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42 CFR Part 2 and PDMPs **February 25, 2021**

Focus:PHI

The Center of Excellence for Protected Health Information



42 CFR Part 2 and Prescription Drug Monitoring Programs



Presentation to the PDMP TTA Center

February 25th, 2021: 4:00-5:00 PM EST

Funded by Substance Abuse and Mental Health Services Administration



Center of Excellence for Protected Health Information

Funded by SAMHSA, the CoE-PHI develops and disseminates resources, training, and TA for states, healthcare providers, school administrators and individuals and families to improve understanding and application of federal privacy laws and regulations, including FERPA, HIPAA, and 42 CFR Part 2, when providing and receiving treatment for SUD and mental illness.

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



CoE-PHI Team and Presenters

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Presentation Objectives

**Explain the basics of 42 CFR Part 2
(including who is covered by Part 2)**

**Identify recent changes to
Part 2 that apply to PDMPs**

**Recognize how to access resources
and technical assistance
through the CoE-PHI**



Fear, shame and stigma are some of the biggest obstacles to substance use disorder treatment. Privacy protections help overcome these obstacles to care.

Understanding the Federal SUD Privacy Law **INTRO TO PART 2**



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

- **“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 #1

True or False?

Only part 2 programs must follow part 2.

- True
- False
- I'm not sure...



Poll Question #1

Answer

FALSE: Part 2's privacy protections generally follow the information even once it 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.



General Rule

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

- Limited exceptions apply



Questions?

Please share with us any questions that you have now



Amendments to 42 CFR Part 2

WHAT CHANGED IN 2020 *FOR PDMPS*



Timeline

Aug. 2019: Proposed Rule (SAMHSA)

Fall 2019: Public Comments

March 2020: CARES Act (Congress),
effective 03/27/21

July 2020: Final Rule (SAMHSA),
effective 08/14/20, *transitional only*

March 2021:
New rulemaking implementing
CARES Act (SAMHSA)



What did NOT change?

- **Confidentiality framework**
 - 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
- **Enforcement**



Changes to Part 2 (2020)

42 CFR §	Provision
2.11	Definition of “records”
2.12	Applicability and re-disclosure
2.31	Requirements for written consent forms
2.32	Notice of prohibition on re-disclosure
2.33	Disclosures permitted with written consent (P/HCO)
2.34	Disclosures by central registries
2.36	Disclosures to prescription drug monitoring programs
2.51	Medical emergencies
2.52	Research
2.53	Audit and evaluation
2.67	Court orders for undercover agents and informants
Guidance	Disposition of records on employees’ personal devices, data segmentation



Background: PDMPs and Part 2

- In 2011 SAMHSA issued guidance stating that OTPs should not make disclosures to PDMPs
 - [Clark HW. Dear Colleague letter. Sept. 27, 2011](#)
- Since that time, PDMPs have not received Part 2-protected records from OTPs



*New § 2.36

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.”



Disclosures to PDMPs

- A Part 2 program or lawful holder may now report SUD medication it prescribes or dispenses to the state PDMP
 - *Only as required by applicable state law*
 - *And **only with written patient consent***



Disclosures to PDMPs

Receiving Part 2 records from a Part 2 program or lawful holder makes the PDMP a “**lawful holder**,” 42 CFR §§ 2.12, 2.13.

- PDMP must protect Part 2 records according to Part 2:
 - Comply with Part 2’s restrictions on re-disclosure, 42 CFR § 2.13.
 - Protect security of records, 42 CFR § 2.16.
 - Only release records to law enforcement with Part 2 compliant court order, 42 CFR § 2.65.



Questions?

Please share with us any questions that you have now



Practical Steps and Case Studies

APPLICATION



Practical Steps Toward Application

Step 1:

Review Your State Law



Step 2:

Review your PDMP's privacy and security measures for Part 2 compliance



Step 1

Review Your State Law

Case Study #1

State Law

- State A permits, but does not require, opioid treatment programs (OTPs) to report information to the PDMP.
- A local OTP asks patients to sign a consent form authorizing disclosure to the PDMP.
- Patients have the right to refuse to sign the consent form.





Case Study #1

State Law

Does it violate Part 2 for the OTP to share the patient records with the PDMP, so long as they only share the records for which patients signed consent?

- a) Yes, this violates Part 2 because state law does not require OTPs to report information.**
- b) No, this does not violate Part 2 because state law permits OTPs to report information.**
- c) No, because the patient consent form is optional.**
- d) No, because SAMHSA has said that PDMPs can be useful in addressing high overdose rates.**



Case Study #1

State Law

Answer

a) Yes, this violates Part 2 because state law does not require OTPs to report SUD medications to the PDMP, 42 CFR § 2.36.

- **Remember** to check your state law to see whether it requires OTPs to report any SUD medication prescribed or dispensed to the PDMP.

Case Study #2

State Law (v2)

- **State B's law requires anyone who prescribes or dispenses SUD medication to report the information to the state PDMP.**
- **State B law does not require patients to consent to disclosures to the PDMP.**
- **State B's Department of Behavioral Health instructs all the OTPs in the state to submit the last six months of SUD medication data to the PDMP, even if patient consent cannot be obtained.**



State Law (v2)

Does it violate Part 2 for the OTPs to share ALL patient records with the PDMP, including records of patients who did not consent?

- a) Yes, this violates Part 2 because State B's PDMP reporting law does not specifically refer to OTPs.**
- b) Yes, because the OTPs must have patient consent.**
- c) No, this does not violate Part 2 because state law requires the report, and state law does not require patient consent.**
- d) No, because the Department of Behavioral Health funds and regulates the OTPs.**



Case Study #2

State Law (v2)

Answer

b) Yes, this violates Part 2 because the OTPs must have written patient consent before sharing records with the PDMP, 42 CFR § 2.36.

- Even though state law does not require written patient consent, Part 2 (federal law) does.
 - **Remember:** if state law requires a disclosure prohibited by Part 2, Part 2 controls, 42 CFR § 2.20.
- OTPs may share SUD medication records for those patients who sign written consent.



Step 2

Review your PDMP's privacy and security measures for Part 2 compliance

Case Study #3

Security

- **State C's PDMP is collecting SUD medication information from OTPs, pursuant to the new provisions in Part 2.**
- **The PDMP follows the HIPAA privacy and security rule for all its records.**



Security



Does the PDMP need to adjust any of its security protocols for the Part 2 data?

- a) No, because Part 2 does not apply to the PDMP's data.**
- b) No, because HIPAA is the applicable security standard.**
- c) Yes, the PDMP needs to adjust its security protocols for all its data.**
- d) Yes, the PDMP needs to adjust its security protocols - but only for the Part 2 records it receives from OTPs.**



Case Study #3

Security

Answer

d) Yes, the PDMP needs to adjust its security protocols – but only for the Part 2 records it receives from the OTPs, 42 CFR § 2.12.

- The PDMP is now a lawful holder, 42 CFR § 2.13.
- Part 2 requires lawful holders to follow the security protocols in Section 2.16 *for the protected Part 2 records only.*



Key Points: Security

Lawful holders must have formal policies and procedures to ***reasonably protect*** against:

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

HIPAA security compliance is a good first step – but not sufficient.

Case Study #4

Law Enforcement

- Casey signs a consent form authorizing their OTP to share SUD medication records with the PDMP, as required by state law.
- The local DA is conducting an investigation into alleged criminal activity by Casey.
- State D requires law enforcement to have a warrant in order to obtain PDMP records.

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COE PHI InFocus Brief
Arrest Warrants & Law Enforcement Inquiries
in SUD Settings

When law enforcement officials arrive at your SUD treatment program with a warrant to arrest a patient, how can you respond without violating federal privacy laws?

What You Need to Know

Some of the clients we provide substance use disorder treatment and support services to have the potential, have been, or are currently involved in the criminal justice system. This means that our jobs may be complicated by inquiries from law enforcement that bring up important questions about our ability to continue to protect patient privacy.

HIPAA permits covered entities to disclose protected health information (PHI) to law enforcement in certain circumstances. (see 45 CFR § 164.512(f)). However, 42 CFR Part 2 ("Part 2") generally does not permit covered SUD treatment programs to disclose protected SUD information to law enforcement without a valid Court Order issued in accordance with the regulation (see 42 CFR § 2.65).

HHS GUIDANCE

The U.S. Dept. of Health and Human Services (HHS) has issued several official guidance letters indicating how

• **Do not assist with the search.**

If law enforcement officials attempt to enter your premises to search for a patient, program personnel are not permitted to assist with the search or to provide any information about a patient "including information about the patient's presence or absence on program premises, or other whereabouts, to law enforcement officials." Opinion Letter 80-14 (May 2, 1980).

However, if law enforcement are in "hot pursuit" of a patient, "program personnel may assist with locating the individual, but may not identify them as a patient." Opinion Letter 81-10 (July 17, 1981).

Hot pursuit is when law enforcement officers follow the fleeing individual into the program.



Law Enforcement

How may the PDMP release Casey's records to the DA?

- a) With a warrant, because that meets the state law requirements.**
- b) With a warrant and a certification that the DA is conducting an active investigation against Casey.**
- c) With a Part 2-compliant court order, finding that the alleged crime is extremely serious and that the public interest outweighs the harm to patient confidentiality.**
- d) The PDMP cannot share any records, because the OTP violated Part 2 by sharing the records in the first place.**



Case Study #4

Law Enforcement

Answer

c) With a Part 2-compliant court order.

- The PDMP is a “lawful holder” of Part 2 records, 42 CFR § 2.12(d)(2), 2.13.
- Part 2 records may only be used to criminally investigate or prosecute a patient after a judge issues a special court order, 42 CFR §§ 2.12(b), 2.13.



Key points: Law Enforcement

- A warrant, subpoena, or certificate of open investigation is not sufficient to authorize disclosure of Part 2-protected records, 42 CFR §§ 2.12(b), 2.13.
- PDMPs may only disclose records if law enforcement produces a court order that meets the requirements of Section 2.65.

(§ 2.65)

Part 2 Court Orders

Procedural requirements:

- Adequate notice to record holder (i.e., PDMP)
- Opportunity to appear and be heard
- PDMP represented by counsel independent of applicant
- Hearing held in judge's chambers
- Order issued by judge (see next slide)

Part 2 Court Orders

Substantive Requirements:

- Court order must make *all* the following findings:
 - Crime alleged is "**extremely serious**"
 - Reasonable likelihood records will be substantially valuable
 - Other ways of obtaining the information not available
 - Potential injury outweighed by public interest

- Disclosure and use limited to minimum necessary, and limited to serious crime specified in application

"Extremely serious" crime means one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.



Looking Ahead

WHAT WILL CHANGE IN 2021



CARES Act

- Coronavirus Aid, Relief, and Economic Security Act (March 2020) amended SUD privacy law, 42 USC § 290dd-2
 - **Effective date: March 2021**
 - **Requires HHS to amend 42 CFR Part 2**
- *Future rulemaking will define practical impact of the CARES Act changes*



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



Poll Question #2

True or False?

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

- True
- False
- I'm not sure...



Poll Question #2

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 largely on a future rulemaking to amend Part 2.*



Questions?

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Accessing the CoE-PHI

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Confidentiality is a cornerstone of recovery. Protecting patient privacy opens doors to communication, understanding, and trust

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QUICK LINKS

- PROJECT OVERVIEW
- WHO IS INVOLVED IN THE INITIATIVE?
 - CORE PROJECT STAFF
 - NATIONAL ADVISORY GROUP MEMBERS
- HOW WILL WE KNOW WE ARE SUCCESSFUL?
 - REQUEST TA
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