

HIPAA and 42 CFR Part 2 Medications for Opioid Use Disorders in Prisons and Jails

May 11, 2023

This project was supported by Grant No. 2019-AR-BX-K061 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and Office of Sex Offender Sentencing, Monitoring, Apprehending, Registering, and Tracking. Points of view or opinions in this webinar are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice.



Welcome and Introductions



Presenter

Christine Khaikin, JD

- Senior Health Privacy Associate, Center of Excellence for Protected Health Information (CoE-PHI)
- Health Policy Attorney, Legal Action Center (LAC)
- Previously worked as an attorney and senior policy analyst with the New York City Department of Health and Mental Hygiene
- Received her Doctor of Jurisprudence degree (JD) from Brooklyn Law School in 2013



Presenter

Courtnie Drigo, JD

- Health Privacy Associate, CoE-PHI
- Previously served as an associate at Cleary Gottlieb Steen & Hamilton and worked as a public defender in the Criminal Defense Practice at Brooklyn Defender Services
- Graduated with honors from Rice University
- Received her JD from Yale Law School





The Center of Excellence for Protected Health Information

HIPAA and 42 CFR Part 2 Medications for Opioid Use Disorders in Prisons and Jails



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

Funded by the Substance Abuse and Mental Health Services Administration (SAMHSA), CoE-PHI develops and disseminates resources, training, and TA for states, healthcare providers, school administrators, individuals, and families to improve understanding and application of federal privacy laws and regulations when providing and receiving treatment for SUD and mental illness.

- **Family Educational Rights and Privacy Act (FERPA)**
- **Health Insurance Portability and Accountability Act (HIPAA)**
- **Code of Federal Regulations 42, Part 2: Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2)**

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



Presentation Objectives

Describe federal privacy laws for SUD treatment records

Explain how HIPAA and Part 2 apply to medications for opioid use disorder (MOUD) in prisons and jails

Identify how to access resources and TA through CoE-PHI

Poll Question #1

What is your role at your organization?

- Administrator/program manager/program director
- Corrections professional
- Law enforcement
- Medical provider (MD, NP, etc.)
- Substance use treatment provider
- Mental health treatment provider
- Peer recovery support
- Program navigator
- Researcher
- Other



Introduction to HIPAA and 42 CFR Part 2 Federal Health Privacy Laws



What laws apply?

- Health Insurance Portability and Accountability Act (HIPAA)
- Substance Use Disorders (SUD) privacy law (42 USC 290dd-2 and 42 CFR Part 2)
- State privacy laws

ALSO: ethical duty of confidentiality, professional licensing requirements



HIPAA

Applies to covered entities (healthcare providers, health plans, healthcare clearinghouses) and business associates

- 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

- **“Part 2” protects the confidentiality of patient records at federally assisted SUD treatment programs.**
 - These programs are called “Part 2 programs.”
 - *Not all SUD treatment providers are Part 2 programs.*
- **Part 2 establishes privacy and security requirements.**
 - Part 2 is just one privacy law. Other laws may also apply (e.g., HIPAA, state law).

Poll Question #2: True or False?

Only Part 2 programs must follow Part 2.

- True
- False
- I'm not sure.



Poll Question #2: Answer

FALSE: Part 2's privacy protections generally follow the information even once that information leaves a Part 2 program.

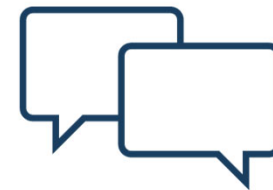
- The *recipient* of the information must also follow Part 2's privacy protections.
- A recipient is known as a "lawful holder."
- See 42 CFR §§ 2.12, 2.13.

https://www.govregs.com/regulations/expand/title42_chapterI_part2_subpartB_section2.13



What does Part 2 protect?

- Part 2 protects information that identifies someone as seeking or receiving SUD services from a Part 2 program.
 - *Examples: name, address, date of birth, social security number, photograph, fingerprints, status in the program, diagnosis, treatment, medications, test results*
- It includes information *in any form*—written, verbal, or electronic.



General Rule

Part 2 generally requires **written** patient consent before making a disclosure of Part 2-protected records.

- Limited exceptions apply



Do you have any questions?



What is a Part 2 program?



What is a Part 2 program?

Part 2 program means...

Federally assisted

+

Program

**Each term is defined in the regulation.*

“Federally Assisted”

Federal assistance includes:

- Authorization to conduct maintenance treatment or withdrawal management.
- Registration to dispense a controlled substance for SUD treatment.
- State or local government unit receiving federal funds eligible to be spent on SUD treatment.

“Program”

| Definition | Jail or Prison Example |
|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| An individual or entity other than a general medical facility that holds itself out as providing SUD services | Standalone inpatient or outpatient SUD treatment program |
| An identified unit within a general medical facility that holds itself out as providing SUD services | Onsite opioid treatment program (OTP) if it is an “identified unit” within the correctional health services’ general medical facility |
| Medical staff or other personnel whose primary function is providing SUD services and who is identified as such a provider | Identified SUD specialist in the jail or prison whose primary function is providing SUD services |

What about correctional settings?

- Determine whether Part 2 applies in jails and prisons
 - Key questions:
 - Is there a Part 2 Program onsite?
 - If not, how does Part 2 apply when contracting with a community-based provider?

What about correctional settings (cont'd.)?

A jail or prison that provides MOUD directly to patients will be a Part 2 program if:

✓ It is *federally assisted*.

and

✓ It meets the regulatory definition of a *program*.

Are the jail/prison's services *federally assisted*?

- A prison or jail providing methadone or buprenorphine is *federally assisted*.
- A prison or jail providing naltrexone (Vivitrol) only is federally assisted if:
 - State or local government unit receiving federal funding that can be used for SUD program; or
 - Contracted with a federal agency and the contract includes funding for the SUD program.

*Still must meet definition of a *program*

Are the jail/prison's services *federally assisted*?

- To be a Part 2 Program, it is not enough to be *federally assisted*.
- It is also necessary to meet the regulatory definition of a *program*.

Case Study #1

- Willow State Prison begins offering MOUD to individuals who are incarcerated.
- Dr. Henry is hired to be the identified SUD provider and to do all buprenorphine prescribing onsite.

Must Willow State Prison follow Part 2?



Poll Question #3

Must Willow State Prison follow Part 2?

- a) Yes, because Dr. Henry offers MOUD.
- b) I'm not sure. I need more information.
- c) Likely yes, but only Dr. Henry is a Part 2 program, not the entire prison.
- d) No, because it is primarily a prison, not a treatment provider.



Poll Question #3: Answer

c) Likely yes, but only Dr. Henry is a Part 2 program.

- Dr. Henry is the identified SUD provider.
- SUD treatment is likely Dr. Henry's primary function.



“Primary Function”

“Primary function” is not defined. Here are guideposts from SAMHSA:

- “Occasional” prescribing for SUD to a “handful” of patients \neq primary function
- “Only” treating patients with SUDs = primary function

See: Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me? (SAMHSA & ONC, 2018).

Case Study #1 Follow-up

Martin is incarcerated at Willow State Prison and sees Dr. Henry for his buprenorphine prescription.

- Martin visits a nurse in Willow State's general health unit.
- Does the nurse need patient consent to obtain information from Dr. Henry about Martin's buprenorphine prescription to coordinate care?



Poll Question #4

Does the nurse need patient consent to obtain information from Dr. Henry about Martin's buprenorphine prescription to coordinate care?

- a) No, written consent is not needed because it is all one health facility.
- b) No, because Martin verbally said it was fine to ask Dr. Henry.
- c) Yes, written consent is needed because only Dr. Henry is a Part 2 program.
- d) What is written consent?



Poll Question #4: Answer

- The answer is **c) Yes, written consent is needed because only Dr. Henry is a Part 2 program.**
- When disclosing treatment records, only share the minimum necessary to accomplish the purpose of the disclosure.
 - There is no need to share case notes or other confidential communications when diagnosis or medication dosage amount is sufficient.

Case Study #2

- Chester Correctional Facility employs several nurses and a physician to provide health services to its population.
- Each nurse and physician is licensed to prescribe controlled substances.
- When an individual is diagnosed with an SUD, any of the providers on staff can prescribe buprenorphine, along with their other health services.



Poll Question #5

Is Chester Correctional Facility a Part 2 program?

- a) Yes
- b) No
- c) Not sure



Poll Question #5: Answer

No, Chester Correctional Facility is not a Part 2 program.

- It is unlikely that any provider's primary function is providing SUD treatment.
- There is no identified unit. MOUD is integrated into general health services.



Case Study #3

- Upon entry to Konrad Prison, Gene requests methadone to treat his OUD.
- Konrad Prison contracts with Sunshine OTP, a local Part 2 program, to provide MOUD. Methadone is delivered weekly to be dispensed by Konrad staff.



Poll Question #6

True or false: Konrad Prison is now a Part 2 Program.

- a) True
- b) False
- c) Not sure



Poll Question #6: Answer

False. Contracting with a community-based program to provide MOUD does not mean the prison is now a Part 2 program.

- How can Sunshine OTP and Konrad Prison communicate about Gene's diagnosis and medication?



Poll Question Answer: Continued

- With written consent, Sunshine OTP can share Gene’s methadone dosage with Konrad Prison so that they can dispense the dose.
- The prison is now a “lawful holder” of this Part-2 protected information and must protect it accordingly.



“Lawful Holders”

- Anyone who receives records from a Part 2 program becomes a “lawful holder.”
- Lawful holders must follow Part 2’s privacy and security requirements but only for the records received from the Part 2 program.

Prisons and Jails as Lawful Holders

- Contracting with a community provider for MOUD treatment (e.g., methadone from a local OTP)
- Collaborating with an individual's existing provider that is a Part 2 program (e.g., MOUD dosage information)
- Communicating with a community-based Part 2 program for reentry planning

Case Study #4: Lawful Holders

- Alexis is incarcerated at Mountain View Prison.
- Prior to being incarcerated, Alexis received SUD treatment from a Part 2 program.
- Alexis signs a consent form authorizing the Part 2 program to share information with Mountain View Prison for continuity of care.



Poll Question #7

Should Mountain View Prison copy Alexis' SUD treatment records into its main prison record system?

- a) Yes
- b) No
- c) Not sure



Poll Question #7: Answer

NO. The Part 2 records should not go into the main file, unless the prison has a system to flag or separate the Part 2 information.

- Mountain View is now a “lawful holder” of Part 2 records and can only share those records as permitted by Part 2.
 - *Consistent with the consent form*
 - *Pursuant to an exception*



Do you have any questions?

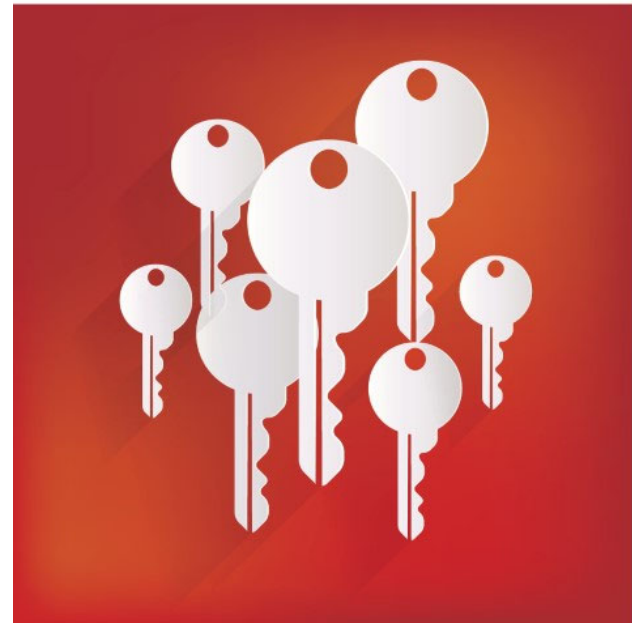


Practical Implications: Applying Part 2



Key Considerations

- Sharing with consent
- Segmenting and separating Part 2 records
- Policies and procedures for securing Part 2 records



Nine Required Elements for Part 2 Consent Forms

| # | Required Element |
|---|------------------------------------------------------------------------------------------------------------------------------|
| 1 | Patient name |
| 2 | Who is making the disclosure |
| 3 | How much and what type of information is to be disclosed *Including an <i>explicit description</i> of any SUD information |
| 4 | Who is receiving the information |
| 5 | Purpose of the disclosure |
| 6 | Patient notice of right to revoke consent |
| 7 | Expiration date, event, or condition |
| 8 | Signature of the patient *And for some minor patients, the parent's signature as well |
| 9 | Date consent is signed |

Interpreting the Consent Form

Once a patient has signed a consent, you may share...

- The information described
- To the parties listed on the consent form
- For the purpose described
- Until the consent form expires or is revoked

Prohibition on Re-disclosure Notice

- **Remember:** Disclosures of Part 2 records must be accompanied by a [Notice Prohibiting Re-Disclosure](#)
 - Notice has a long and short version.

August 2020, long version was changed, § 2.32(a)(1)

- Now clarifies that prohibition on re-disclosure only applies to Part 2 records, not entire patient file

Segmenting or Separating Part 2 records

Part 2 records must be flagged and separated from the rest of the patient's files and the rest of the facility's administrative records.

- To ensure records are only shared as permitted by Part 2
 - With patient consent
 - According to one of Part 2's limited exceptions



Security

Part 2 programs and lawful holders must have formal policies and procedures to ***reasonably protect*** against:

- Unauthorized uses and disclosures of Part 2 records (paper and electronic).
- Reasonably anticipated security threats, 42 CFR § 2.16(a).

Do you have any questions?



Looking Ahead: What Changes Are Coming



CARES Act

- Coronavirus Aid, Relief, and Economic Security (CARES) Act (March 2020) amended SUD privacy law, 42 USC § 290dd-2.
- Notice of Proposed Rulemaking (NPRM) was issued in December 2022. The public comment period is closed.

Current Part 2 rules remain in effect.

Summary of CARES Act Provisions

| 42 USC § 290dd-2 | Change |
|-------------------------|---------------------------------------------------------------------------------------------------|
| (b)(1) | Disclosures for treatment, payment, and healthcare operations |
| (b)(2)(D) | De-identified records shared with public health authorities |
| (c) | Prohibition on use or disclosure of records in criminal, civil, or administrative contexts |
| (f) | Penalties and enforcement |
| (i) | Antidiscrimination provisions |
| (j) | Notification in case of breach |
| (k) | Definitions cross-referencing HIPAA |

Anti-discrimination Protections*

- CARES Act prohibits use of Part 2 records against patients in any of the following:
 - Healthcare
 - Employment or worker's compensation
 - Housing
 - Access to courts
 - Access to benefits
 - Access to services provided with federal funds

*Not included in recent NPRM

Enforcement Provisions

CARES Act extends some of HIPAA's enforcement provisions to Part 2 programs.

- Part 2 programs must comply with HIPAA's breach notification requirements.
- Part 2 programs are subject to same enforcement provisions as HIPAA-covered entities.
- HIPAA penalties will apply for Part 2 violations.

Poll Question #8

The CARES Act amended the SUD privacy law to be the same as HIPAA.

- True
- False
- I'm not sure.



Poll Question #8: Answer

FALSE. The CARES Act amended the SUD privacy law to permit certain redisclosures of information for treatment, payment, and healthcare operations (after a patient's initial written consent).

- *The impact of the CARES Act changes will depend on what is included when the proposed rules are finalized.*

Do you have any questions?



Resources



Resource

Go to the CoE-PHI website to learn more about privacy considerations for medication-assisted treatment in jails and prisons.



Focus:PHI
The Center of Excellence for Protected Health Information



Privacy Considerations for Medication Assisted Treatment in Jails and Prisons

WHAT YOU NEED TO KNOW

Jails and prisons around the country are implementing programs to provide medication for opioid use disorder (MOUD) for substance use disorder (SUD). In designing their MOUD programs, jails and prisons need to determine whether the federal privacy and security requirements for substance use disorder (SUD) treatment records, 42 CFR Part 2 (Part 2), will apply to their operations.¹ If so, they must identify the required privacy and security protections for Part 2-protected records.

Maintaining the confidentiality of patients' SUD treatment records is not only required by law, but also is a crucial element of quality SUD treatment and positive patient treatment outcomes. Privacy protections ensure that patients receiving SUD treatment are not made *more vulnerable* to negative outcomes than had they not sought treatment.² These protections are particularly salient in jails and prisons.

DETERMINING WHETHER PART 2 APPLIES IN JAILS AND PRISONS

Part 2 applicability depends on the specific structure of a jail or prison's SUD treatment program, including who is providing MOUD and how the services are organized. Below, we describe two possible program designs and how Part 2 might apply:

① **JAILS AND PRISONS OFFERING MOUD DIRECTLY: IDENTIFYING WHETHER THERE IS A "PART 2 PROGRAM" ON-SITE**

A jail or prison that provides MOUD directly to patients (as opposed to through a contractor) will need to comply with Part 2's privacy and security requirements *if the MOUD program meets the definition of a "Part 2 program."*³ In order to be considered a "Part 2 program," a provider or unit must –

- Be *federally assisted* and
- meet the regulatory definition of a *program*.⁴

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Accessing 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/

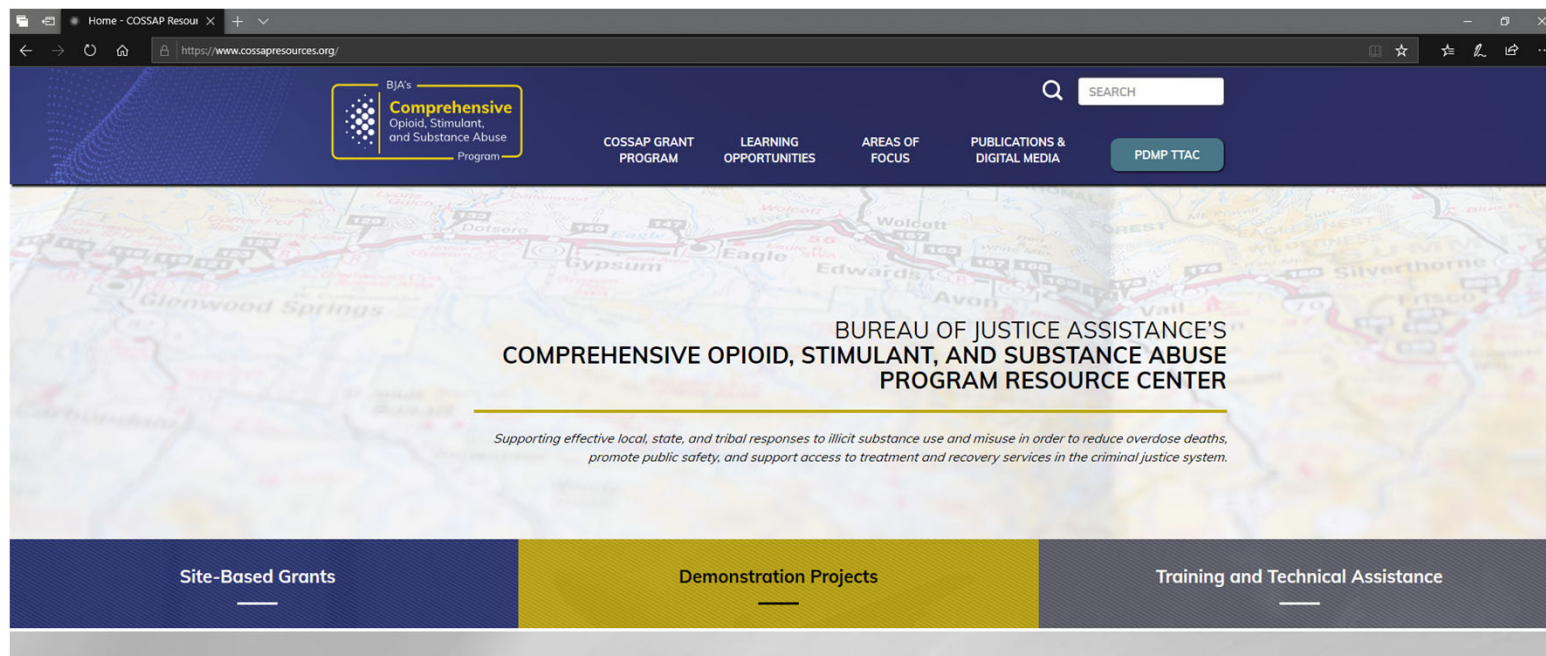


THANK YOU!

Fear, shame and stigma are some of the biggest obstacles to SUD and mental health treatment.

Privacy protections help overcome these obstacles to care.

Bureau of Justice Assistance's Comprehensive Opioid, Stimulant, and Substance Use Program (COSSUP) Resource Center



www.cossapresources.org



<https://cossapresources.org/Program/TTA>



COSSAP GRANT PROGRAM

LEARNING OPPORTUNITIES

AREAS OF FOCUS

PUBLICATIONS & DIGITAL MEDIA

PDMP TTAC

SEARCH

TRAINING AND TECHNICAL ASSISTANCE

The COSSAP training and technical assistance program offers a variety of learning opportunities and assistance to support BJA COSSAP grantees and other local, tribal, and state stakeholders to build and sustain multidisciplinary criminal justice responses to illicit substance use and misuse.

Training and technical assistance is provided in a variety of formats, including virtual and in-person training events, workshop and meeting presentations, and online resources.

REQUEST TTA

If you are interested in requesting training and technical assistance, please complete the form at <https://www.cossapresources.org/Program/TTA>



COSSUP Resources

Tailored Assistance—The COSSUP training and technical assistance (TTA) program offers a variety of learning opportunities and assistance to support local, tribal, and state organizations, stakeholders, and projects in building and sustaining multidisciplinary responses to the nation’s substance abuse crisis. ***You do not need to be a COSSUP grantee to request support.*** TTAs are provided in a variety of formats, including virtual and in-person training events, workshop and meeting presentations, and online resources. Request TTA to support your activities at <https://cossapresources.org/Program/TTA/Request>.

Funding Opportunities—Current COSSUP and complementary funding opportunities are shared at <https://www.cossapresources.org/Program/Applying>.

Join the COSSUP community! Send a note to COSSUP@iir.com with the subject line “Add Me” and include your contact information. We’ll be happy to ensure you receive the latest-and-greatest COSSUP opportunities, resources, and updates.

