Focus:PHI

The Center of Excellence for Protected Health Information

Frequently Asked Questions Regarding 42 CFR Part 2 & Prescription Drug Monitoring Programs (PDMPs)

WHAT YOU NEED TO KNOW

The federal law and regulations for substance use disorder treatment records, 42 CFR Part 2 (also known as "Part 2") protect the privacy and security of records created by certain federally assisted programs for SUD treatment. **This resource provides information about how Part 2 applies to information that may be shared with Prescription Drug Monitoring Programs (PDMPs).**

FREQUENTLY ASKED QUESTIONS REGARDING 42 CFR PART 2

Q *What is 42 CFR Part 2?*

A **The federal law and regulations, 42 USC 290dd-2 and 42 CFR Part 2 (known as "Part 2"), are the federal privacy protections for substance use disorder (SUD) treatment information.**

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Q *Who must follow Part 2?*

A **Part 2 applies to "Part 2 programs" – individuals and entities that are federally assisted and meet the definition of a "program." 42 CFR § 2.11. Examples of being "federally assisted" include being a certified Medicaid/Medicare provider, being a non-profit, receiving federal funds, or being licensed to prescribe or dispense methadone or buprenorphine. Examples of "programs" include stand-alone inpatient or outpatient SUD treatment providers, the SUD treatment unit in an FQHC, or an outpatient SUD treatment wing of a hospital. Not all providers who prescribe medication for opioid use disorder (MOUD), such as office-based opioid treatment (OBOT) providers, are Part 2 programs.**

For More Information about who must follow Part 2, please see the following CoE-PHI Resources:
CoE-PHI Decision Tree- I Provide SUD Services in an FQHC: Does Part 2 Apply to Me?
CoE-PHI InFocus Brief- Prescribing Medication Assisted Treatment (MAT) in a General Medical Facility

Recipients of Part 2-protected information must also protect that information according to Part 2. They are called "lawful holders."

Q *What does Part 2 protect?*

A **Part 2 protects the privacy and security of information that reasonably identifies an individual as seeking or receiving SUD treatment from a Part 2 program, including name, date of birth, and treatment records such as prescription information.**

Q *Does 42 CFR Part 2 require patient consent before you disclose the information?*

A **As a general rule, 42 CFR Part 2 requires patients to authorize most disclosures by signing a written consent, except in limited circumstances.**

Q *Is there a difference between HIPAA and 42 CFR Part 2?*

A **Yes. HIPAA protects the privacy and security of general health information and applies to covered entities (healthcare providers, health plans, healthcare clearinghouses) and business associates. The purpose of HIPAA is to protect health data integrity, confidentiality, and accessibility. HIPAA permits disclosures without patient consent for treatment, payment, and healthcare operations.**

42 CFR Part 2 protects the privacy and security of records identifying individuals as seeking or receiving SUD treatment from a "Part 2 program." The purpose is to encourage people to enter and remain in SUD treatment by guaranteeing confidentiality. The regulation requires patient consent for most disclosures, including for treatment, payment, and healthcare operations, with limited exceptions.

Q *Did the CARES Act amend 42 CFR Part 2 privacy regulations to be the same as HIPAA privacy requirements?*

A **No. The CARES Act amended the SUD privacy law to permit certain redisclosures of information for treatment, payment, and healthcare operations, but the patient's initial written consent is still required. The impact of the CARES Act changes will depend largely on future rulemaking to amend 42 CFR Part 2. SAMHSA announced that it is planning to release its notice of proposed rulemaking later in 2021.**

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FREQUENTLY ASKED QUESTIONS REGARDING PRESCRIPTION DRUG MONITORING PROGRAMS

Q *Does 42 CFR Part 2 permit Part 2 programs to report data to PDMPs?*

A **Yes. A Part 2 program or lawful holder is permitted to report protected records (e.g., SUD medication prescribed or dispensed) to the applicable PDMP if required by state law, and if the patient consents. The Part 2 program or lawful holder must obtain patient consent to disclose records to a PDMP under § 2.31 prior to reporting of such information. 42 CFR §2.36.**

Q *When PDMPs receive Part 2-protected records, is the PDMP required to follow 42 CFR Part 2?*

A **Yes. Upon receipt of records from a Part 2 program, a PDMP becomes a lawful holder and is required to protect those records according to Part 2's privacy and security requirements. This means that the PDMP may only use and re-disclose the records as permitted by Part 2.**

Q *Is there any state that currently requires Part 2 programs to report dispensations to PDMPs?*

A **Some state laws may already apply to opioid treatment programs (OTPs), and other states are contemplating passing such laws. However, it is unknown where any state's PDMP currently has the ability to segment patient data in order to protect records as required by Part 2, particularly with respect to access by law enforcement.**

Q *According to 42 CFR Part 2, how must PDMPs protect Part 2 data?*

A **As a lawful holder of 42 CFR Part 2 data, the PDMP must:**

1. **Comply with 42 CFR Part 2's restrictions on re-disclosure (42 CFR § 2.13),**
2. **Protect security of records (42 CFR § 2.16), and**
3. **Only release records to law enforcement with a Part 2-compliant court order (42 CFR § 2.65).**

SAMHSA has not yet issued any guidance addressing PDMP compliance with Part 2 data.

Q *If a patient consents to a disclosure of their Part 2 records to their state's PDMP, does that allow the PDMP to share the patient's data with another state?*

A **No. The PDMP may not re-disclose Part 2 protected records without patient consent.**

Q *If state law permits, but does not require, OTPs to report information to the PDMP, does it violate 42 CFR Part 2 for the OTP to share the patient records with the PDMP, as long as they have the patient's signed consent?*

A **Yes. OTPs may only report information with patient consent if required by state law, 42 CFR § 2.36.**

Q *Does it violate 42 CFR Part 2 for an OTP to share ALL its patient records with the PDMP, including records of patients who did not consent?*

A **Yes. This violates 42 CFR Part 2 because the OTP must have written patient consent from each individual patient before sharing records with the PDMP (42 CFR § 2.36). Even if state law does not require written patient consent, 42 CFR Part 2 does. Even if state law requires a disclosure prohibited by 42 CFR Part 2, Part 2 takes precedent because it is the federal law and a stricter standard. 42 CFR §2.20.**

Q *Does 42 CFR Part 2 apply to prescriptions for MOUD that are dispensed at a retail pharmacy?*

A **No. Since the pharmacy is not a 42 CFR Part 2 program, Part 2 does not apply.**

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Q *If a PDMP already follows the HIPAA Privacy and Security Rules for its records, does the PDMP need to adjust any of its security protocols for the 42 CFR Part 2 data?*

A **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). 42 CFR Part 2 requires lawful holders to follow the security protocols in 42 CFR § 2.16 for the protected Part 2 records only.**

HIPAA security compliance is a good first step, but not sufficient. In particular, PDMPs must have formal policies and procedures to protect against uses and disclosures of Part 2 records, if such use or disclosure would violate Part 2.

Q *Is it important for a PDMP to keep track of which records are protected by 42 CFR Part 2?*

A **Yes. Once the PDMP receives a Part 2 record, the PDMP becomes a lawful holder and must comply with 42 CFR Part 2 privacy and security protections.**

Q *How is a PDMP notified when a patient revokes their consent?*

A **SAMHSA has not issued guidance that specifically addresses PDMP procedures.**

FREQUENTLY ASKED QUESTIONS REGARDING LAW ENFORCEMENT

Q *When may a PDMP release a Part 2 record to a law enforcement entity?*

A **PDMPs may only disclose records if law enforcement produces a court order that meets the requirements of 42 CFR § 2.65. 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).**

Q *May a PDMP disclose Part 2 records to law enforcement if their state law allows law enforcement entities access to PDMP data without a subpoena or court order?*

A **No. A PDMP must follow the more stringent federal law and only provide Part 2 records pursuant to a Part 2 compliant court order.**

Q *What are the procedural requirements for a Part 2 court order?*

A **There must be adequate notice to the record holder (i.e., PDMP) from law enforcement requesting the records. Upon notification, the record holder has opportunity to appear and be heard before a judge and the record holder can be represented by counsel independent of applicant. The hearing is held in judge's chambers (not open court) to protect the patient's privacy. Following the hearing, the judge makes the determination to issue the court order.**

Q *What findings must a court make in order to issue a 42 CFR Part 2 court order?*

A **The court order must make all the following findings:**

1. **Crime alleged is "extremely serious" which is defined as a crime 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**
2. **There is a reasonable likelihood that records will be substantially valuable to the investigation**
3. **Other ways of obtaining the information are not available**
4. **Public interest outweighs the potential injury to the patient**

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Disclosure and use are limited to the minimum necessary for the investigation and limited to the extremely serious crime specified in application.

Q *According to some state laws, law enforcement may only access PDMP records when investigating violations of controlled substances laws. Do these types of violations meet the definition of "extremely serious"?*

A **SAMHSA has not issued guidance that specifically addresses Part 2 records being disclosed to a PDMP housed in a law enforcement agency.**

For More Information

Resources

This resource is one of many that are available within the Center of Excellence for Protected Health Information's resource library, which can be found at coephi.org.

Request Technical Assistance

You can request brief, individualized technical assistance and join our mailing list for updates, including news about the publication of new resources and training opportunities, here.

Disclaimer

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