

Navigating Privacy in Deflection: HIPAA & 42 CFR Part 2

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Welcome to Today's Session

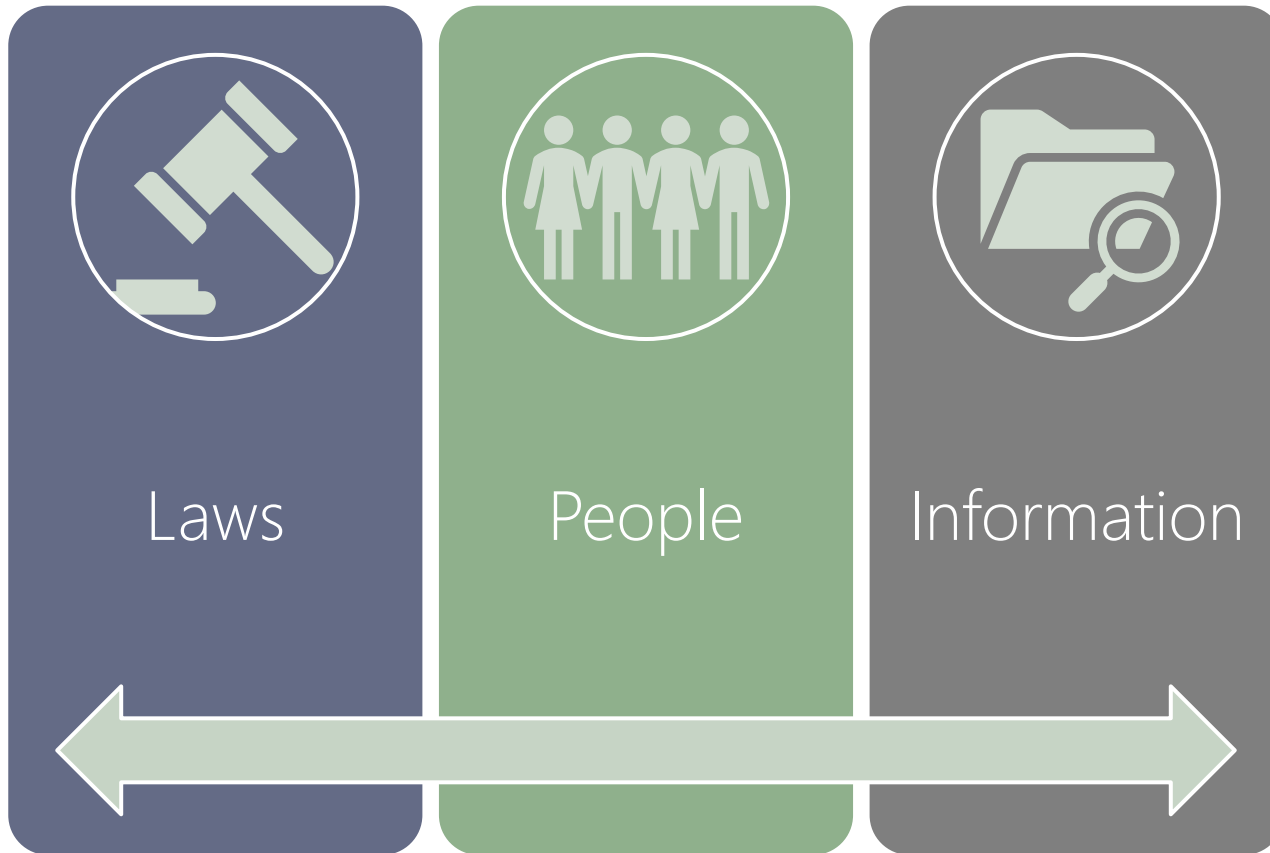
Roadmap

- A practical introduction and refresher on HIPAA and 42 CFR Part 2, with a deflection lens
- A look ahead at upcoming changes and enforcement in 2026
- A space for open discussion and Q&A, where teams can share barriers they encounter and strategies they've used in the field

Today's session offers an opportunity to assess the applicability and potential implications of federal privacy laws for your program. It's not legal advice and is limited to select highlights.



The Goal: Integration



The Laws

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996.

- Sections 261 through 264 of HIPAA require the Secretary of HHS to publicize standards for the electronic exchange, privacy and security of health information. Collectively these are known as the Administrative Simplification provisions.

PART 2

42 USC §290dd–2. Confidentiality of records (initial effective date July 1, 1944, with SUD protections first added in 1970)

- 42 CFR Part 2 – The Secretary of HHS shall prescribe regulations to carry out the purposes of this section; SAMHSA

Am I Covered Under the Laws?

HIPAA Covered Entity

- Health plan, health care clearinghouse, health care provider (of any size) who
- Transmits any health information in electronic form in connection with a transaction covered by this subchapter

Part 2 Program

- Part 2 Program = a federally assisted + program
- Program –
 - An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment
 - Identified unit or staff member in a general medical facility with this primary function

Relationship to Covered Entity, Part 2 Program

- Business Associate, Qualified Service Organization, Lawful Holder

What is Protected?

HIPAA: Protected Health Information (PHI)

- all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.

PART 2: Patient Records

- Identify and contain any information about a patient as having or having had a substance use disorder for the purpose of treating, making a diagnosis for that treatment, or making a referral for that treatment.
 - **Patient** means any individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a part 2 program.
 - **Diagnosis** means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment.

Disclosures

General Information

- Permitted - Deidentified, Aggregated data that neither identifies nor provides a reasonable basis to identify an individual
- Minimum Necessary
- Redisclosures - Part 2 restrictions!

HIPAA and Part 2 - consider categories of protection

HIPAA Permitted Disclosures

Permitted Uses and Disclosures. A covered entity is **permitted, but not required**, to use and disclose protected health information, **without an individual's authorization**, for the following purposes or situations:

- To the Individual (unless required for access or accounting of disclosures);
- Treatment, Payment, and Health Care Operations;
- Opportunity to Agree or Object;
- Incident to an otherwise permitted use and disclosure;
- Public Interest and Benefit Activities (twelve); and
- Limited Data Set for the purposes of research, public health or health care operations.

Part 2: Restricted Disclosure

Disclose means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.

The **presence of an identified patient** in a health care facility or component of a health care facility that is publicly identified as a place where only substance use disorder diagnosis, treatment, or referral for treatment is provided may be acknowledged only if the patient's written consent is obtained or by court order.

Restricts the disclosure of SUD treatment records **without written patient consent**, other than as statutorily authorized –

- bona fide medical emergency (with subsequent notice)
- scientific research, audit, or program evaluation
- appropriate court order.

Part 2 Final Rule Changes

Implements statutory amendments from section 3221 of the CARES Act (2020)

- increase coordination among providers treating patients for SUDs
- strengthen patient confidentiality protections through civil enforcement
- enhances integration of behavioral health information with other medical records to improve patient health outcomes

Timing:

- 42 CFR Part 2 Final Rule was published: February 16, 2024
- Effective Date: April 16, 2024
 - Provisions of the final rule may be implemented as of this date
- Compliance Date: February 16, 2026
 - Persons subject to the final rule would have until this date to comply with the applicable requirements

HHS: New Rule Highlights

- **Single patient consent** given once for all future uses and disclosures for treatment, payment, and health care operations.
- **Redisclosure of Part 2 records by HIPAA covered entities and business associates** in accordance with the HIPAA Privacy Rule, with certain exceptions.
- **New patient rights** under Part 2 and HIPAA Privacy Rule to obtain an accounting of disclosures and to request restrictions on certain disclosures.
- **HHS enforcement authority**, including the potential imposition of civil money penalties for Part 2 violations.
- **New breach notification requirements** for Part 2 records.

Highlights: Consent for TPO

- **Permits a single written consent** given once for all such future uses and disclosures for treatment, payment, health care operations (TPO) as permitted by HIPAA regulations
 - No longer requires names of individuals at an organization
 - For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the recipient may be described as “my treating providers, health plans, third party payers, and people helping to operate this program” or a similar statement.
 - Case management and care coordination are part of “operations”
 - Service providers receiving referrals from case management/care coordination may still need to be named

TPO Consent: 3 Types of Permitted Redisclosures

- **Covered Entity or Business Associate** – as permitted by the consent and in accordance with the HIPAA regulations
 - except for certain proceedings against the patient, where a consent or court order are required
 - covered entities and business associates must follow HIPAA business associate agreement requirements
- **Part 2 Program that is NOT a covered entity** – see the language in the consent
- **Lawful Holder** that is NOT a covered entity or business associate - as needed to carry out the activities specified in the consent
 - **Note** - *consider how this applies to qualified service organizations*

More on Disclosures & Redisclosures

- **Notification** - Each disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear explanation of its scope
- **Segregating or Segmenting Part 2 Records** – generally not required except for counseling notes, which require an additional consent
- **Restrictions and Revocation** - Use and disclosures are subject to patient directed restrictions and revocation, including
 - a patient right to request restrictions on disclosures of records otherwise permitted for TPO purposes
 - a patient right to obtain restrictions on disclosures to health plans for services paid in full by the patient
 - A patient right to revoke the consent in writing

Intermediaries

- **Intermediaries**
 - means a person, other than a part 2 program, covered entity, or business associate, who has received records under a general designation in a written patient consent
- **Written Consent** – must include the name(s) of the intermediary(ies) and:
 - name(s) of the member participants of the intermediary; or
 - A general designation of a participant(s) or class of participants - *limited to participant(s) having treating provider relationship with the patient whose information is being used or disclosed.*
- **Requirements for intermediaries**
 - Upon request, an intermediary must provide to patients who have consented to the disclosure of their records using a general designation, a list of persons to which their records have been disclosed pursuant to the general designation.

Enhanced Protections

Limitations on use in the courts (criminal, civil, administrative, legislative)

- By court order
- By separate patient written consent for this express purpose

Special protection for SUD counseling notes

- New definition for an SUD clinician's notes analyzing the conversation in an SUD counseling session that the clinician voluntarily maintains separately from the rest of the patient's SUD treatment and medical record
- Requires specific consent from an individual and cannot be used or disclosed based on a broad TPO consent
- This is analogous to protections in HIPAA for psychotherapy notes

Separate nondiscrimination rule

Part 2 Obligations

Part 2 Compliance Documentation and Requirements include:

- ✓ Notice of Privacy Practices - at the time of admission to a part 2 program
- ✓ Patient Consent / Restrictions / Revocation
- ✓ Notice/Copy of Consent with all (Re)disclosures
- ✓ Qualified Service Organization Agreement
- ✓ Patient Access to Records (timely)
- ✓ Accounting of Disclosures - past 3 years
- ✓ Breach Notifications
- ✓ Formal Policies and Procedures - to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information.

Enforcement

U.S. Department of Health and Human Services (HHS), **Office for Civil Rights (OCR)** – designated to also enforce Part 2

- Noncompliance with Part 2 is now treated in the same manner as they apply to covered entities and business associates for noncompliance with HIPAA
- Criminal and Civil Monetary Penalties
- A person may file a complaint to the Secretary for a violation of this part by a part 2 program, covered entity, business associate, qualified service organization, or lawful holder

Example - Cadia Healthcare Facilities

- “Success story” program on website
 - Included patient name, photograph and information pertaining to the patient’s conditions, treatment, and recovery
 - Without first obtaining a valid, written HIPAA authorizations
- Violation
 - Impermissible disclosure, failure to have appropriate safeguards, no breach notification
- Settlement
 - \$182,000 paid to OCR
 - Corrective action plan that will be monitored by OCR for two years

Example - Cadia Healthcare Facilities

Also take the following steps to improve compliance:

- Reviewing and, to the extent necessary, developing, maintaining, and/or revising, its written policies and procedures to comply with the HIPAA Privacy and Breach Notification Rules
- Providing all members of their workforce, including marketing personnel, with training on their HIPAA policies and procedures
- Notifying any and all individuals, or the individual's personal representative, whose PHI was disclosed by Cadia Healthcare Facilities on any of its facility websites, social media accounts, or through other marketing or promotional materials without a valid authorization, that their PHI has been breached

Best Practices – Documentation!

- ❑ Notice of Privacy Practices with Written Acknowledgment
- ❑ **Authorization/Consent to Share Protected Information**
 - Individual; group; redisclosure
 - Who signs? Esp. with minors and foster care applications
- ❑ Revocation of Authorization/Consent - also watch for expirations

- ❑ Information Mapping; Framework Analysis
- ❑ Business Associate/Qualified Service Organization Agreement/Contract
- ❑ Data Sharing (or other) Agreement/MOU/Other?

- ❑ Policies and Procedures
- ❑ Accounting of Disclosures

Mapping the Data Flow

- Who is part of your deflection team?
 - Members - CE, BA, P2P, QSO, Lawful Holder
 - Partners - referral sources, funders, researchers
- How do the members and partners of your deflection team participate in information sharing?
 - Contribute information
 - Access information
 - (Re)disclose information
- What is the type of data shared / protection required?
 - HIPPA PHI
 - Part 2 Patient Record
 - Deidentified/Aggregated

Government Resources - HIPAA

Covered Entities and Business Associates – HHS Guidance

<https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>

Are you a Covered Entity – CMS Resources

<https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa/covered-entities>

Covered Entity Decision – CMS Tool

<https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/Downloads/CoveredEntitiesChart20160617.pdf>

Government Resources – Part 2 (new rule)

The Part 2 Final Rule - Federal Register

<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2>

Part 2 Final Rule Fact Sheet - HHS

www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html

Part 2 Webinar - OCR

OCR's YouTube channel: www.youtube.com/watch?v=F3ZZgCXpT4k

OCR's website: www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-part-2/index.html

Centers of Excellence

***Criminal Justice Coordinating Center of Excellence –
a NEOMED CCoE***

<https://www.neomed.edu/cjccoe/>

***Center of Excellence for Protected Health Information –
funded by SAMHSA***

<https://coephi.org/about-coe-phi/>

ADDITIONAL RESOURCES

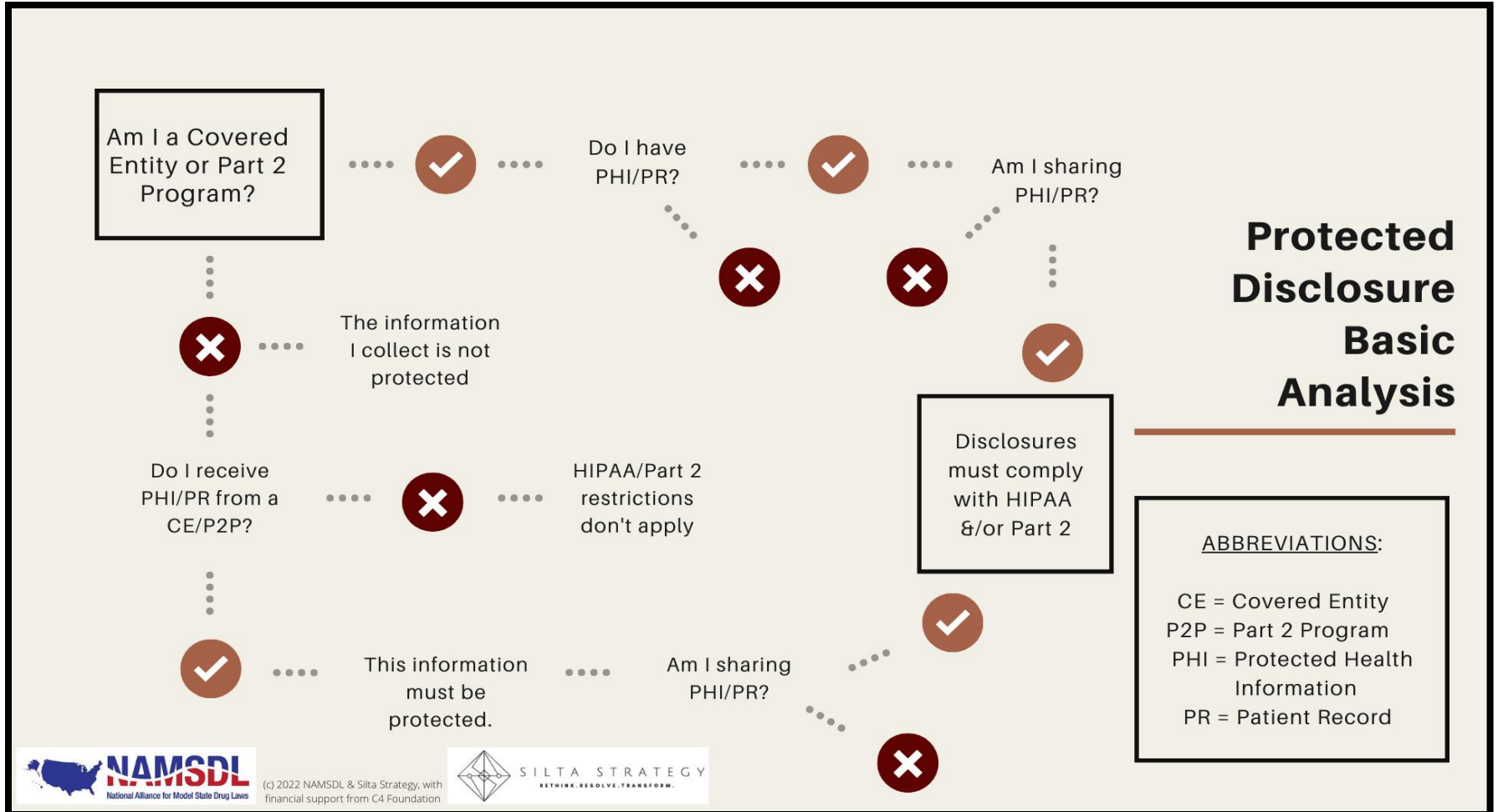
Compliance Is Doable! A Framework for Navigating Privacy Regulations in Public Health and Public Safety Partnerships

Journal of Public Health Management and Practice, Volume 28 - Issue Supplement 6, November/December 2022, p S367-S371

Balancing Data Privacy with Access to Health Services and Research: Facilitating Confidential Information Sharing in US Multi-System Collaborations

Value in Health Journal, Volume 26, Issue 9, September 2023, Pages 1325-1328

RESOURCES – Framework



What Are Your Experiences?

- Common privacy or information-sharing challenges you face
- Questions that arise most often in your work
- Examples or approaches that could help other teams

Let's Continue the Conversation



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