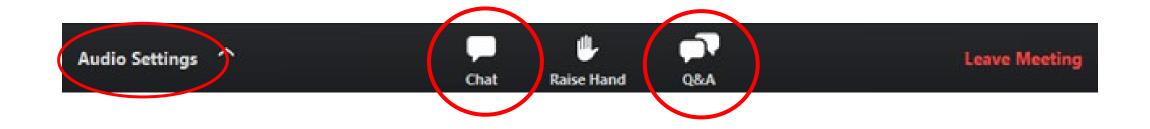
Part 2 Final Rule: Implementing Changes to SUD Privacy Rules

CoE-PHI





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 Part 2 to practical scenarios within case studies
- Explore steps that organizations can take to implement the new requirements
- Identify CoE-PHI resources to support implementation of Final Rule requirements
- Describe how to access resources and technical assistance through the CoE-PHI







Overview of 2024 Part 2 Final Rule



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
- For more information on the 2024 Final Rule see:
 - <u>December 2024 Archived Webinar: 42 CFR Part 2 Final</u> Rule - What You Need to Know

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

Redisclosures of records with TPO consent

Consent: legal proceedings

Consent: SUD counseling notes

Notice with disclosures

Accounting of disclosures

Complaints, penalties, and

enforcement

Right to request restriction

Patient notice

KEY:

Changes related to...

- Consent
- Patient rights
- Breach

Breach notification

TPO Consent

- Key terminology borrowed from HIPAA: TPO
 - Treatment / Payment / Healthcare Operations
- Single consent can authorize all future uses and disclosures for purposes of TPO
- After patient signs a TPO consent...
 - 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

New and Revised Terms

• Use <u>and</u> disclosure

 "Person" = natural person, 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



CoE-PHI Resources to Support Implementation

Suite of Implementation Resources

- <u>Implementation Fact Sheet</u>
- Notice to Accompany Disclosures
- SUD Counseling Notes Infobrief
- Coming Soon! Templates for Part 2 Patient Notice & Consent Form

Exploring Preparation and Implementation Activities



Poll 1: Has your organization or agency taken steps toward updating any of the following forms? (Check all that apply)

- Consent forms (to share patient information)
- Notice of Privacy Practices/Part 2 Patient Notice
- Notice to Accompany Disclosures of Information
- Other



Poll 2:

To what extent has your organization taken steps toward updating policies and procedures?



Poll 3:

To what extent has your organization taken steps toward updating organizational training material?

CoE-PHI Resources for Training

- Three complete health privacy law training packages that can be used to train staff on understanding and applying these laws in:
 - New employee orientations
 - Annual staff core-competency trainings
 - Stand-alone trainings
- Trainings packages are accompanied with training overviews, pre & post tests, and evaluation tools



Welcome Privacy, Compliance and Quality Officers!

Access our Suite of Organizational Training Material on this page.

We know that it can be difficult to find easy-to-use staff training resources on the federal privacy laws that apply to substance use treatment information. We're here to help!

To support you in your role, we developed a set of three health privacy law training packages that can be used to train staff on understanding and applying these laws in new employee orientations, annual staff corecompetency trainings and stand-alone trainings. Our team of legal, quality, behavioral health and training experts crafted these high-quality resources, informed by years of experience delivering this very same content to audiences across the nation.

These training packages were originally developed by the CoE-PHI Team in 2021, and have been updated in 2025 to reflect the 2024 Final Rule changes to 42 CFR Part 2 so that your staff can have the most up-to-date information.

Please also consider joining our dedicated mailing Listserv for Privacy, Compliance and Quality Officers through **this link** to receive updates regarding the materials, including information about any additions made to the suite of materials in the future.



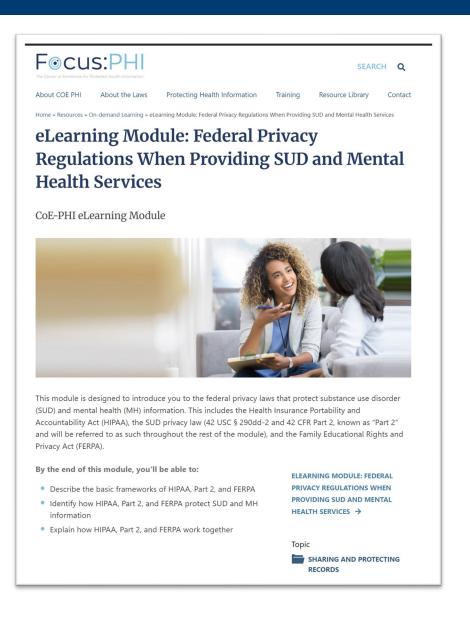
CoE-PHI Resources for Training

 Suite of 6 e-learning modules

 All modules are compliant with the 2024 changes to the Part 2

 Can be used for organizational staff training

No cost to download!





Putting Changes into Practice

Case study: Applying Learning to Lee's Care Experience



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 #4

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 #4 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 #5

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
- 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 #5 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 by 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 #6

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

Green Hill Part 2 Program Lee's records protected by 42 CFR Part 2

Indigo Hospital (received Part 2 Records with TPO consent) Lee's Part 2 records can be used and shared pursuant to HIPAA, except that those records cannot be used or disclosed for legal proceedings against Lee

Violet Dialysis
Clinic (received
Part 2 records
pursuant to
HIPAA)

 Lee's Part 2 records are no longer protected by Part 2; Violet Dialysis Clinic may release records to CPS as permitted by HIPAA

Implementation Steps Taken by Green Hill

Green Hill Updates to Existing Forms:

- Notice of Privacy Practices / Patient Notice
- Consent forms:
 - Single TPO consent for treatment, payment, and healthcare operations
 - Consent for non-TPO uses and disclosures, including for patients who may not wish to sign a single TPO consent
- Notice to accompany disclosures of information

Green Hill Updates to Policies and Procedures:

- Policies, procedures and related workflows associated with:
 - Obtaining informed consent to share Part 2 records and
 - Sharing Part 2 records with patient consent
- Breach notification procedure for Part 2 records
- Staff training on updated P&P and related forms, and how to counsel patients about consent forms





Hearing from You: Implementation Needs

CoE-PHI Resources to Support Implementation

- Implementation Fact Sheet
- Notice to Accompany Disclosures
- SUD Counseling Notes Infobrief
- Coming Soon! Templates for Part 2 Patient Notice & Consent Form
- To Train Staff:
 - PCQ Officer Materials
 - E-Learning Module Suite



Chat in:

What else do you need to support implementation?

What do you need to support your understanding of the requirements of Part 2?





Closing



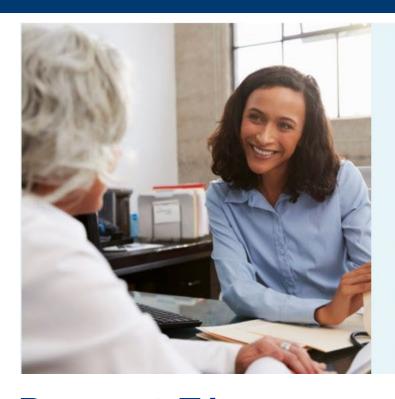


Evaluation

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

Resource Library 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

The Center of Excellence for Protected Health Information