



LEGAL ACTION CENTER

Breaking Barriers. Defending Dignity.

42 CFR Part 2 Implementation

SUD Treatment Data Privacy and
Data Sharing for PDMPs

2024 Harold Rogers PDMP National
Conference – PDMPs: Collaborating to
Address the Prescription Drug Crisis



LEGAL ACTION CENTER

Breaking Barriers. Defending Dignity.

Presenter

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Deputy Director of Health Privacy

No conflicts to disclose.

Breaking Barriers. Defending Dignity.

The Legal Action Center (LAC) uses legal and policy strategies to fight discrimination, build health equity, and restore opportunity for people with arrest and conviction records, substance use disorders, and HIV and AIDS.

**Language Matters.
Words Have Power.
People First.**

The Legal Action Center uses affirming language to promote dignity and combat stigma and discrimination.

How LAC works to protect health privacy



- Legal advocacy



- Technical assistance and education

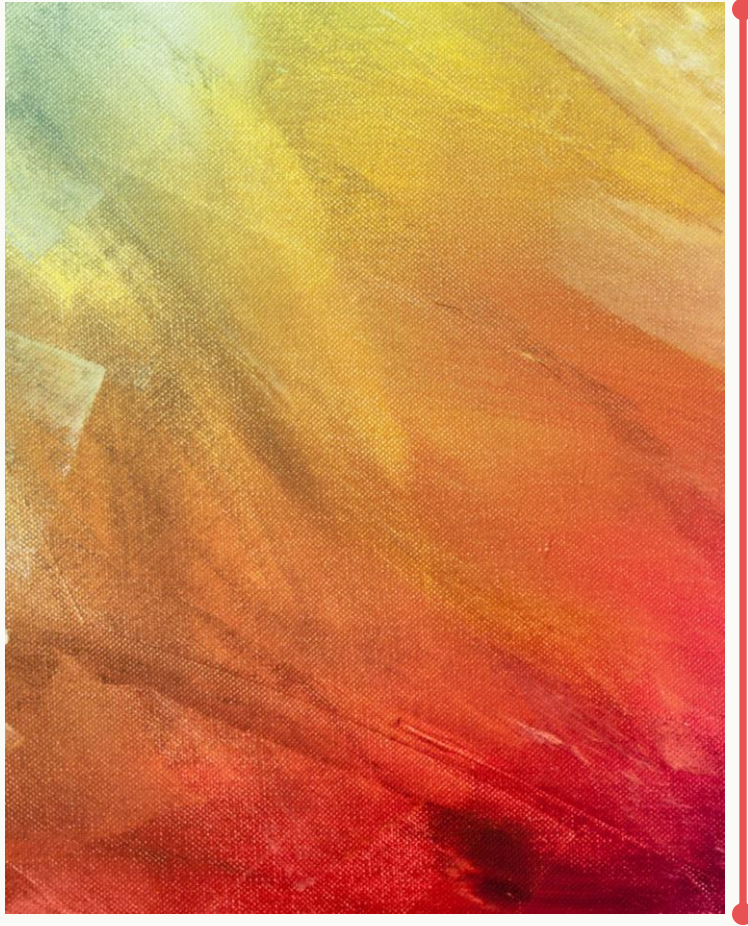
- Research and reports

- Policy advocacy



- Coalitions and collaborations

Agenda and learning objectives



- I. **Context:** What is Part 2 and why it matters
- II. **Implementation:** Applying Part 2 to PDMPs
- III. **Discussion** and resources

Poll: What brings you here today?

- General interest in SUD data privacy and data sharing
- Work for a PDMP
- Regularly interact with a PDMP
- Policy questions
- Other



Poll: Is your state's PDMP currently collecting Part 2 data?

- Yes
- No
- Not yet
- Not sure



I. Context

What is Part 2 and why it matters



Why is privacy important for treating SUD?

- Encourages **access** to treatment
- Improves **quality** of treatment and treatment outcomes
- **Protects** people from stigma, discrimination, or criminalization on account of their treatment records



Part 2 refresher



Statute: 42 USC § 290dd-2
Regulations: 42 CFR Part 2

*Federal (national) privacy protections for **SUD treatment records***



Generally **stricter** than HIPAA
Privacy Rule

Where Part 2 is stricter, HIPAA defers to Part 2 standard



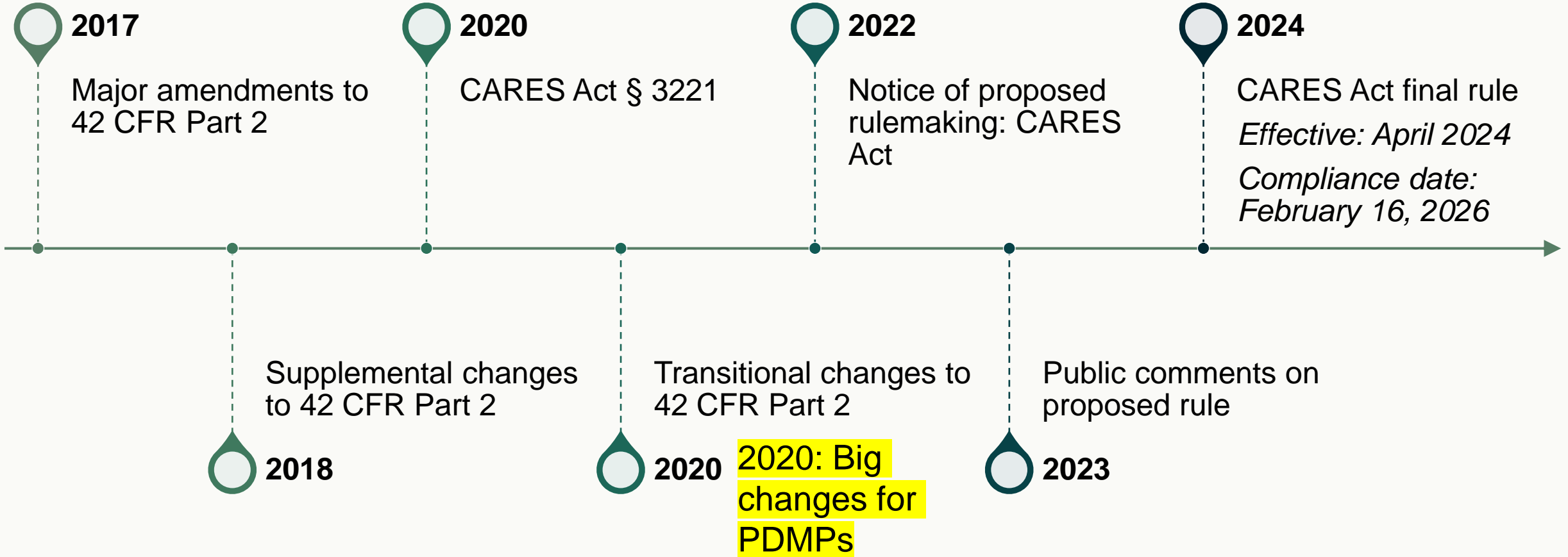
Only applies to records from **Part 2 Programs**

Does not apply to all types of treatment settings or all drug use-related information

How does Part 2 work?

- **Initial patient consent generally required** for most disclosures of Part 2 records, *including for treatment, payment, and healthcare operations*
- **Limited exceptions** for medical emergencies, internal communications, court orders, and more
- **Part 2 is “sticky”**
 - Privacy protections generally **follow the records** even after sharing, although big changes in 2024 amendments

Recent changes to SUD privacy law and regs



II. Implementation

Applying Part 2 to PDMPs



§ 2.36: OTP disclosures to PDMPs

“A part 2 program or other lawful holder is permitted to report any SUD medication prescribed or dispensed by the part 2 program to the applicable state prescription drug monitoring program if required by applicable state law. A part 2 program or other lawful holder must obtain patient consent to a disclosure of records to a prescription drug monitoring program under §2.31 prior to reporting of such information.”

Translation: OTPs can report MOUD it prescribes or dispenses to a state PDMP ...

- Only if required by state law
- +
- Only with written patient consent

Case study: state law

- State A law requires anyone who prescribes or dispenses MOUD to report the information to the state PDMP.
- State A's Department of Behavioral Health instructs all the OTPs in the state to submit the last six months of MOUD data to the PDMP, even if patient consent cannot be obtained.
- An OTP asks you if they can disclose the records.



Case study: state law

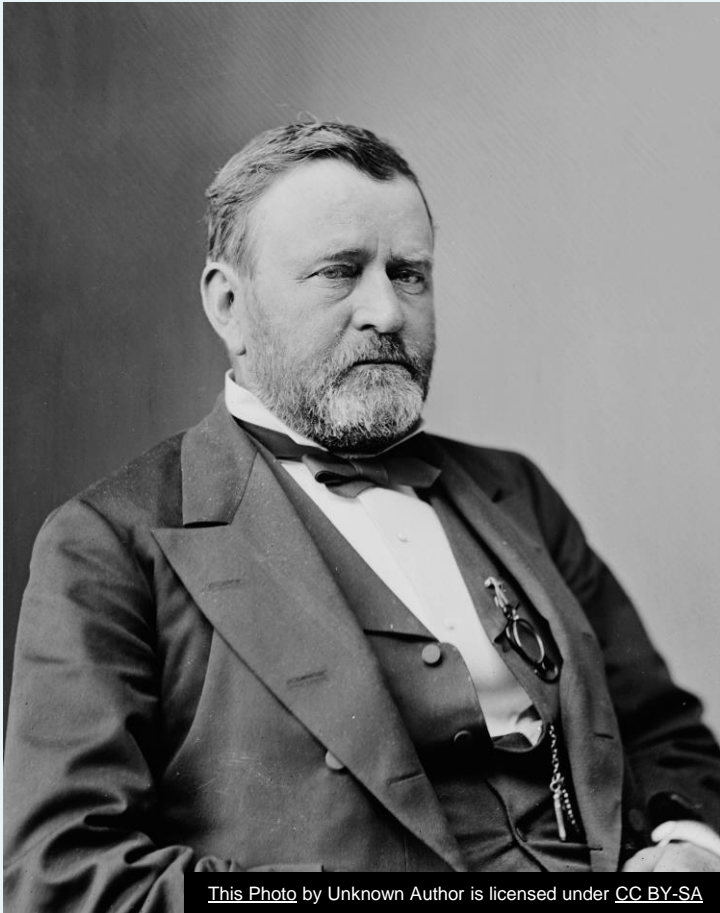
- This would violate Part 2; the OTP must have written patient consent from *each* patient before sharing records with the PDMP.
- Does not matter whether state law permits sharing without patient consent:
 - Part 2 requires patient consent, and Part 2 controls, 42 CFR § 2.20
- OTPs may only share data for those patients who signed written consent.



PDMP receives Part 2 data: what next?

- Receiving Part 2 records makes the PDMP a “**lawful holder**” → PDMP must protect Part 2 records according to Part 2:
 1. Comply with Part 2’s restrictions on use and re-disclosure
 - Records cannot be used to criminally investigate or prosecute a patient, or in any criminal, civil, administrative, or legislative proceedings against a patient, without (a) Part 2 court order or (b) separate written consent
 2. Protect security of records with Part 2 security policy

Case study: authorized users



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- Grant signs a consent allowing their OTP to share their methadone dosage with the state's PDMP.
- Grant gets treatment in a state where law requires OTPs to submit data to the PDMP.
- Can the PDMP share Grant's methadone data with all the "authorized users" of the PDMP?

Case study: authorized users



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It depends on...

- The terms of the consent
 - Who is identified recipient
 - What is identified purpose
- Whether the authorized user is reflected on consent
- Whether the purpose is reflected on consent

No disclosures to law enforcement for criminal investigation or prosecution of *patient* without Part 2 court order or separate written consent

Case study: inquiries by law enforcement

- Casey signs a consent authorizing their OTP to share their MOUD data with the PDMP, as required by state law.
- Police are conducting an investigation into alleged criminal activity by Casey.
- State law requires police to obtain a subpoena to access PDMP records.



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Case study: inquiries by law enforcement

How may the PDMP release records?

- a) With Part 2 court order finding that the alleged crime is “extremely serious”
- b) With subpoena, as required by state law
- c) With any formal request, because Casey signed a consent to the PDMP and that includes disclosures to law enforcement
- d) With a new consent signed by Casey, specifically authorizing this disclosure



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Case study: inquiries by law enforcement

The answer is both (a) and (d).

- Part 2 permits uses and disclosures with a special court order (see § 2.65) to criminally investigate or prosecute the patient.
- The 2024 changes now also permit a patient to consent to their own records to be used against them in a criminal proceeding.
 - Consent may not be combined with other consents.
 - No guidance yet on dealing with legal and ethical issues.

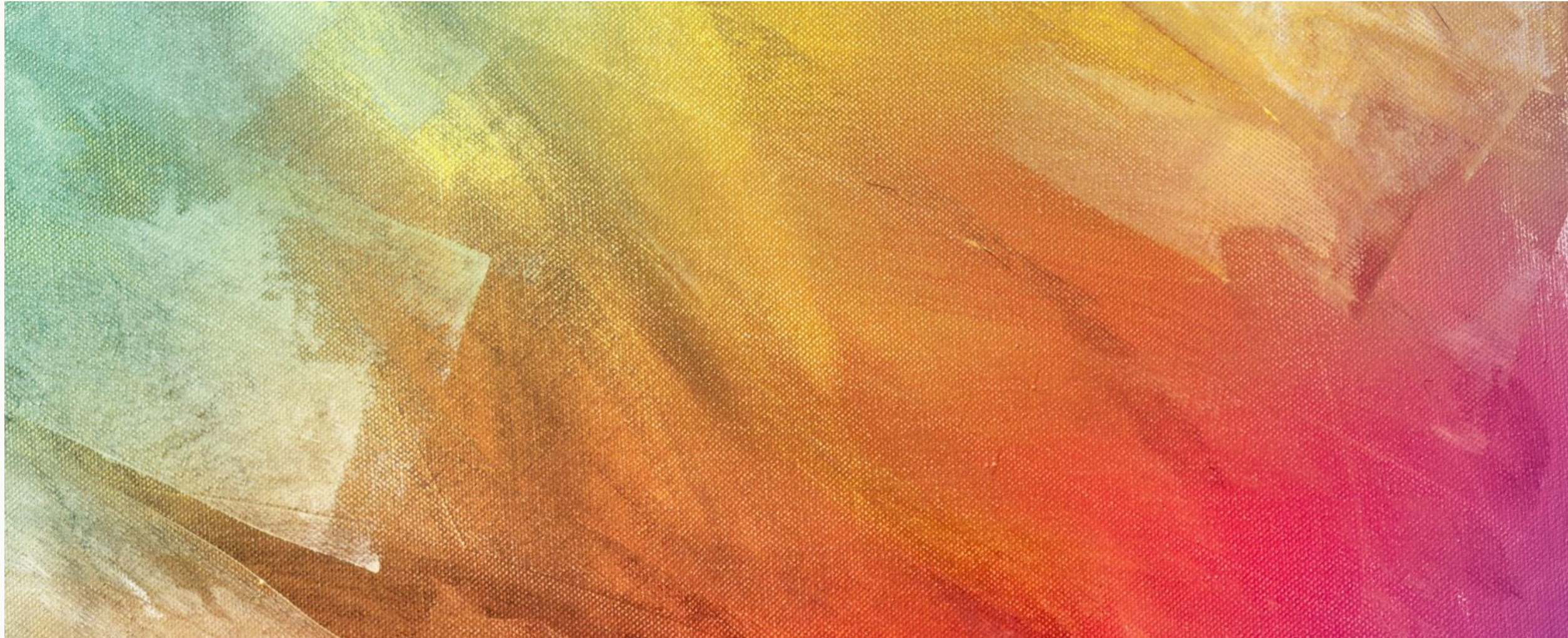
See § 2.13(b) *Unconditional compliance required.*

“The restrictions on use and disclosure ... apply whether or not the . . . lawful holder of the patient identifying information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency or official or other government official, has obtained a subpoena, or asserts any other justification for a use or disclosure which is not permitted by the regulations in this part.”

§ 2.3: Safe harbor (2024)

- New limit on civil or criminal liability for investigative agencies that act with “reasonable diligence” to determine whether records are protected by Part 2 before requesting records during investigation
 - Only applies to investigations of Part 2 programs and record holders; *not* investigations of patients
- New requirement to take certain steps if an investigative agency learns it received Part 2 records without first obtaining the requisite court order, § 2.66(a)(3) and § 2.68

III. Discussion and resources



Questions

- What happens if a patient revokes consent?
- How is a PDMP notified when a patient revokes consent?
- What happens when the PDMP is operated by a law enforcement agency?

Resources

- Sign up for **health privacy emails** from Legal Action Center for updates on upcoming resources, trainings, and release date for next edition of our book
 - ***Confidentiality and Communication***: A guide to the federal privacy laws for SUD treatment records (9th edition – forthcoming 2025)
- Questions about the privacy law? Contact the **Center of Excellence for Protected Health Information** for free technical assistance and more resources and on-demand training
 - www.coephi.org

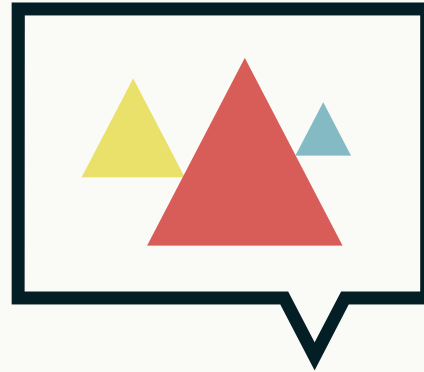


Stay in touch!

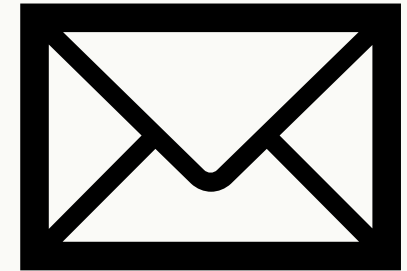
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If you have any questions,
you can contact us at
212-243-1313.



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Thank you.

Key Part 2 provisions for PDMPs

§ 2.36

- OTP data shared with patient consent to PDMP

§ 2.11

- Definition of lawful holder

§ 2.12

- Restrictions on use and disclosure

§ 2.13

- Confidentiality restrictions and safeguards

§ 2.3

- Safe harbor

Subpart E

- Court orders

Overview: Major changes to 42 CFR Part 2 in 2024 rulemaking

Still forthcoming: anti-discrimination protections in CARES Act

Single consent for TPO

Redislosures of records with TPO consent

Consent: legal proceedings

Consent: SUD counseling notes

Copy of consent with disclosures

Accounting of disclosures*

Right to request restriction

Complaints, penalties, and enforcement

Breach notification

Patient notice