consent requirements of Part 2. However, one authorization/consent form may be used that satisfies both HIPAA and Part 2

See Authorization/Consent Checklist for comparison of required elements under each law

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Part 2 Consent Form Requirements

Name of Patient
Who is making the disclosure "From Whom"
How much and what kind of information is to be disclosed *Including an *explicit description* of SUD information that may be disclosed
Who is receiving the information "To Whom" *
Purpose of the disclosure *
Patient notice of right to revoke consent
Expiration date, event, or condition
Signature of the patient
Date consent is signed

Plus, written records must be accompanied by a Notice On Re-Disclosure.

Minimum necessary rule under both HIPAA and Part 2 applies to most exceptions:

Data provider must limit disclosure of identifiable information to the minimum necessary for the intended purpose.

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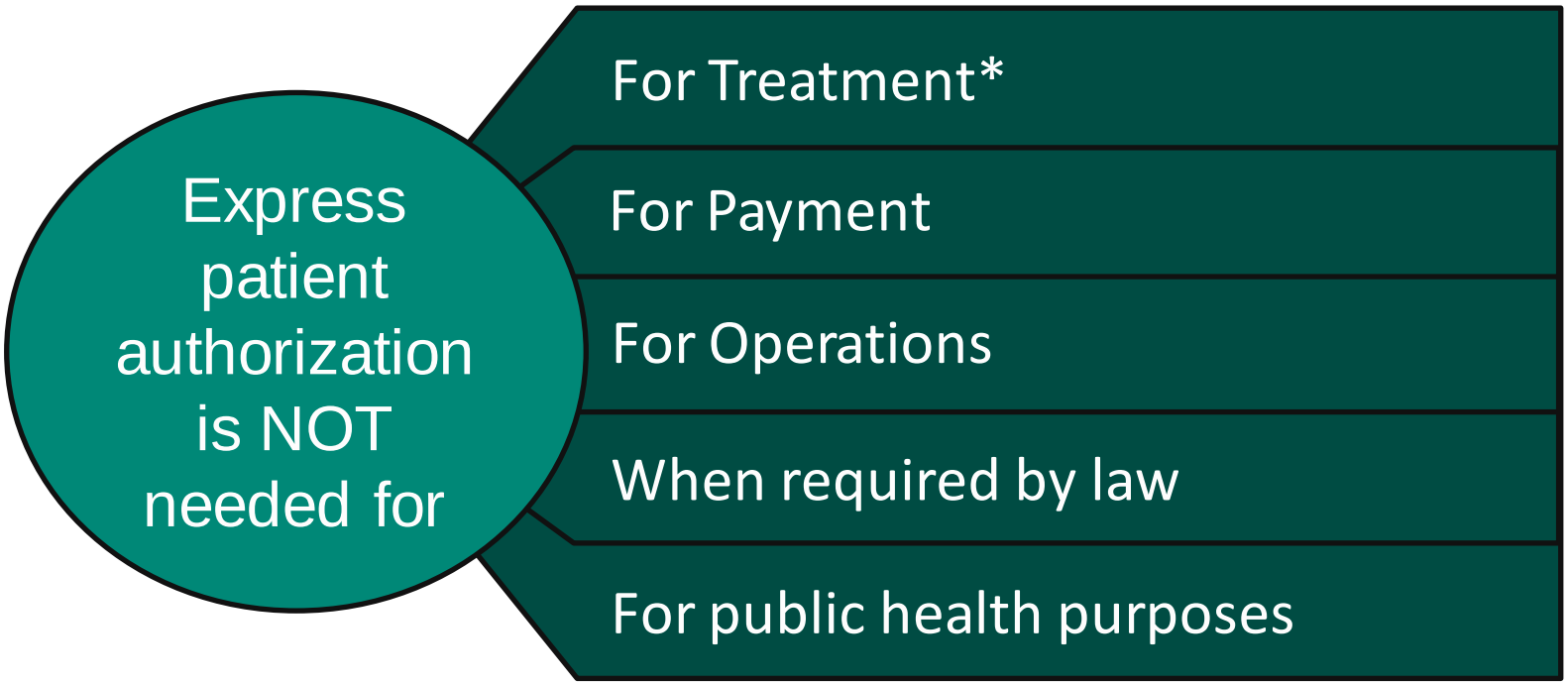
HIPAA: Authorization Not Needed



* A provider's coordination or management with a social service organization for services related to the individual's health, directly or indirectly, is explicitly included in the HIPAA definition of "treatment".

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.
  - Example: statute or regulation that requires reporting of drug overdose
- **"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** (mandate not required, includes disclosure of information if public health is permitted to collect it)

Several exceptions exist to the general rule that no Part 2 data can be released without patient consent.

Exceptions Include		
Court order	**De-identified information**	**Research**
Internal communication	**FDA request (health threat of product)**	Audit and evaluation
Medical emergency	Reporting suspected child abuse	**Qualified Service Organization (QSO)**

Note: there is no public health exception.

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"Part 2 won't allow me to release that data to you" isn't always the correct or only answer…

- Health care providers are a crucial source of information needed by health departments to protect and improve the public's health.
- Providers may question or deny access to information.
- Rule provides some exceptions that permit disclosure.
- Rule is not necessarily a barrier for health care providers to disclose identifiable information needed by public health.
- How can you engage Part 2 providers to include you in their efforts that achieve public health objectives?

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Thank you

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