

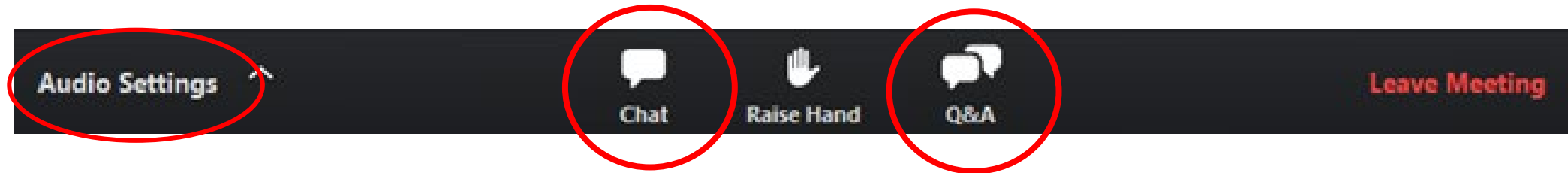
# 42 CFR Part 2 Final Rule - What You Need to Know

CoE-PHI



December 11, 2024

# Zoom Webinar Logistics



This meeting is being recorded and will be archived on the CoE-PHI site following the webinar.

# Center of Excellence for Protected Health Information (CoE-PHI)

The CoE-PHI develops and disseminates resources, training, and TA for state and municipal agencies, healthcare providers, school-based professionals, and individuals and families to improve understanding and application of health privacy laws and regulations, including 42 CFR part 2 (part 2), the Health Insurance Portability and Accountability Act (HIPAA), and the Family Educational Rights and Privacy Act (FERPA), when providing or receiving treatment for substance use and mental health conditions.

CoE-PHI also provides TA regarding the intersection of state law and federal health privacy laws.

***Resources, training, technical assistance, and any other information provided through the CoE-PHI do not constitute legal advice.***



# Center of Excellence for Protected Health Information (CoE-PHI)



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*The content of this presentation was authored by the CoE-PHI and the views expressed are not necessarily those of SAMHSA or HHS.*

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# Learning Objectives

- Describe February 2024 Final Rule changes to 42 CFR Part 2 (Part 2)
- Apply recent changes to practical scenarios within case studies
- Identify how to access resources and technical assistance provided by the CoE-PHI

# Overview

**Confidentiality regulations protect patient privacy, give you flexibility to provide the best possible treatment, and help clarify the boundaries in protecting and sharing patient information.**

# 42 CFR Part 2

- **Part 2 protects the confidentiality of patient records at federally assisted SUD treatment programs**
  - These programs are called “Part 2 programs”
    - See [CoE-PHI resources on Part 2 Applicability](#)
- Not all SUD-related patient information is protected by Part 2
- Part 2’s privacy protections generally *follow* the record upon disclosure



# 2024 Final Rule Snapshot

- **Implements** changes required by CARES Act (2020) to align certain aspects of Part 2 with HIPAA
  - See [HHS factsheet on Final Rule](#)
- **Key dates:**
  - Effective date: April 16, 2024
  - Compliance date: February 16, 2026

# What did NOT change?

- Concept of Part 2-covered program
  - Federally assisted SUD program, defined in § 2.11
- General rule: patients must consent in writing to disclosures of their Part 2-records, unless an **exception** applies
  - No major changes to exceptions
- Concept of “lawful holder”
  - And now defined in § 2.11
- Court order requirements

# Notable 2024 Final Rule Changes

Single consent for  
TPO

Redislosures of  
records with TPO  
consent

Consent: legal  
proceedings

Consent: SUD  
counseling notes

Notice with  
disclosures

Accounting of  
disclosures

Right to request  
restriction

Patient notice

Complaints,  
penalties, and  
enforcement

Breach notification

# New and Revised Terms

- Use and disclosure
- “Person” = natural person (meaning a human being who is born alive), trust or estate, Partnership, corporation, professional association or corporation, or other entity, public or private
- SUD counseling notes
- Intermediary

# Anti-discrimination Protections

- CARES Act (2020) included new **anti-discrimination** protections for individuals with Part 2 records
  - Prohibition on using Part 2 records to discriminate against an individual in making certain decisions regarding that individual's healthcare, employment, housing, access to courts, social services, and benefits
- HHS to implement the CARES Act anti-discrimination protections for Part 2 records in a separate Proposed Rule



## Poll: Part 2 refresher

Which of the following does Part 2 protect?

- a) Any information about drug use in any health record
- b) Any information about substance use disorder diagnosis or treatment in any health record
- c) Any information about a patient receiving diagnosis, treatment, or referral for treatment for a substance use disorder created by a Part 2 program



## Poll: Part 2 refresher

The correct answer is c) Any information about a patient receiving diagnosis, treatment, or referral for treatment for a substance use disorder created by a Part 2 program

# Section 1: Disclosures with consent




# Refresher: Basic rule

- Part 2 permits disclosures of Part 2 records with a patient's *written consent*
  - Part 2 “consent” sometimes known as “authorization” or “release of information” (ROI)
    - See: HIPAA “authorization”
  - Part 2 consent is **not** consent to treatment
- Recipient becomes **lawful holder** of Part 2 Records
  - Part 2 “follows” the records

# Written consent requirements (§ 2.31)

- Final Rule aligns many of the required elements of a Part 2 written consent with the requirements for valid HIPAA authorization
- **New “TPO consent” for all future uses and disclosures**
  - **TPO = treatment, payment, healthcare operations**
- New prohibitions on combining certain consents
  - Consents authorizing disclosure of SUD counseling notes
  - Consents for legal proceedings against the patient



**Focus:PHI**

**SAMPLE CONSENT**  
AUTHORIZING DISCLOSURE OF CONFIDENTIAL SUD PATIENT RECORDS

*REMEMBER: Records disclosed pursuant to patient consent must be accompanied by the notice prohibiting redisclosure.*

I, \_\_\_\_\_,  
[patient's name]

authorize \_\_\_\_\_  
[name or general designation of individual or entity making the disclosure]

to disclose \_\_\_\_\_  
[describe how much and what kind of information may be disclosed, including *explicit description* of any substance use disorder information to be disclosed; should be as limited as possible]

to \_\_\_\_\_  
[name of individual(s) or entity(ies) who will receive the information]

for the purpose of \_\_\_\_\_  
[describe the purpose of the disclosure; should be as specific as possible]

## New flexibilities for consent forms

- Can describe the recipient of the information as a “class of persons,” e.g., “my treating providers” or “health plans”

## Part 2 consent form elements:

- Patient name
- Description of records
- Purpose of disclosure
- “To” and “From”
- Revocation statement
- Expiration
- Signed and dated

# TPO Consent

- Key terminology: TPO
  - Treatment
  - Payment
  - Healthcare Operations
- Defined by HIPAA Privacy Rule
  - See [45 CFR 164.501](#)
  - [HHS guidance](#)
  - Examples: Billing and collection activities, eligibility and benefits checks, risk adjustment, care coordination, etc.

# TPO Consent, cont.

- Single consent can authorize all future uses and disclosures for purposes of TPO
  - Recipient: “my treating providers, health plans, third-Party payers, and people helping to operate this program,” or similar statement
  - Purpose: “treatment, payment, or healthcare operations”
  - Expiration: “end of treatment” or “none”

# TPO Consent: Redisclosures

- After patient signs a TPO consent
  - Recipients that are Part 2 programs or HIPAA Covered Entities or Business Associates can use and disclose records for TPO
  - Recipients that are Covered Entities or Business Associates can further disclose those records in accordance with HIPAA regulations
    - EXCEPT uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient

# Case study: Lee and TPO Consent



# Case study

Lee enters treatment for opioid use disorder at Green Hill, a Part 2 program within a Federally Qualified Health Center (FQHC).

Lee signs a TPO consent form permitting the Part 2 program to use and disclose his Part 2 Records:

- To his treating providers, health plans, third-Party payers, and people helping to operate this program
- For treatment, payment, and healthcare operations
- Expiring upon the end of treatment





## Poll #1

Which of the following disclosures are permitted with Lee's TPO consent?

- a) Green Hill can share Lee's records with other providers in the FQHC for treatment
- b) Green Hill can share Lee's records with a provider at a local hospital for treatment
- c) Green Hill can bill Lee's insurance for reimbursement
- d) Green Hill can share Lee's records with a health plan for care coordination activities
- e) All the above



## Poll #1 Answer

The answer is e): All the above.

- Lee's TPO consent permits the Green Hill Part 2 program to make disclosures of his Part 2 Records to a variety of people for a variety of purposes related to "treatment, payment, and healthcare operations."



## Poll #2

Once Indigo Hospital System receives Lee's Part 2 Records from Green Hill pursuant to the TPO consent, how can the hospital use and redisclose Lee's records?

- a) Any use or disclosure permitted by HIPAA
- b) Any use or disclosure permitted by HIPAA, except for uses and disclosures for legal proceedings against Lee
- c) Any use or disclosure related to treatment, payment, and healthcare operations
- d) Any use or disclosure related to treatment



## Poll #2 Answer

The correct answer is b): Indigo Hospital System can use or disclose Lee's Part 2 Records as permitted by HIPAA, except uses and disclosures for legal proceedings against Lee.

- Uses and disclosures for legal proceedings against the patient must be authorized by the patient in a written consent or a Part 2 court order.



## Case study, cont.

Lee begins receiving treatment at Violet Dialysis Clinic. To assist in treating Lee, Violet Dialysis Clinic requests a copy of all Lee's medical records from Indigo Hospital System.

Indigo Hospital System shares all Lee's records as permitted by HIPAA, including Lee's SUD treatment records from the Part 2 program.



## Poll #3

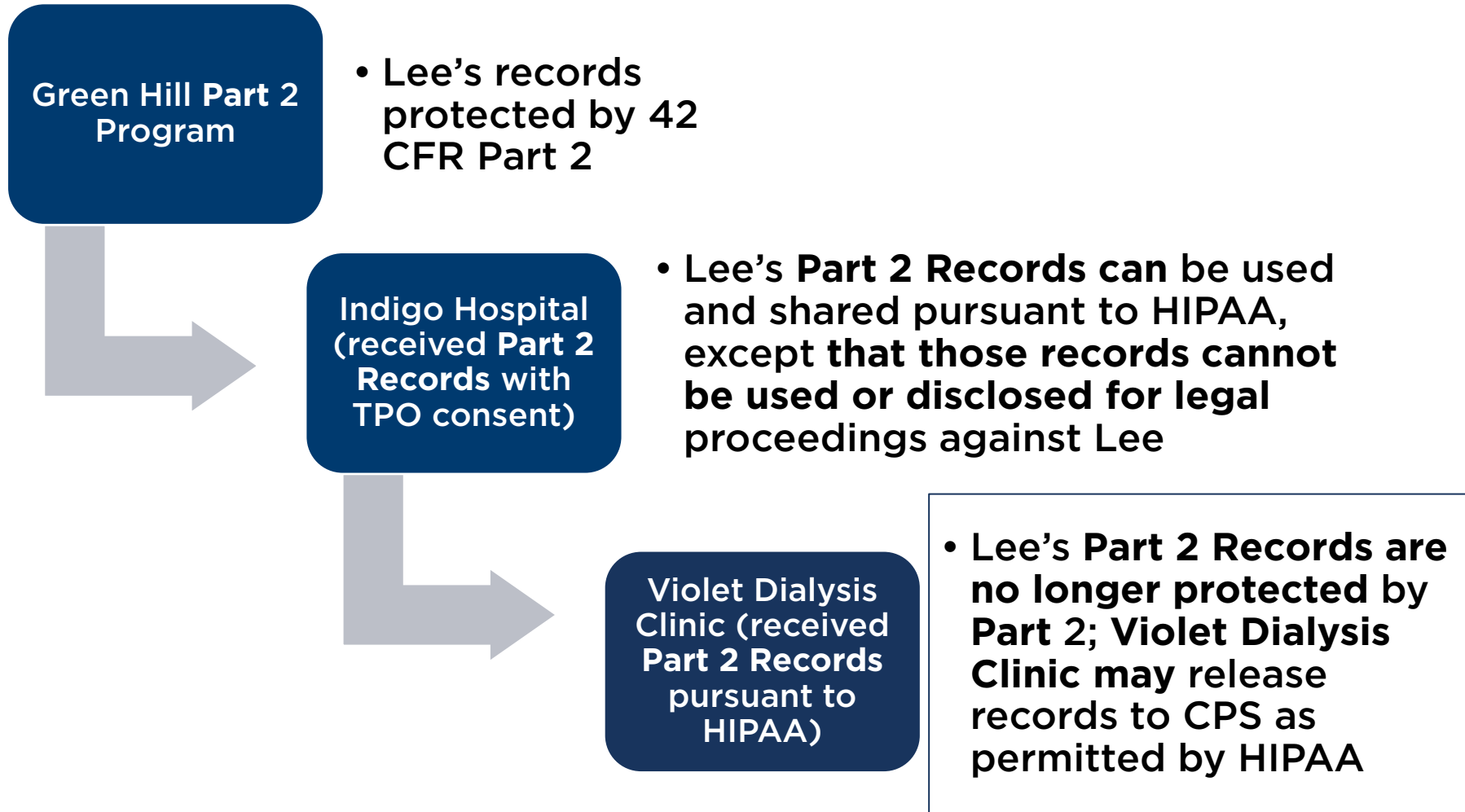
While investigating an allegation against Lee, Child Protective Services requests a copy of Lee's records from the Green Hill Part 2 program, Indigo Hospital System, and the dialysis clinic.

Which of the following can release Lee's Part 2 in response to the request?

- a) Green Hill Part 2 program
- b) Indigo Hospital System
- c) Violet Dialysis Clinic
- d) It depends

# Case study: Flow of information

Answer is d): It depends



# Written Consent and SUD Counseling Notes

## (§ 2.31)

- Part 2 program must obtain consent for any use or disclosure of SUD counseling notes, except:
  - Certain TPO:
    - Originator of notes can use notes for treatment
    - Part 2 program can use or disclose notes internally for training clinicians
    - Part 2 program can use or disclose notes to defend itself in legal action brought by the patient
  - As required by the Secretary of HHS to investigate Part 2 compliance
  - As permitted by limited exceptions for mandated reports of suspected child abuse/neglect, deceased patients, oversight activities, and court orders



# Written Consent and SUD Counseling Notes, (*cont.*) (§ 2.31)

- Consent permitting use or disclosure of SUD counseling notes **cannot** be combined with consents authorizing the use and disclosure of other types of records
  - **HOWEVER**, it is **permitted** to obtain one consent that authorizes multiple uses and disclosures of SUD counseling notes
- Part 2 program **may not** require the patient to sign a consent for use or disclosure of SUD counseling notes as a condition of the patient receiving treatment or other services.

# CoE-PHI Resource: SUD Counseling Notes

*\*See Related CoE-PHI Resource:*

## Substance Use Disorder Counseling Notes



### Substance Use Disorder Counseling Notes: What Behavioral Health Providers and Administrators Need to Know In 2024 About 42 CFR Part 2's New Protections for SUD Counseling Notes

In 2024, HHS amended the substance use disorder (SUD) confidentiality regulations at 42 CFR Part 2 to improve alignment with HIPAA (the Health Insurance Portability and Accountability Act).<sup>1</sup> One of these changes involves new protections for "substance use disorder (SUD) counseling notes," which has a definition similar to the definition for psychotherapy notes within HIPAA.<sup>2</sup> Part 2 now provides stricter confidentiality protections for these notes than for other parts of a patient record.<sup>3</sup>

#### WHAT YOU NEED TO KNOW

##### **SUD counseling notes, defined.**

SUD counseling notes are notes by an SUD or mental health professional at a Part 2 program, in which they document or analyze the contents of a conversation from an SUD counseling session.<sup>4</sup> SUD counseling sessions include private and group sessions, as well as joint or family SUD counseling sessions.<sup>5</sup> Notes may be in "any medium,"<sup>6</sup> including paper or electronic notes. In the context of explaining HIPAA's psychotherapy notes, HHS has stated that these notes are the personal notes of a therapist, intended to help the therapist recall the discussion and of little or no use to others not involved in the therapy.<sup>7</sup>

The definition of SUD counseling notes specifically **excludes** medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment provided, results of clinical tests, and any summary of the following: diagnosis, functional status, treatment plan, symptoms, prognosis, or progress to date.<sup>8</sup>

# Documentation Accompanying Disclosures

## § 2.32

- **Remember:** Part 2 Records disclosed with consent must be accompanied by a **notice** of the prohibition on redisclosure
  - February 2024 Final Rule contains **required language** for both short and long versions of notice
  - Disclosures must be accompanied by a copy of the consent form **or** a clear explanation of the scope of the consent provided by the patient

# Section 2: New patient rights and enforcement changes

# Enforcement § 2.3

- Penalties for Part 2 violations now aligned with penalties for HIPAA violations
  - Civil money penalties for failing to comply
    - See [42 USC 1320d-5](#)
  - Criminal penalties for knowingly and wrongfully using or disclosing Part 2 Records
    - See [42 USC 1320d-6](#)
- HHS will now investigate and enforce violations instead of DOJ
  - **HOWEVER**, cases involving the knowing and wrongful use or disclosure of Part 2 Records may still be referred to the DOJ for investigation and enforcement

# Complaints § 2.4

- Patients may now submit complaints regarding a Part 2 program's compliance with Part 2 requirements to the Part 2 program directly or to the HHS Secretary (or both)
  - Part 2 programs must have process for receiving complaints
- No retaliation for filing complaint or exercising patient rights
- No permissible waiver of rights

# Breach notification § 2.16

- Part 2 programs must notify patients of a breach of unsecured Part 2 Records
  - Breach notification requirements aligned with HIPAA
  - “Breach” defined by reference to HIPAA
- HHS interpretation: “breach” includes uses or disclosures that violate Part 2
  - See [Final Rule at page 12,496.](#)

# Patient Rights

- Right to request privacy protection for Part 2 Records § 2.26
  - Right to obtain certain restrictions of disclosures when services paid in full
- Right to an accounting of disclosures
  - By Part 2 program § 2.25
  - By an intermediary § 2.24
- Right to discuss notice of patient rights § 2.22
- Right to opt out of fundraising communications § 2.22



# Right to request restrictions § 2.26

- Part 2 program must permit a patient to request a restriction on uses or disclosures of Part 2 Records to carry out TPO
  - “Programs and covered entities are expected to do more than merely establish policies and procedures on the right to request restrictions – they need to make a concerted effort to evaluate how they can reasonably accommodate patients’ requests.” HHS
- *If* the Part 2 program agrees, **must** honor the restriction unless there is an emergency
- Part 2 program **must** agree only when patient requests restriction on disclosure to health plan for those services for which patient has paid in full (see [45 CFR § 164.522](#))

# Right to accounting of disclosures § 2.25

- Right to an accounting of certain disclosures made by Part 2 program with patient's consent within the past 3 years
  - Accounting of TPO disclosures only for disclosures made through electronic health record
  - Subject to HIPAA standards; see [45 CFR 164.528\(a\)\(2\) and \(b\) through \(d\)](#)
- Not yet in effect; compliance date delayed until HITECH rule

# Section 3: Next steps and review

# Next steps for implementation

- Patients:
  - Understand differences between types of consent
    - Patients need to know and understand scope of consent
  - Know and understand patient rights, including limitations on those rights
- Providers:
  - Update policies and procedures
  - Update consent forms and notices prohibiting redisclosure
  - Training for staff



## Closing Chat-in Question

*What resources do you need from CoE-PHI to assist you with understanding and applying the February 2024 Final Rule changes to Part 2?*

# Review: Main Points

- **Initial patient consent** still required for use and disclosure of Part 2 records
  - New prohibitions on combining certain consents
- **One-time “TPO consent”** for using and sharing Part 2 records for treatment, payment, and healthcare operations
  - TPO consent creates looser redisclosure permissions for HIPAA Covered Entities and Business Associates
- **Disclosures with consent** must be accompanied by updated notice prohibiting redisclosure and a copy of the consent form or a summary of its scope
- **Providers have until Feb. 16, 2026 to implement changes**



**Questions?**

# Closing





## Evaluation

Following this webinar, you will receive an email with a link to complete an evaluation.

Your opinions improve our future trainings and resources.

# Accessing the CoE-PHI



## Technical Assistance

Technical assistance (TA) provided by the Center of Excellence for Protected Health Information (CoE-PHI) aims to support implementation of relevant federal confidentiality and privacy laws for providing mental health and substance use disorder services to clients in practice.

TA is designed to clarify confidentiality regulations and laws, link professionals to helpful resources, and identify strategies to support practical implementation of confidentiality and privacy regulations in practice.

Before requesting Technical Assistance, consider visiting our Resource Library, as answers to many frequently asked questions regarding federal health privacy laws are contained within our resources.

[REQUEST TECHNICAL ASSISTANCE](#) →

## Request TA

[coephi.org/technical-assistance](https://coephi.org/technical-assistance)

## Resource Library

[coephi.org/resource-library/](https://coephi.org/resource-library/)

**Confidentiality is a cornerstone of recovery.  
Protecting patient privacy opens doors to  
communication, understanding, and trust.**



**Thank  
you!**

**F**  **cus:PHI**

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