Focus:PHI

The Center of Excellence for Protected Health Information

A CAI LAC LEGAL ACTION CENTER Partnership

PHI regulations protect patient privacy, give you flexibility to provide the best possible treatment, and help clarify the boundaries in protecting and sharing patient information.

FAQs About 42 CFR Part 2

A CLOSER LOOK AT 42 CFR PART 2

Following a webinar hosted by APA, AAAP, and ASAM regarding 42 CFR Part 2, the Center of Excellence for Protected Health Information (CoE-PHI) prepared the following answers to frequently asked questions (FAQs) that were raised by participants.

PART 2 APPLICATION

Q How do I know if Part 2 applies to me?

A The recent final rule released by the Substance Abuse and Mental Health Services Administration (SAMHSA) that went into effect on Friday, August 14, 2020, does not change who must follow 42 CFR Part 2. Part 2 continues to apply to individuals and entities that meet BOTH of the following requirements:

1. "Federally assisted" (defined at § 2.12 (b)), which encompasses a broad set of activities, including management by a federal office or agency, receipt of any federal funding, or registration to dispense controlled substances related to the treatment of SUDs. Many SUD treatment programs are federally assisted.

2. A "program" (defined at § 2.11) is an individual, entity (other than a general medical facility), or an identified unit in a general medical facility, that "holds itself out" as providing and provides diagnosis, treatment, or referral for treatment for a SUD. "Holds itself out" means any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment. Medical per sonnel or other staff in a general medical facility who are identified as providers whose **primary function** is to provide diagnosis, treatment, or referral for treatment for a SUD are also Programs.

If only one requirement is met, such as a substance use disorder treatment provider that is not federally assisted, it would not be considered a "Part 2 Program."

The CoE-PHI has created a Decision Tree to assist in determining whether Part 2 applies to you. SAMHSA has also issued guidance to help stakeholders understand their rights and obligations under Part 2.

in collaboration with SAMHSA Substance Abuse and Mental Health Services Administration · AMERICAN PSYCHIATRIC ASSOCIATION · ASAM American Society of Addiction Medicine · AAAP American Academy of Addiction Psychiatry Translating Science. Transforming Lives.

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Q Do peer support providers for SUD working in a primary care facility fall under Part 2?

A Yes, if the peer support provider meets the definition of a Part 2 program. A peer support provider could meet the definition if they are federally assisted and either:

1. Work in an identified unit of a primary care facility that holds itself out as providing and provides diagnosis, treatment, or referral for treatment for a SUD; or
2. Is an identified SUD provider whose primary function is to provide diagnosis, treatment, or referral for treatment for a SUD.

Q Can you clarify the difference between a Part 2 Program and a non-Part 2 provider providing substance use disorder services?

A If a clinician, such as a primary care provider, provides SUD services, including being DATA Waivered, but does not meet the two requirements above, most notably, holding itself out as providing diagnosis, treatment, or referral for treatment for SUD, then it would not be considered a Part 2 program.

CoE-PHI has created a factsheet to assist providers prescribing Medication for Addiction Treatment (MAT) in primary care or other general medical facilities to determine if they are a Part 2 program.

Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD record previously received from a Part 2 provider is incorporated into such records.

PART 2 APPLICATION TO SUD RECORDS

Q Does 42 CFR Part 2 apply to military personnel SUD records?

A Part 2 applies to records obtained by "any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice" except for records exchanged internally within the Armed Forces.

Part 2 does not apply to SUD treatment records maintained in connection with the Department of Veterans Affairs (VA)'s provision of certain health services, or between the VA and the Armed Forces. 42 CFR § 2.12(c).

The confidentiality requirements of both the HIPAA Privacy Rule and 42 CFR Part 2 apply to SUD patient records maintained by the Military Health System (MHS) healthcare providers and TRICARE.

Covered SUD patient records may only be used or disclosed if the requirements of both DoD 6025.18-R and the 42 CFR Part 2 regulation are satisfied. Thus, if a use or disclosure is permitted by one regulation and prohibited by the other, the use or disclosure is prohibited.. For more information please view these DoD Factsheets:

1. TMA Civil Liberties and Privacy Office Information Paper and Military Command Exception, and Disclosing PHI of Armed Forces Personnel

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PART 2 CONSENT

Q What information about the recipient is required on consent forms?

A The name(s) of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made. The recent Part 2 Amendments that became effective in August 2020 now permit a SUD patient to consent to disclosure of the patient's Part 2 treatment records to any entity, even if it does not have a treating provider relationship with the patient (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure. 42 CFR § 2.31(a).

Q Can consent be given orally?

A No, the Part 2 rules expressly require written consent for most uses and disclosures of SUD patient records, unless an exception applies.

Q Can providers implement an "opt-out" consent process similar to that under HIPAA?

A No, Part 2 does not authorize opt-out consent processes.

Q Where can I find sample consent forms and redisclosure notices?

A The CoE-PHI and Legal Action Center and the have developed sample consent forms and a sample notice prohibiting redisclosure that incorporate the July 2020 amendments to 42 CFR Part 2.

DISCLOSURE OF PART 2 PROTECTED INFORMATION

Q Can Part 2 providers disclose information without consent for payment or healthcare operations (e.g., to obtain prior authorization for medication)?

A No, disclosures for the purpose of "payment and health care operations" are only permitted with written consent. Part 2 permits the disclosure of information without consent to treat a medical emergency or in other limited situations. Written consent is still required to disclose information for all other purposes.

Q How may Part 2 programs disclose information to law enforcement entities?

A Part 2 permits the disclosure of SUD treatment records to law enforcement without written consent in the following certain limited circumstances.

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1. For reporting crimes or threats on program premises or against program personnel.

   - Part 2 permits Part 2 programs to make limited disclosures to law enforcement to report a crime or threat of a crime committed on the program premises or against program personnel. The disclosure must be limited to the circumstances of the event, the patient's name, address and last known whereabouts. 42 CFR §§ 2.12(c)(5). Any follow up information may only be disclosed with patient consent or a court order.

2. For disclosures to investigate or prosecute patients

   - Warrants and subpoenas are not sufficient to compel disclosure of Part 2 protected records. The Coe-PHI has created a **resource for providers** who are asked to disclose records in response to an arrest warrant.
   - A disclosure may only be made with a valid court order that meets the criteria in 42 CFR § 2.65 for an "extremely serious crime," such as 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).

3. For disclosures to investigate or prosecute a Part 2 program

   - 42 CFR § 2.66 permits the issuance of court orders authorizing disclosure of patient records to investigate or prosecute a Part 2 program (or its employees/agents), if certain conditions are met.

Law enforcement agencies can be notified if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel.

4. Part 2 programs and health care providers and HIOs who have received Part 2 patient information, can make reports to law enforcement about an immediate threat to the health or safety of an individual or the public if patient-identifying information is not disclosed.

5. Or, if there is an existing threat to life or serious bodily injury, a Part 2 program or "any person having a legally recognized interest in the disclosure which is sought" can apply for a court order to disclose information.

6. Once Part 2 information has been initially disclosed (with or without patient consent), no redisclosure is permitted without the patient's express consent to redisclose or unless otherwise permitted under Part 2. Disclosures made with patient consent must be accompanied by a statement notifying the recipient that Part 2 redisclosure is prohibited, unless further disclosure is expressly permitted by the written consent of the person to whom it pertains.

7. When disclosures are made without patient consent under the following circumstances, limited redisclosures without obtaining the patient's consent are permitted, such as medical emergencies [42 CFR § 2.51], child abuse reporting [42 CFR § 2.12(c)(6)], crimes on program premises or against program personnel [42 CFR § 2.12 (c)(5)], and court ordered disclosures when procedures and criteria are met [42 CFR §§ 2.61-2.67].

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