# **Federal Privacy Protections for Patients Receiving SUD Treatment** in Integrated Settings

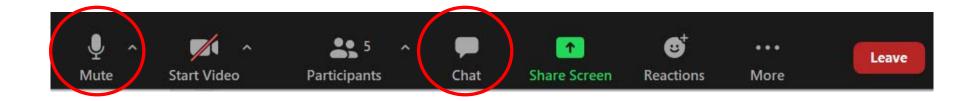


Thursday, September 11<sup>th</sup>, 2025





# **Zoom Meeting Logistics**





For questions, please utilize the Q&A Function

## **ASL Interpretation Services**

- American Sign Language (ASL) interpretation is being provided for todays event for anyone who needs it.
- You should be able to see our ASL interpreters at the top of your screen during today's session.
- If you are having difficulty seeing our ASL interpreters today, please send us a message in the chat.

## 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.

## **CoE-PHI Presenters**



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## Learning Objectives

- Explain when 42 CFR Part 2 ("Part 2") applies within integrated care settings
- Understand how Part 2 allows sharing of information within integrated settings (and externally) for purposes of care coordination
- Recognize how to apply learning through case study examples representing common scenarios
- Identify how to access resources and technical assistance through the CoE-PHI

# **Opening Poll**

In which setting(s) do you provide, oversee, fund and/or collaborate with integrated care?

(check all that apply)

- State or Municipal provider agency
- CCBHC
- CMHC
- FQHC
- Hospital
- Correctional setting
- Child welfare
- Other





## Overview of 42 CFR Part 2



# Why Confidentiality Matters

- Encourages access to treatment
- Promotes engagement in treatment and better treatment outcomes
- Protects against stigma, discrimination, criminalization on basis of treatment records

# Federal Health Privacy Law Cross-walk

#### **HIPAA**

**Applies to** covered entities (healthcare providers, health plans, healthcare clearinghouses) and BAs

Protects privacy and security of general health information

**Purpose:** to protect health data integrity, confidentiality, and accessibility

**Permits** disclosures without patient consent for treatment, payment, and healthcare operations

#### 42 CFR Part 2

**Applies to** SUD patient records from federally-assisted "Part 2 programs"

 Protects privacy and security of records identifying individual as seeking/receiving SUD treatment

**Purpose:** to encourage people to enter and remain in SUD treatment by guaranteeing confidentiality

**Requires** patient consent for treatment, payment, and healthcare operations, with limited exceptions

## 42 CFR Part 2 Snapshot

- Federal law and regulations protect the confidentiality of patient records at federally assisted SUD treatment programs
  - 42 USC § 290dd-2 and 42 CFR Part 2
- Not all SUD-related patient information is protected by Part 2; only records from "Part 2 programs"
- Part 2 generally requires the patient's written consent before sharing Part 2 records, including for *treatment*, *payment*, *and healthcare operations*
- Part 2's privacy protections generally *follow* the record upon disclosure

# Determining When Part 2 Applies

Remember, Part 2 only applies to records from Part 2 programs: providers that meet the definition of a "program" and are "federally assisted"

"Program" (42 CFR § 2.11)



"Federally assisted" (42 CFR § 2.12(b))

## Determining When Part 2 Applies: "Program"

Remember, Part 2 only applies to records from Part 2 programs: providers that meet the definition of a "program" and are "federally assisted"

#### "Program" (42 CFR § 2.11)

- (1) A person (other than a general medical facility) that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- (2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- (3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

## Determining When Part 2 Applies: "Federally Assisted"

Remember, Part 2 only applies to records from Part 2 programs: providers that meet the definition of a "program" and are "federally assisted"

"Federally assisted" (42 CFR § 2.12(b))

Conducted by federal agency (except VA); or

Carried out under federal license, certification, registration, or other authorization

- Medicare provider
- Authorization to conduct maintenance treatment or withdrawal management
- DEA registration to dispense controlled substance; or

Supported by federal funds; or

Tax exempt status

## Determining When Part 2 Applies: Integrated Settings

Remember, Part 2 only applies to records from Part 2 programs: providers that meet the definition of a "program" and are "federally assisted"

#### Is there a "program"? (42 CFR § 2.11)

Look for program type (2) or (3):

- (2) An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- (3) Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

#### Is it "federally assisted"? (42 CFR § 2.12(b))

Look for public programs, Medicaid/Medicare, registration to treat OUD with methadone/buprenorphine, or non-profit status





# **Interactive Case Studies:**Determining When Part 2 Applies





# Case Study #1

Dr. H prescribes buprenorphine for the treatment of opioid use disorder (OUD) at an FQHC, among other substance use disorder treatment and mental health services.



## Poll #1

## Is Dr. H a "Part 2 program?"

- A. Yes, because Dr. H is providing SUD treatment services and the FQHC is "federally assisted."
- B. No, because FQHCs are never covered by Part 2.
- C. It depends / more information is needed.

## Case Study #1: Answer

## The correct answer is C: It depends/more information is needed.

- We know that Dr. H and the FQHC are "federally assisted," but we still need to determine whether there is a "program."
- Does Dr. H work in an identified SUD unit within the FQHC, and does the FQHC hold itself out as providing SUD services?
  - If yes, the unit is a Part 2 program.
- Or is Dr. H's primary function providing SUD services and are they identified as such a provider?
  - If yes, Dr. H is a Part 2 program.



## Case Study #2

Green Valley CCBHC is beginning to incorporate SUD treatment services into its longstanding mental health services.

Green Valley hires Mary as an addiction specialist. Mary only treats patients with substance use disorders, although she also treats co-occurring mental health issues.



## Poll#2

### Does Part 2 apply?

- A. Part 2 applies to all Mary's patients' records, because Mary meets the definition of a "program" and the CCBHC is "federally assisted."
- B. Part 2 only applies to the SUD-related information in Mary's patient records.
- C. Part 2 does not apply, because Mary works in a CCBHC.
- D. It depends / more information is needed.

## Case Study #2: Answer

The correct answer is A: Part 2 applies to all Mary's patients' records, because Mary meets the definition of a "program" and she works at the CCBHC, which is "federally assisted."

- Mary is a "program" because her primary function is providing SUD services, and she is identified as such.
- Part 2 protects any information that identifies a patient as seeking or receiving services from Mary (the Part 2 program), including information about a patient's co-occurring mental health diagnosis and treatment.

See SAMHSA Guidance, "Does Part 2 Apply to Me?" Scenario 2



## Case Study #3

Green Valley CCBHC also hires Sherie, an LCSW, to provide counseling services to adolescents.

Sherie has credentials as a Master Addiction Counselor, and provides counseling related to substance use when needed, but many of her patients do not have an SUD diagnosis.



## Poll #3

#### Does Part 2 apply?

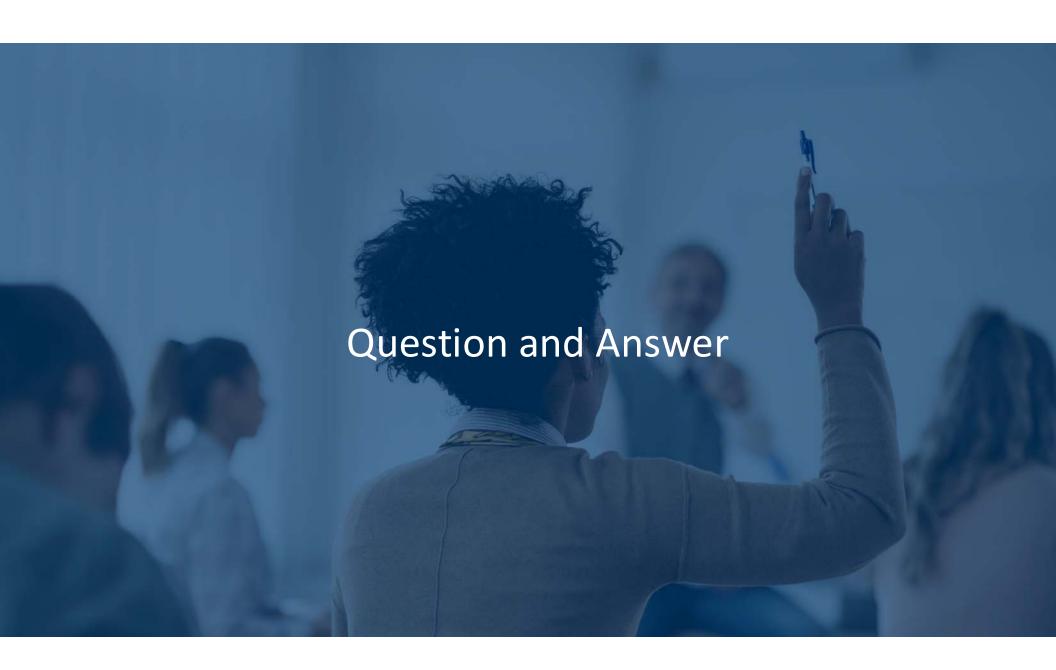
- A. Yes, Part 2 applies to the records of Sherie's patients with SUD diagnoses, but not any other patients.
- B. Yes, Part 2 applies to any records related to substance use, but not other records.
- C. No, Part 2 does not apply because Sherie is not a "program."
- D. It depends / more information is needed.

## Case Study #3: Answer

The correct answer is C: No, Part 2 does not apply because Sherie is not a "program." Sherie is not:

- In an identified SUD unit; or
- An identified SUD provider whose primary function is providing SUD services.

• Notice that even though Sherie is providing SUD services and the CCBHC is federally assisted, Part 2 does not apply.







# Sharing Part 2 Records in Integrated Settings



## Part 2 Programs and Lawful Holders

- Recap: Integrated settings need to follow Part 2 if there is a unit or provider that meets the definition of a "Part 2 program."
  - Part 2 applies to all the patient records within the Part 2 program
- Integrated settings also need to follow Part 2 when they are "lawful holders" of Part 2 records
  - A lawful holder is anyone who receives Part 2-protected records pursuant to the patient's consent (with an accompanying notice of disclosure), or pursuant to one of Part 2's exceptions.

## Part 2 Highlights: Sharing in Integrated Settings

- Internal communications
- Medical emergencies
- Consent

## **Internal Communications**

- Part 2 programs can use and share information within the "program" in connection with providing SUD diagnosis, treatment, or referral for treatment
  - Also known as the internal "need to know" rule
- Part 2 programs can also share records with administrative staff at an entity that has direct administrative control over the program
  - **Example**: Part 2 program in FQHC shares information with FQHC's billing office to handle reimbursements

## Medical Emergency

- Part 2 programs can use and share information with medical personnel to treat a bona fide medical emergency
  - Example: sharing patient name, date of birth, and current medications with Emergency Medical Services (EMS) responding to patient emergency

## Consent to Share in Integrated Settings

- Single consent for all future uses and disclosures for TPO purposes permits program to share with other providers, but records may lose protections downstream
- Narrower consent can tailor disclosures:
  - Specific providers or practices or units
  - Specific types of information (e.g., diagnosis and medication but not progress notes)
  - Maintains downstream protections

#### Consent for Uses and Disclosures of Substance Use Disorder Treatment Information, 42 CFR Part 2

#### 1. PATIENT NAME: Patient Name

I understand that my substance use disorder treatment records are protected under federal law, including 42 CFR Part 2 and HIPAA, and any applicable state laws. My treatment records can only be used or disclosed with my written consent, except as permitted by 42 CFR Part 2, HIPAA, and applicable state law.

I understand that I have the right not to sign this consent form. If I do not sign, the consequences will be:

Write NONE or describe the applicable consequences.

#### 2. AUTHORIZATION.

 a. I authorize the following person or types of people to use and disclose my records:

Write the name(s) or other specific identification of the person(s) or class of persons authorized to receive the requested disclosure.

b. I authorize the following person or types of people to receive my records:

Write the name(s)or other specific identification of the person(s) or class of persons authorized to receive the requested disclosure. 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. If the recipient is an intermediary, the consent must include the name(s) of the intermediary(ies) and either (A)the name(s) of the intermediary's member participants, or(B) a general designation of a participant or class of participants with a treating provider relationship to the patient (e.g., all my treating providers).

c. RECORDS TO BE USED AND DISCLOSED. I authorize the following information to be used or disclosed:

Describe the information to be used or disclosed in a specific and meaningful fashion. Hover for additional instructions.

#### New CoE-PHI Resource:

Template Consent for Uses and Disclosures of Part 2 Records

Access resource <u>here</u>

## Verbal Disclosures

#### **Loophole for verbal disclosures:**

". . . information conveyed orally by a part 2 program to a provider who is not subject to this part for treatment purposes with the consent of the patient does not become a record subject to this part in the possession of the provider who is not subject to this part merely because that information is reduced to writing by that provider who is not subject to this part."

42 CFR § 2.11

#### **Bottom line:**

Part 2 records may lose privacy protections if patient consents to disclosures for treatment purposes and the Part 2 program *verbally* shares Part 2-protected info with another provider





# **Interactive Case Studies:**Sharing Part 2 Records in Integrated Settings





## Case Study #4

Elena is a patient at a Part 2 program that is part of Blue Skies FQHC. She signs a single consent for all future uses and disclosures for treatment, payment, and healthcare operations (TPO).



#### Poll #4

# Which of the following uses and disclosures are permitted?

- A. Disclosures to other providers within the FQHC for treatment purposes
- B. Disclosures to providers outside the FQHC for treatment purposes
- C. Disclosures to insurance for reimbursement
- D. Disclosures to the FQHC's quality assessment and improvement team (healthcare operations)
- E. All of the above

## Case Study #4: Answer

#### The correct answer is E: All of the above.

Covered entities and business associates that receive Elena's Part 2 records may use and redisclose the records pursuant to HIPAA, except for legal proceedings against Elena.



### Case Study #5

Green Valley CCBHC offers outpatient SUD and MH counseling, but does not have a unit or provider that meets the definition of a Part 2 program.

Green Valley CCBHC regularly refers patients to inpatient SUD treatment at Red Mountain Residential, a Part 2 program and designated collaborating organization.



#### Poll #5

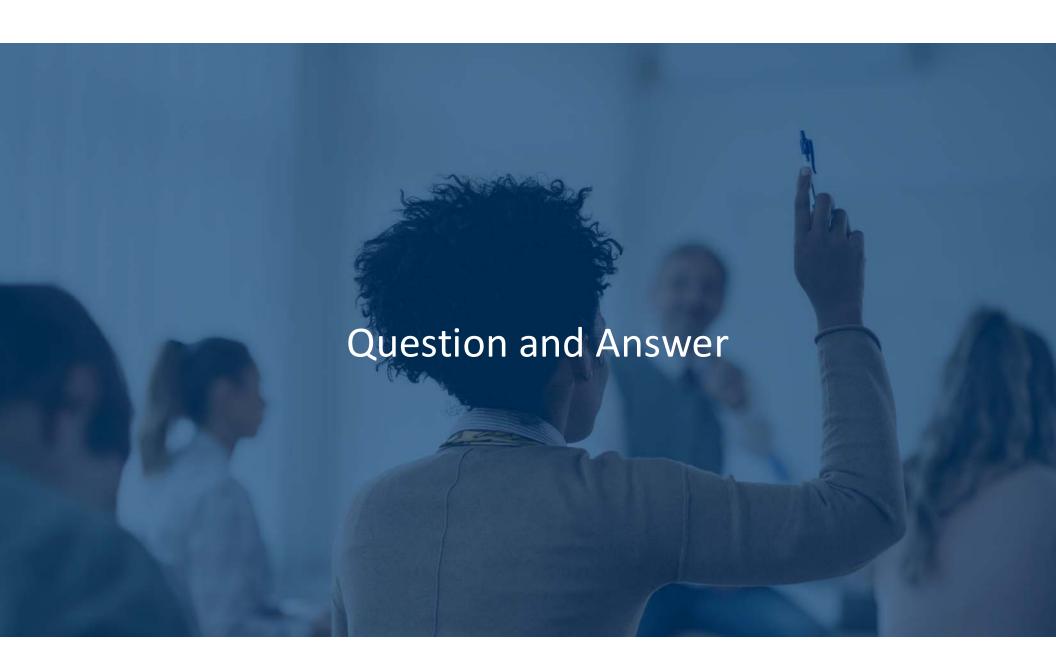
Does Green Valley CCBHC need patient consent when referring patients to Red Mountain Residential?

- A. Yes, because Green Valley is disclosing SUD-related information.
- B. Yes, because Red Mountain Residential is a Part 2 program.
- C. No, because Red Mountain Residential is a designated collaborating organization.
- D. No, because Green Valley CCBHC is not a Part 2 program and therefore Part 2 does not apply to its referrals.
- E. It depends/needs more information.

#### Case Study #5: Answer

The correct answer is D: No, because Green Valley CCBHC is not a Part 2 program and therefore Part 2 does not apply to its referrals.

\*But note: Green Valley CCBHC needs patient consent to *receive* information from Red Mountain Residential, including confirmation that a referred patient arrived for treatment.



#### 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 Rule What You Need to Know</u>

# CoE-PHI Implementation Resources

<u>Implementation Fact Sheet</u>

**SUD Counseling Notes** 

Template Consent for Uses and Disclosures of Part 2 Records

**Template Patient Notice for Part 2 Programs** 

**Notice to Accompany Disclosures of Information** 

#### **Key Points**



Part 2 protects confidentiality of SUD treatment records from "Part 2 programs"



Many integrated settings that provide SUD treatment services do not necessarily meet the definition of a Part 2 program

Look for "identified units" and "identified providers," plus federal assistance



When Part 2 applies in integrated setting, data can be shared with consent or pursuant to a few exceptions



Upcoming compliance date for 2024 changes to 42 CFR Part 2:

**February 16, 2026** 





# Closing



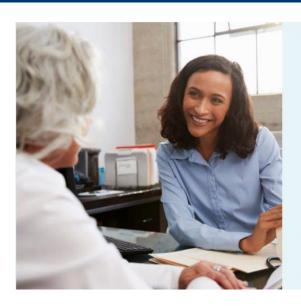


#### **Evaluation**

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

#### **Visit Our 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!



The Center of Excellence for Protected Health Information