

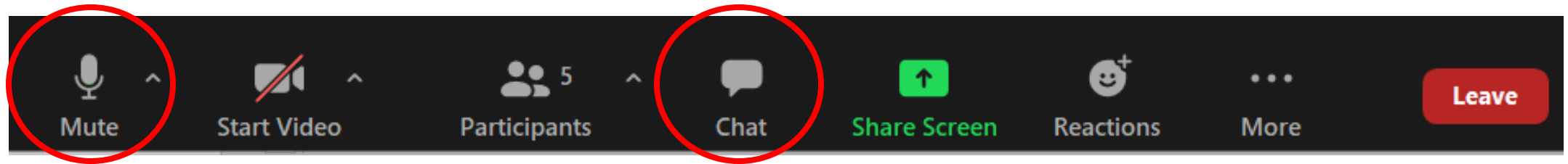
# 42 CFR Part 2 Final Rule on SUD Privacy

*What State Agency Leaders Need to Know to Support Implementation*



July 17, 2024 for NASADAD

# Zoom Meeting Logistics



For questions, please utilize the Q&A Function

# ASL Interpretation Services



- To view our ASL interpreters for today, please click on the Interpretation icon on your Zoom toolbar, and select “American Sign Language”

# 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 administrators 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.

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

**Confidentiality is a cornerstone of recovery.**

Protecting patient privacy opens doors to communication, understanding and trust.



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



*This project is funded by SAMHSA of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award, with 100% funded by SAMHSA/HHS.*

# Learning Objectives

- Understand recent changes to 42 CFR Part 2
- Apply recent changes to practical scenarios within case studies
- Define practical steps for implementing recent changes to Part 2
- Identify how to access resources and technical assistance provided by the CoE-PHI

# Poll

Please rate your state's progress implementing the necessary changes to comply with the 2024 Part 2 Final Rule:

- a) We are still reviewing the Final Rule
- b) We have reviewed and identified major implications for our state
- c) We are already implementing and beginning to troubleshoot
- d) We have fully implemented and ready to train other states



# 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”
  - Not all SUD-related patient information is protected by Part 2
    - See [CoE-PHI resources on Part 2 applicability](#)
- **Part 2 generally *stricter than* HIPAA Privacy Rule**
  - Part 2’s privacy protections *follow* the record upon disclosure
  - Strict protections against use or disclosure for criminal investigation or prosecution of patients

# 2024 Final Rule Snapshot

- **Implements** changes required by CARES Act (2020) to align certain aspects of Part 2 with HIPAA and new public health provision
  - **\*See:**
    - [HHS factsheet on final rule](#)
    - [CoE-PHI Archived Webinar: 42 CFR Part 2 Final Rule – What You Need to Know](#)
- **Key dates:**
  - Effective date: April 16, 2024
  - Compliance date: February 16, 2026
- **Still forthcoming:** anti-discrimination rulemaking
  - Prohibition on using Part 2 records to discriminate against a patient in healthcare, employment, housing, access to courts, social services, and benefits

# What did NOT change?

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

# Overview of Major Changes in 2024 Rulemaking

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

# Key Changes for NASADAD

- New requirements and permissions for disclosures with patient consent
  - 42 CFR §§ 2.31, 2.32, 2.33
- New provisions for reporting to public health authorities
  - 42 CFR § 2.54

# Written Consent Requirements (§ 2.31)

- Changes align many of the required elements in Part 2 written consent with requirements for valid HIPAA authorization
- New requirements and rules for “TPO consent” authorizing all future uses and disclosures for treatment, payment, and 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 instructions/flexibilities for consent forms

- Key change: can now describe the recipient of the information as a “class of persons,” e.g., “my treating providers” or “health plans”

## Part 2 consent form requires:

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

# NEW: Single consent for TPO

- Key terminology: **TPO**
  - **T**reatment
  - **P**ayment
  - Healthcare **O**perations
- Defined by HIPAA Privacy Rule

*\*See:*

- [45 CFR 164.501](#)
- [HHS Guidance: Uses and Disclosures for Treatment, Payment, and Health Care Operations](#)



# 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, cont.

- Required statement #1 on TPO consent: notice to patient of redisclosures and potential loss of privacy protections
  - If recipient is a covered entity or business associate, the patient's record (or information contained in the record) may be redisclosed in accordance with the permissions contained in the HIPAA regulations, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient

# TPO Consent, cont.

- Required statement #2 on TPO consent: consequences if patient does NOT sign the consent
  - A program should not condition treatment on a TPO consent unless it has some capacity to fulfill patients' requests for restrictions on uses and disclosures for TPO
- HHS and Congress intend programs to make “every reasonable effort” to fulfill patient requests for restrictions on TPO uses and disclosures

# TPO Consent: Redisclosures

- After patient signs a TPO consent...
  - Recipients that are Part 2 programs, covered entity, 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
  - Subsequent re-disclosures lose all Part 2 protections

# Case Study #1: Lee



## Case Study #1

Lee enters treatment for opioid use disorder at Green Hill, a Part 2 program within an FQHC.

Lee signs a TPO consent form authorizing use and disclosures:

- **To:** my treating providers, health plans, third-party payers, and people helping to operate this program
- **For:** treatment, payment, and healthcare operations
- **Expiring:** upon end of treatment



## Poll #1(a)

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

- a) Green Hill can share all Lee's records with other providers in the FQHC for treatment
- b) Green Hill can share all 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 of the above



## Poll #1(a) Answer

The answer is (e) “all of the above.”

- Lee’s TPO consent authorizes the Green Hill Part 2 program to make disclosures to a variety of people for a variety of purposes related to “treatment, payment, or healthcare operations.”





## Poll #1(b)

Once Indigo Hospital System receives Lee's 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 #1(b) Answer

The correct answer is (b): the hospital 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 patient consent or a Part 2 court order.



## Case Study #1, cont.

Lee begins receiving treatment at a local dialysis clinic, and the clinic asks for a copy of all Lee's records from Indigo hospital.

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



## Poll #1(c)

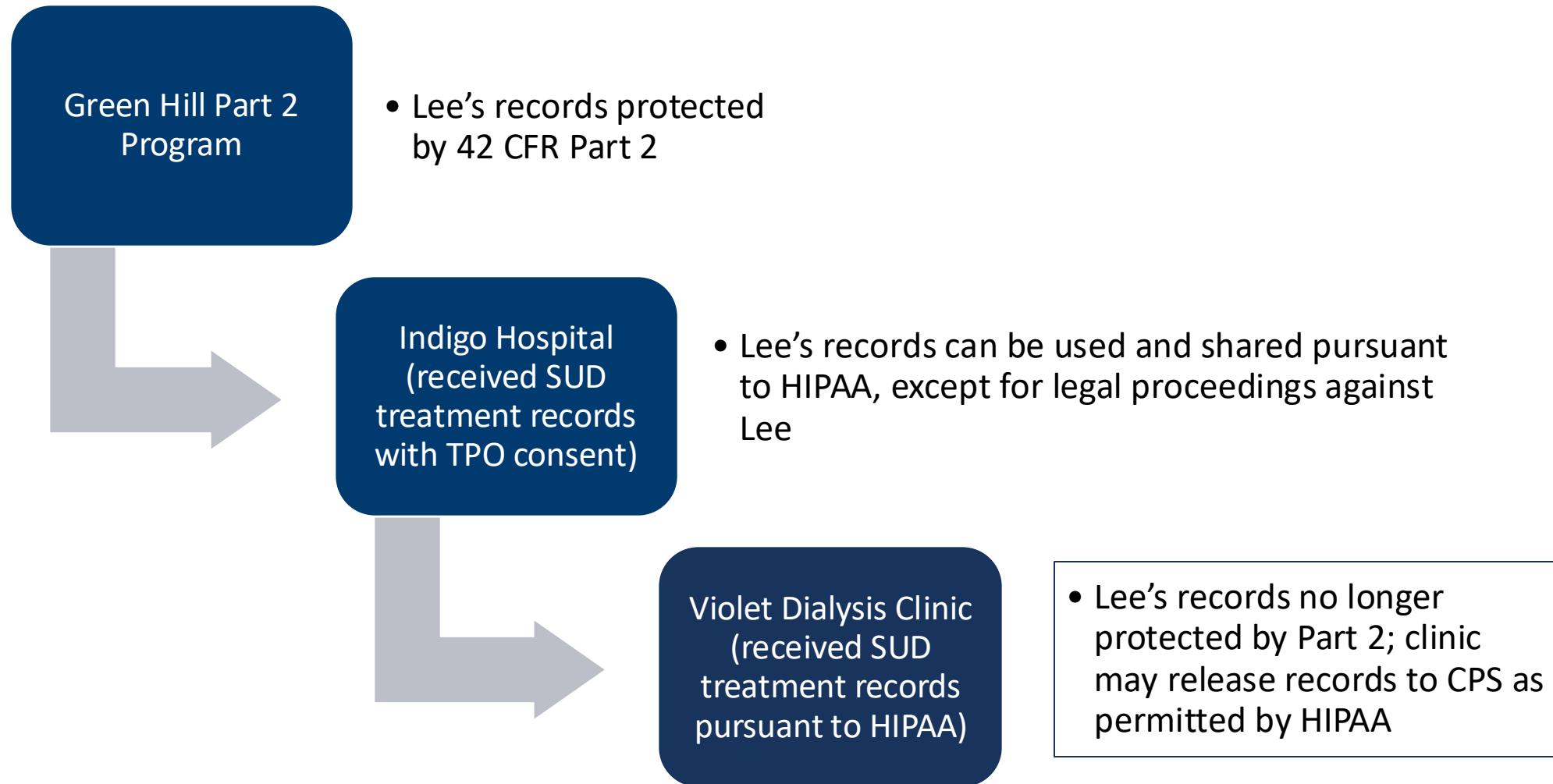
During an investigation of an allegation against Lee, Child Protective Services requests a copy of Lee's health records from the Part 2 program, the hospital, and the dialysis clinic.

Which of the following can release Lee's SUD treatment records in response to the request?

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

# Case study #1(c): Flow of information

The correct answer is (d): it depends.



# Case Study #2: Claudia



## Case Study #2

- Claudia signs a consent form authorizing her Part 2 program to share her SUD treatment records with her primary care doctor.
  - Claudia signs a consent form for purpose of treatment.



## Poll #2

Which of the following is true?

- a) The primary care doctor must continue following Part 2's restrictions on use and disclosure for the records it received
- b) The primary care doctor may use and redisclose Claudia's records pursuant to HIPAA, except for uses and disclosures in legal proceedings against the patient





## Poll #2 Answer

a) The primary care doctor must continue following Part 2's restrictions on use and disclosure for the records it received.

- Even though Claudia authorized disclosure for “treatment” purposes, she did not authorize disclosures for all TPO uses and disclosures

# Written Consent and SUD Counseling Notes (§ 2.31)

- New definition in § 2.11:

*Substance use disorder (SUD) counseling notes* means notes recorded (in any medium) by a part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private SUD counseling session or a group, joint, or family SUD counseling session and that are separated from the rest of the patient's SUD and medical record.

*SUD counseling notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

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

- Part 2 program must obtain consent for any use or disclosure of SUD counseling notes, except:
  - Certain TPO
  - As required by the Secretary of HHS to investigate Part 2 compliance
  - As permitted by limited exceptions

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

- Consent authorizing use or disclosure of SUD counseling notes cannot be combined with other consents
  - Okay to combine multiple consents authorizing uses and disclosures of SUD counseling notes
- **Part 2 program may not condition treatment or other services on signing a consent for use or disclosure of SUD counseling notes**

# Making Disclosures with Consent § 2.32

- **Remember:** Part 2 records disclosed with consent must be accompanied by a **notice** of the prohibition on redisclosure
- **What changed:**
  - *New 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

# Public Health Reporting § 2.54

- **Remember:** disclosures to public health permissible with patient consent or if no patient-identifying information
- **Now:** CARES Act introduced new statutory provision regarding public health reporting, reflected in new Section 2.54 of 42 CFR Part 2
  - Reporting to public health authority permissible with patient consent or disclosure meets HIPAA standard for de-identified information
- Public health authority defined by reference to definition in HIPAA at 45 CFR § 164.501

Questions?

# Section 2: Implementation and Review



# Next steps for implementation: #1

## #1: Update Part 2 consent forms and required notices

- Updated consent(s)
  - Updated sample consent **forthcoming**
  - State agencies may consider creating unified consent for state
- Updated notice to accompany disclosures available [here](#)
- Updated patient notice forthcoming

# Next steps for implementation: #2

## #2: Revise agency policies and procedures

- Programs and other stakeholders\* need to update their policies and procedures for:
  - Obtaining consent
  - Making disclosures with consent
  - Receiving Part 2-protected records (non-Part 2 programs only)
  - Implementing new patient rights (Part 2 programs only)

\* Stakeholders include: behavioral health providers, general healthcare providers, health plans, accountable care organizations, investigative agencies, law enforcement, courts (including drug court), and oversight agencies

# Next steps for implementation: #3

## #3: Train all staff on new policies and procedures

- Training is opportunity to refresh and reinforce:
  - Basic concepts of confidentiality and importance for patients / clients
  - Techniques for addressing stigma and discrimination against people who use drugs, people in treatment, people in recovery
  - Basics of an agency's privacy procedures
- Privacy and compliance officers can join the COE-PHI's dedicated list for training materials and resources, [here](#).

Questions?

# Review: Key Points

- **Initial patient consent** still required for use and disclosure of Part 2-protected records
  - New prohibitions on combining certain consents
- **One-time “TPO consent”** for using and sharing records for treatment, payment, and healthcare operations
  - TPO consent creates looser redisclosure permissions for 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**

# Closing

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*The Center of Excellence for Protected Health Information*



## Evaluation

Please complete our evaluation following the training.

The evaluation will be emailed to those who attended.

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/)

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Thank you!

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