

Update on 42 CFR Part 2: Confidentiality of Substance Use Disorder Treatment Records

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Setting the stage...

- **In September 2018 SAMHSA began work on a new revision to 42 CFR Part 2**
 - To improve the flexibility of disclosure requirements for SUD patient records
 - As a part of the broader HHS “Sprint to Coordinated Care” initiative
 - And address the opioid epidemic by enhancing coordination of care efforts
- **The part 2 Notice of Proposed Rule Making (NPRM) was published on August 26, 2019**
- **Public comment period on the NPRM closed on October 26, 2019**

Outline

- **Setting the stage...**
- **Today's part 2 rules: Lightning overview**
- **What's changing under the new proposed rule?**
- **So now, let's discuss**

Lightning overview of today's part 2 rules (I)

- **What do the part 2 rules protect?**

- “Records” – defined as “Any information, whether recorded or not, created, received, or acquired by a part 2 program relating to a patient.”

- **How are SUD records protected under the part 2 rules?**

- Patient consent is required for a disclosure of part 2 records, other than:
 - In a medical emergency
 - For the purposes of research, audit, or program evaluation
 - Following a court order granted after showing of good cause
- Part 2 records may not be used to criminally investigate or prosecute a patient, except pursuant to a court order as described above

Lightning overview of today's part 2 rules (II)

- **What are the implications of today's part 2 consent requirements?**
 - These do not match the HIPAA privacy rule (TPO)
 - Disclosing a record from a SUD treatment program to a PCP (e.g.)
 - Requires a specific patient consent
 - And that consent requirement follows the SUD record into the hands of the PCP!
- **This has resulted in a major barrier to disclosing SUD records for treatment**

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What changed under the August NPRM on part 2?

Topic Area	Section Number
Definitions	§ 2.11
Applicability	§ 2.12
Disposition of Records by Discontinued Programs	§ 2.19
Consent Requirements	§ 2.31
Prohibition on Redisclosure	§ 2.32
Disclosures Permitted with Written Consent	§ 2.33
Disclosures to Prevent Multiple Enrollments	§ 2.34
Disclosures to Prescription Drug Monitoring Programs	§ 2.36
Medical Emergencies	§ 2.51
Research	§ 2.52
Audit and Evaluation	§ 2.53
Orders Authorizing the Use of Undercover Agents and Informants	§ 2.67

When can a non-part 2 provider create a SUD treatment record not covered by part 2? (I)

■ Re: Applicability and Re-Disclosure (§ 2.12)

- Treatment records created by a non-part 2 provider based on her own patient encounters will not be covered by part 2
- Segregating a part 2 record previously received can be used to distinguish “new” patient records created by the non-part 2 provider

When can a non-part 2 provider create a SUD treatment record not covered by part 2? (II)

■ Definition of Records (§ 2.11)

- “Records means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient...”
- *“...provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient does not become a record subject to this Part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider.”*

Enhancing disclosures to, and access of data from, Central Registries (§ 2.34) and PDMPs (§ 2.36)

- **Opioid epidemic demonstrates the need for all SUD treatment providers to access key records, e.g., re: opioid and MAT prescriptions**
- **Two separate systems exist for recording opioid prescribing and dispensing data**
 - OTPs operate Central Registries, presently only available to other OTPs
 - States operate PDMPs, which may be accessed by OTPs, but do not allow for OTP reporting in
- **The NPRM proposed to fix these reporting and data access gaps**
 - Fix to § 2.34, to permit Central Registries to share limited data with non-OTP treating providers
 - Added new § 2.36, to allow for OTP reporting into PDMPs

Revising § 2.51 on “medical emergencies”

- Natural and major disasters can disrupt access to SUD treatment and records on a regional basis
- At present, these disasters are not “*bona fide medical emergencies*,” so as to allow disclosure of Part 2 records without patient consent
- The NPRM amends § 2.51 on medical emergencies, in order to cover natural and major disasters

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Which of the following big picture issues around part 2 would you most like to talk about?

- **Part 2 and responding to the opioid epidemic**
- **Harmonizing the part 2 rule with the HIPAA privacy rule**
- **Part 2 and EHR systems interoperability**

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