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Prescription Drug Monitoring Program Training and Technical Assistance Center

Prescription Drug Monitoring Program

42 CFR Part 2 and PDMPs Frequently Asked Questions

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Patient privacy and confidentiality is extremely important for patient outcomes and it is also the law. Federal and state privacy laws, including those applicable to prescription drug monitoring programs (PDMPs), provide protection for patients who seek or obtain medical care, and there are heightened legal protections for the privacy substance use disorder (SUD) treatment information. 42 CFR Part 2 (known as "Part 2") serves to protect patient records created by certain federally assisted programs for SUD treatment.

These regulations, "Confidentiality of Substance Use Disorder Patient Records," were first promulgated in 1975 to address concerns about the potential use of SUD information against patients. 42 CFR Part 2 regulations are intended to ensure that a patient receiving SUD treatment from a 42 CFR Part 2 Program does not face adverse consequences. 42 CFR Part 2 protects the confidentiality of SUD patient records by restricting the circumstances under which 42 CFR Part 2 Programs or other lawful holders can disclose such records.

In July 2020, 42 CFR Part 2 regulations were revised to further facilitate better coordination of care in response to the opioid epidemic while maintaining confidentiality protections against unauthorized disclosure and use. The revised regulations went into effect on August 14, 2020. Some of the revisions have a direct impact on PDMPs' operations.

The PDMP Training and Technical Assistance Center (TTAC), in its continuing effort to assist PDMPs and be responsive to their needs, engaged representatives from the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide information about the revised 42 CFR Part 2 regulations and how they impacted PDMPs. The Center of Excellence for Protected Health Information (CoE-PHI) was identified by SAMSHA as its technical assistance provider and had the expertise to provide guidance on the newly revised 42 CFR Part 2. CoE-PHI is funded by SAMHSA to develop and disseminate resources, training, and technical assistance for states, health care providers, and other stakeholders to improve understanding and application of federal privacy laws and regulations for providing and receiving treatment for SUD and mental illness.

As a result, TTAC hosted a training webinar on February 25, 2021, in which staff members of the CoE-PHI provided valuable information on the changes to 42 CFR Part 2 and the roles of PDMPs that are recipients of 42 CFR Part 2 data from a 42 CFR Part 2 program. The webinar was very well attended, with representatives from virtually all of the PDMPs.

This Technical Assistance Guide (TAG) has been produced by TTAC to memorialize the information provided on the webinar in a frequently-asked-questions (FAQ) format. The FAQs contained in this TAG have been reviewed and vetted by staff members of the CoE-PHI. The FAQs are broken up into three main categories: (1) general Information concerning 42 CFR Part 2; (2) FAQs pertaining to PDMPs; and (3) FAQs pertaining to law enforcement. There were also questions during the COE-PHI webinar that could not be answered because SAMHSA has not issued guidance specifically addressing those questions. The questions are included in the FAQ; TTAC will seek guidance from SAMHSA concerning them and will update the FAQs as more information from SAMHSA is received.

It should be noted that resources, training, technical assistance, or any other information provided by CoE-PHI or TTAC does not constitute legal advice. TTAC encourages all PDMPs to seek advice from their own legal offices or the state's Attorney General's Office on questions related to patient privacy and confidentiality of patient records.

General Information Concerning 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.

Q: What is a Part 2 Program?

A: "Part 2 Program" refers to certain federally assisted Substance Use Disorder (SUD) treatment programs. It is important to note that not all SUD treatment programs are Part 2 Programs.

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 nonprofit, 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, a SUD treatment unit in an FQHC, or an outpatient SUD treatment wing of a hospital. Not all providers that prescribe medication for opioid use disorder (MOUD), such as office-based opioid treatment (OBOT) providers, are Part 2 programs.

For more information, 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: Is it true that only Part 2 programs must follow Part 2 confidentiality regulations?

A: No. The privacy protections in 42 CFR Part 2 generally follow the information even when it leaves a Part 2 program. A lawful holder of Part 2 information must also protect the privacy and security of that information according to Part 2.

Q: What is a lawful holder?

A: Any individual or entity who receives Part 2-protected records pursuant to written patient consent or one of the exceptions to the consent requirement. 42 CFR § 2.12(d)(2)(i)(C).

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 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 form that meets the requirements of 42 CFR Part 2, 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 (health care providers, health plans, health care 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 health care 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 health care 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 health care 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.

Q: Does 42 CFR Part 2 apply to prescriptions for medication-assisted treatment (MAT) that are dispensed at a retail pharmacy?

A: No. Since the pharmacy is not a Part 2 program, Part 2 does not apply.

FAQs Pertaining to PDMPs

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: Is there any obligation for a Part 2 program to ask for and obtain patient consent as a condition of receiving treatment? (detail scenario)

A: No, Part 2 does not require Part 2 programs to get patient consent as a condition of receiving treatment; however, written consent is required to disclose information except in limited circumstances.

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 redisclose 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 whether any state's PDMP currently has the ability to segment patient data to protect records as required by Part 2, particularly with respect to access by law enforcement.

Q: According to Part 2, how must PDMPs protect Part 2 data?

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

1. Comply with Part 2's restrictions on redisclosure (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 his or her Part 2 records to the state's PDMP, does that allow the PDMP to share the patient's data with another state?

A: No. The PDMP may not redisclose Part 2-protected records without patient consent.

Q: If a patient signs a consent to disclose Part 2-protected data from an OTP to the PDMP and the OTP is required by state law to report that data to the PDMP, can the PDMP share the data with the authorized users of the PDMP?

A: SAMHSA has not issued guidance on how PDMPs can share data with authorized users of the PDMP, including when authorized users are members of law enforcement.

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

A: Yes, it violates Part 2. OTPs may report information only 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 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: 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 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). 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: If a patient signs the consent form and subsequently revokes his or her consent, can the PDMP continue to share the prescription records that were received during the period when the consent was authorized?

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

Q: How is a PDMP notified when a patient revokes his or her consent?

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

Q: Is there an ASAP field available to identify a 42 CFR Part 2 record?

A: A field is not available in the current version of ASAP.

Q: In order to comply with 42 CFR Part 2, what conditions must be met for Part 2 data to be shared with PDMPs?

A: A Part 2 program or lawful holder may now report substance use disorder (SUD) medication prescribed or dispensed to the PDMP, but only:

- As required by applicable state law;
- **and** ONLY with written patient consent.

FAQs Concerning Law Enforcement

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

A: PDMPs may disclose records only 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 its 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 the 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 to issue a 42 CFR Part 2 court order?

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

1. The crime alleged is **"extremely serious,"** which is defined as a crime that 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.

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

Q: Under some current state PDMPs laws, a law enforcement entity is permitted access to patient records only for investigations of violations of controlled substances laws. Do these types of violations meet the definition of "extremely serious"?

A: The determination is made by the judge issuing the Part 2 court order based on the merits of the investigation.

What happens when the PDMP is housed by a law enforcement agency?

SAMHSA has not issued guidance that specifically addresses 42 CFR Part 2 records being disclosed to a PDMP housed in a law enforcement agency. Guidance from SAMHSA is forthcoming.

For more information:

Q: Where do I go to learn more about 42 CFR Part 2?

A: For additional resources and technical assistance about the federal health privacy laws for SUD and mental health records, visit the Center of Excellence for Protected Health Information's Resource Center. (click on logo)