

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

CoE-PHI

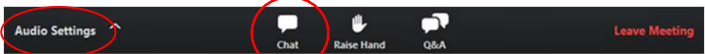


May 21, 2024

Focus:PHI
The Center of Excellence for Protected Health Information

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Zoom Webinar Logistics



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

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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.



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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.

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CoE-PHI Presenters



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Learning Objectives

- Describe the recent changes to 42 CFR 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.



The Center of Excellence for Patient Health Information

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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

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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

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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

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Overview of Major Changes in 2024 Rulemaking



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Forthcoming: Anti-discrimination Protections



- CARES Act (2020) also included some new **anti-discrimination** protections
 - Prohibition on using part 2 records to discriminate against a patient in healthcare, employment, housing, access to courts, social services, and benefits
- Proposed rule forthcoming
 - See [HHS Unified Agenda \(Fall 2023\)](#)

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New Terms and Concepts

- Use and disclosure
- “Person” = individual or entity
- SUD counseling notes
- Intermediary



Section 1: Disclosures with Consent



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Refresher: Basic Rule

- Part 2 permits disclosures of covered SUD treatment records with a patient's **written consent**
 - "Consent" also sometimes known as "authorization" or "release of information" (ROI)
 - Remember: part 2 consent is **not** consent to treatment
- Recipient becomes **lawful holder** of part 2 records
 - Part 2 "follows" the records

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Written Consent Requirements (§ 2.31)

- Aligns many of the required elements in part 2 written consent with 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

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SAMPLE CONSENT
AUTHORIZING DISCLOSURE OF CONFIDENTIAL SUD PATIENT RECORDS

Reminder: 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 and 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

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NEW: Single consent for TPO

- Key terminology: **TPO**
 - Treatment
 - Payment
 - Healthcare Operations
- Defined by HIPAA Privacy Rule
 - See [45 CFR 164.501](#)
 - HHS guidance, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html>

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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”

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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

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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

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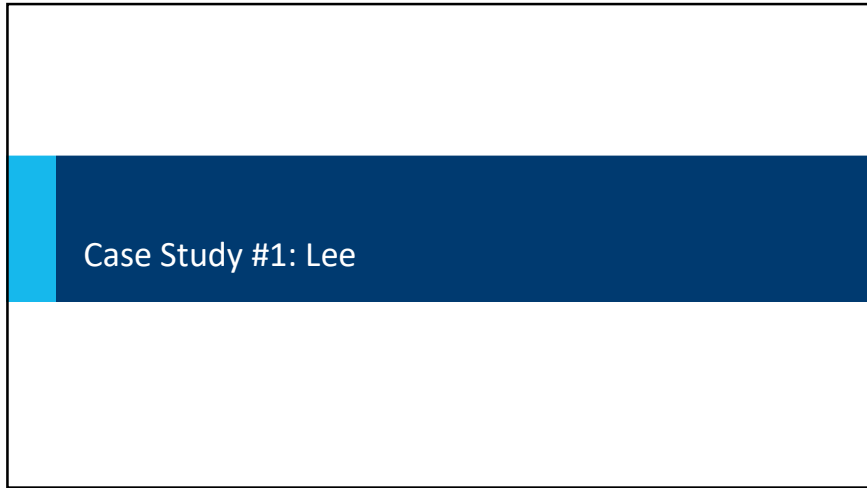
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TPO Consent: Redislosures

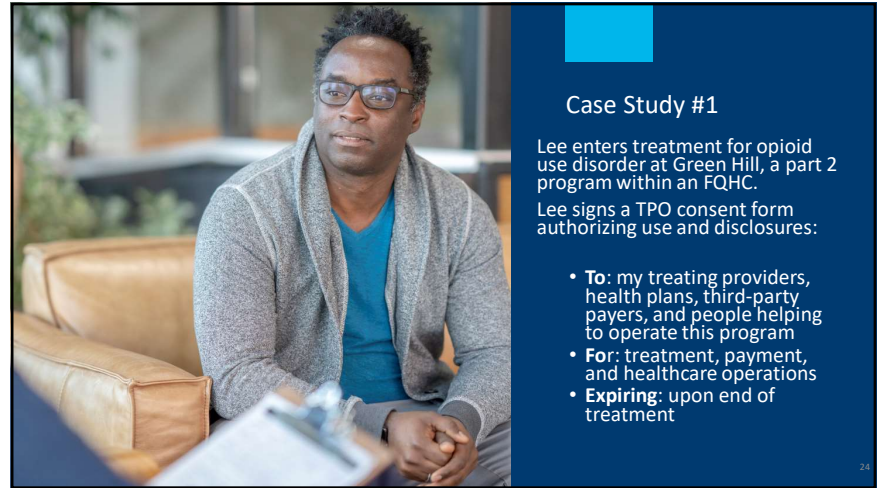
- After patient signs a TPO consent...
 - Recipients that are Part 2 programs, covered entity, or business associates can use and disclose records for TPO
 - Recipients that are covered entities or business associates can further disclose those records in accordance with HIPAA regulations
 - EXCEPT uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient

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Case Study #1: Lee



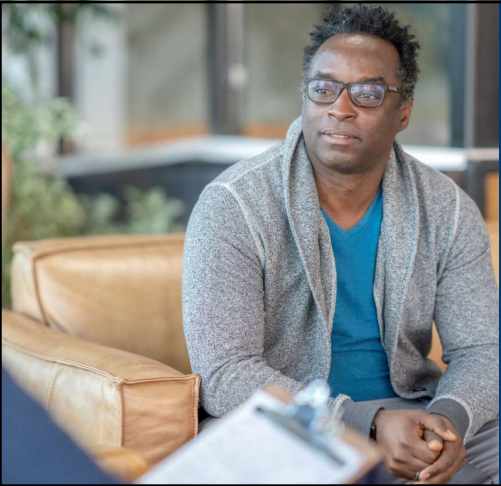
Case Study #1

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

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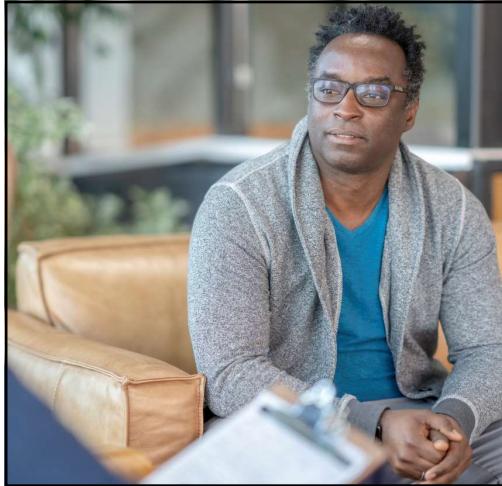


Poll #1(a)

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

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

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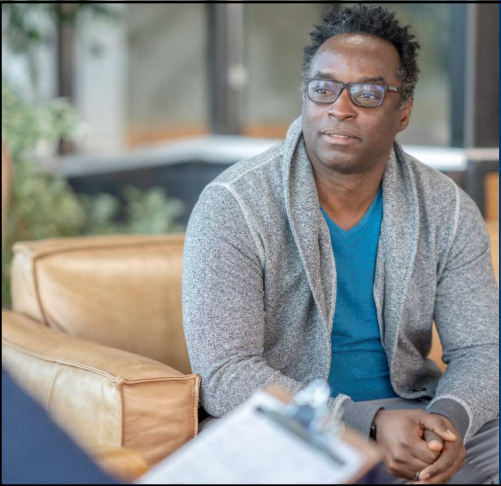


Poll #1(a) Answer

The answer is "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."

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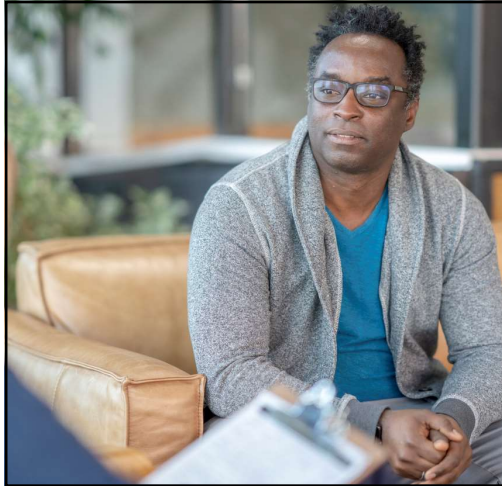


Poll #1(b)

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?

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

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Poll #1(b) Answer

The correct answer is option two (2) 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.

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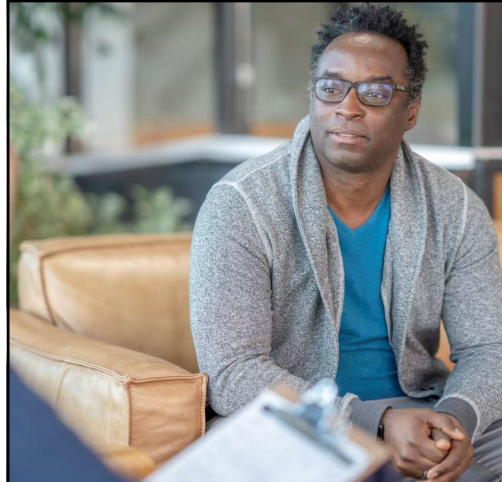


Case Study #1, cont.

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.

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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?

- Green Hill part 2 program
- Indigo Hospital
- Violet Dialysis Clinic
- It depends...

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Case study #1(c): Flow of information

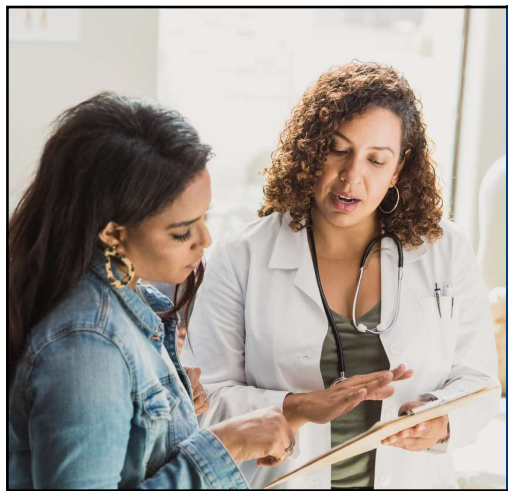
The correct answer is option four (#4) it depends.

```
graph TD; A[Green Hill part 2 Program] --> B[Indigo Hospital (received SUD treatment records with TPO consent)]; B --> C[Violet Dialysis Clinic (received SUD treatment records pursuant to HIPAA)];
```

- Green Hill part 2 Program
 - Lee's records protected by 42 CFR part 2
- Indigo Hospital (received SUD treatment records with TPO consent)
 - Lee's records can be used and shared pursuant to HIPAA, except for legal proceedings against Lee
- Violet Dialysis Clinic (received SUD treatment records pursuant to HIPAA)
 - Lee's records no longer protected by part 2; clinic may release records to CPS as permitted by HIPAA

Case Study #2: Claudia

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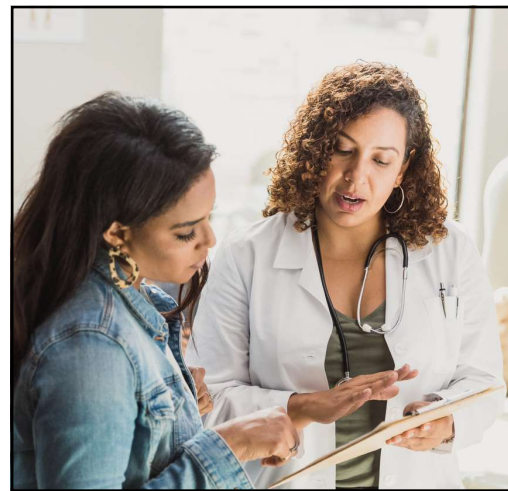


Case Study #2

- 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.

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Poll #2

Which of the following is true?

- The primary care doctor must continue following part 2's restrictions on use and disclosure for the records it received
- 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

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Poll #2 Answer

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

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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 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

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

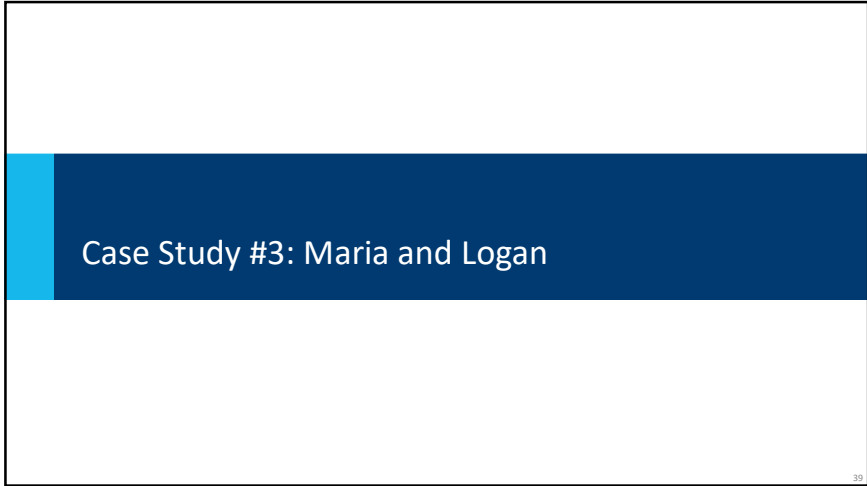
- Consent authorizing use or disclosure of SUD counseling notes cannot be combined with other consents
 - Okay to combine multiple consents authorizing uses and disclosures of SUD counseling notes
- **Part 2 program may not condition treatment or other services** on signing a consent for use or disclosure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

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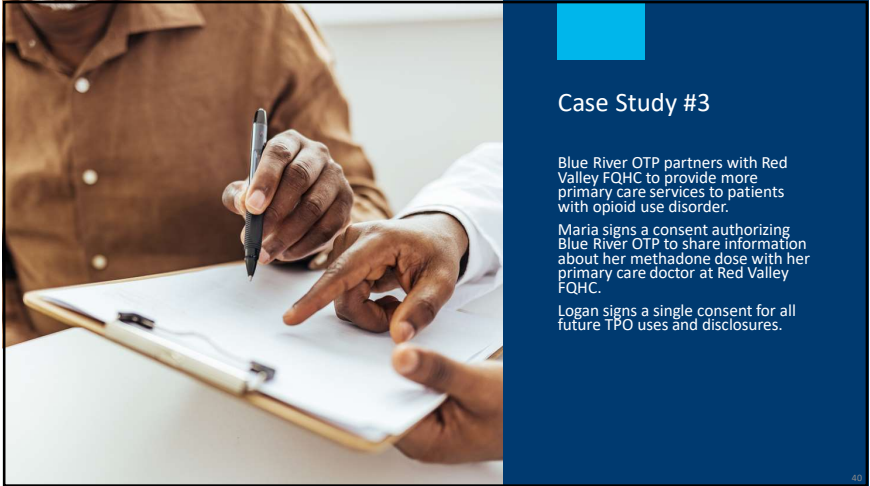
Making Disclosures with Consent § 2.32

- **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

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Case Study #3

Blue River OTP partners with Red Valley FQHC to provide more primary care services to patients with opioid use disorder.

Maria signs a consent authorizing Blue River OTP to share information about her methadone dose with her primary care doctor at Red Valley FQHC.

Logan signs a single consent for all future TPO uses and disclosures.




Case Study #3, cont.

Blue River OTP shares Maria and Logan's part 2 records with Red Valley FQHC, but forgets to include a copy of the consent forms. Red Valley FQHC receives the records.

- Even though different restrictions apply to Maria and Logan's part 2 records (because Maria signed a more limited consent), **Red Valley FQHC has no way of knowing** the different levels of restrictions for Maria vs. Logan's records.

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Case Study #3, cont.

Considerations for Red Valley FQHC:

- Red Valley cannot assume that all the records are subject to part 2's stricter protections
 - Logan signed a TPO consent, and it would likely constitute Information Blocking if Red Valley did not share information as permitted by the consent
- Red Valley cannot assume that all the records are subject to the looser protections for TPO consents
 - Maria signed a more limited consent and Red Valley has an obligation as a lawful holder to only use or disclose Maria's records as permitted by the consent form and part 2

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Section 2:
New Patient Rights and Enforcement Changes

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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 records
 - See [42 USC 1320d-6](#)
- HHS will now investigate and enforce violations instead of DOJ

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Complaints § 2.4

- Patients may now submit complaints to part 2 program or 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

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Breach Notification § 2.16

- Part 2 programs must notify patients of a breach of 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](#).

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New Patient Rights

- Right to request privacy protection for records § 2.26
 - Right to obtain certain restrictions of disclosures when services paid in full
- Right to an accounting of disclosures (not yet in effect)
 - 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

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Right to Request Restrictions § 2.26

- Part 2 program must permit a patient to request a restriction on uses or disclosures of patient 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](#))

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Right to Accounting of Disclosures § 2.25

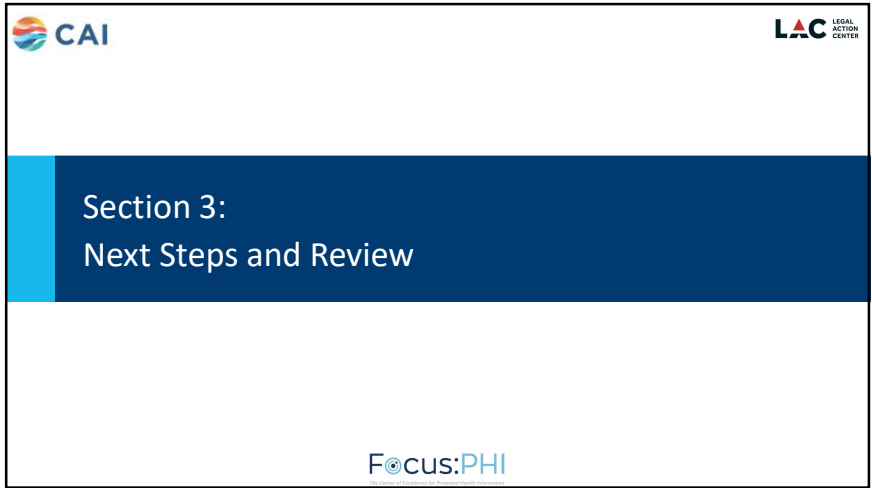
- Right to an accounting of disclosures made by Part 2 program with patient’s consent for the past 3 years
 - Accounting of TPO disclosures only for disclosures through electronic health record
 - Subject to HIPAA standards; see [45 CFR 164.528\(a\)\(2\) and \(b\) through \(d\)](#)
- Not yet in effect;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

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Next Steps for Implementation

- Patients:
 - Understand differences between types of consent
 - Patients need to know and understand scope of consent
 - Learn new patient rights
- Providers:
 - Update policies and procedures
 - Update consent forms and notices prohibiting redisclosure
 - Training for staff

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Review: Main 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 most changes**

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Closing

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Evaluation

Please click on the link in the chat to access the evaluation.

Your opinions improve our future trainings and resources.

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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/

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Thank you!

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