

What Substance Use Treatment Providers Should Know About Changes to Confidentiality Regulations (42 CFR Part 2) – January 2018 Final Rule

January 22, 2018

On January 3, 2018, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) issued a [Final Rule](#) amending 42 CFR Part 2 (“Part 2”), the federal substance use disorder confidentiality regulations.¹ This was the second time that SAMHSA issued a Final Rule amending Part 2. The previous Final Rule amending Part 2 was issued by SAMHSA in January 2017. For more information about the January 2017 final rule, please visit our [website](#).

The January 2018 Final Rule is based on the [Supplemental Notice of Proposed Rulemaking](#) (“SNPRM”). This synopsis describes the changes made by the January 2018 [Final Rule](#), which substance use disorder treatment providers should be prepared to address by February 2, 2018, when the Final Rule becomes effective (except as noted in the regulations). ***However, this fact sheet is not a complete review of the changes made by the January 2018 Final Rule, so stakeholders should also review the new regulations in their entirety and consult the Legal Action Center (“LAC”)’s future updates, sample forms, and publications at this [link](#).*** Substance use treatment programs in states that subscribe to our “[Actionline](#)” can also call with questions regarding Part 2 and speak with a LAC attorney.

WHAT THINGS HAVE NOT CHANGED?

The vast majority of Part 2’s protections remain in place.

1. Written patient consent is still required for disclosures of substance use disorder (“patient-identifying”) information unless another exception applies.²
2. The prohibition on re-disclosure still applies to information protected by Part 2.
3. There are no changes to the definition of “Part 2 program” or the type of information protected by Part 2.³
4. Part 2’s statute still provides more stringent federal protections than other health privacy laws, including the Health Insurance Portability and Accountability Act (“HIPAA”), in order to encourage individuals with substance use disorders to seek treatment.⁴

¹ Confidentiality of Substance Use Disorder Patient Records, 83 Fed. Reg. 239 (Jan. 3, 2018). 42 CFR Part 2 is the regulation for the authorizing statute, 42 U.S.C. § 290dd-2.

² 42 CFR § 2.13.

³ 42 CFR § 2.11.

⁴ 42 U.S.C. § 290dd-2.

5. Substance use disorder records may be disclosed or used only as permitted by Part 2, and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceeding conducted by a federal, state, or local authority.⁵
6. In the preamble to the final rule, SAMHSA continues to recognize the importance of protecting the confidentiality of substance use records, in order to encourage individuals to enter treatment and protect patients who could be subject to discrimination and legal deprivation of rights on the basis of seeking treatment.⁶

WHAT THINGS HAVE CHANGED?

1. Optional Abbreviated Notice of Prohibition on Re-Disclosure - § 2.32:

- The Notice of Prohibition on Re-Disclosure of patient-identifying information must still accompany patients' written consent forms, but now the Notice can be abbreviated to the following: "42 CFR Part 2 prohibits unauthorized disclosure of these records."⁷ SAMHSA indicated it made this change in order to conform to standard free-text space within electronic health record systems.
- SAMHSA encourages Part 2 programs and other lawful holders using the abbreviated Notice to discuss the requirements with those to whom they disclose patient identifying information.⁸
- The existing Notice of Prohibition on Re-disclosure is still permissible.⁹

2. Permitted Disclosures with Written Patient Consent - § 2.33:

A) Disclosures by Lawful Holders:

- Once patients consent to a disclosure of their patient records for payment and/or health care operations purposes, lawful holders who receive these records pursuant to patient consent may further disclose the records as necessary to their contractors, subcontractors, or legal representatives, in order to perform the payment and/or health care operations functions designated on the consent form.¹⁰

B) Notice of Prohibition Requirement:

- Lawful holders must provide their contractors, subcontractors, or voluntary legal representatives with a Notice of Prohibition on Re-disclosure.¹¹

C) Reporting Requirement:

⁵ 42 CFR § 2.13(a).

⁶ 83 Fed. Reg. at 240 (preamble to the Final Rule).

⁷ 42 CFR § 2.32(a)(2).

⁸ 83 Fed. Reg. at 240 (preamble to the Final Rule).

⁹ 42 CFR § 2.32(a)(1).

¹⁰ 42 CFR § 2.33(b).

¹¹ 42 CFR § 2.33(c).

- Lawful holders must require their contractors, subcontractors, or voluntary legal representatives to report any unauthorized uses, disclosures, or breaches of patient-identifying information to the lawful holders.¹²
- D) Types of Permissible Payment and Health Care Operations Activities:
- A list of permissible activities that qualify as “payment and/or health care operations” can be found in the preamble.¹³ SAMHSA clarified that this list is meant to illustrate the types of activities that qualify for the purposes of Section 2.33, and is not an exhaustive list.
- E) Prohibitions on Disclosures for Healthcare Treatment Purposes:
- Disclosures to a lawful holder’s contractors, subcontractors, and legal representatives *are not* permitted for activities related to a patient’s diagnosis, treatment, referral for treatment, or care coordination.¹⁴
- F) Contract Provisions for Disclosures for Payment and Health Care Operations Purposes
- Lawful holders who wish to disclose patient-identifying information for payment and/or health care operations activities must have a written contract or other legal instrument with their contractors, subcontractors, or voluntary legal representatives, which says they are fully bound by Part 2’s provisions when they receive the patient’s substance use disorder information.¹⁵
 - Lawful holders may not disclose patient-identifying information without a contract in place; the deadline for contract compliance is February 2, 2020.¹⁶
 - Contractors, subcontractors, and legal representatives are not required to produce a copy of the written contract or legal instrument before a Part 2 program releases any information.¹⁷

3. Audit and Evaluation - § 2.53:

- Lawful holders can disclose patient-identifying information in order to comply with an audit or evaluation performed in compliance with Part 2.
- Parties authorized to conduct an audit or evaluation of a Part 2 program or a lawful holder may disclose patient-identifying information to a contractor,

¹² 42 CFR § 2.33(c).

¹³ 83 Fed. Reg. at 243 (preamble to the Final Rule) provides 17 examples of permissible payment and health care operation activities under § 2.33(b).

¹⁴ 83 Fed. Reg. at 241, 243 (preamble to the Final Rule). In contrast, HIPAA permits disclosures without patients’ consent for health care activities, including case management and care coordination. 45 CFR § 164.501.

¹⁵ 42 CFR § 2.33(c).

¹⁶ 83 Fed. Reg. at 239 (preamble to the Final Rule).

¹⁷ 83 Fed. Reg. at 246 (preamble to the Final Rule).

subcontractor, or lawful representative for the purposes of carrying out the audit.

IMPORTANT ADDITIONAL INFORMATION:

The preamble to the Final Rule also indicated that SAMHSA is considering additional rulemaking and sub-regulatory guidance on the protections in Part 2, including the extent to which Part 2 should move towards a less protective standard like the one in HIPAA.¹⁸ In addition, SAMHSA is convening stakeholders for a [public listening session](#) on January 31, 2018 at SAMHSA headquarters.¹⁹ The purpose of the listening session is to provide an opportunity for the public to provide their input regarding the effect of Part 2 on “patient care, health outcomes, and patient privacy,” as well as possible regulatory changes and future sub-regulatory guidance. LAC will appear in person and submit written comments to the public listening session, and encourages others to submit their own comments about the importance of protecting patients’ substance use disorder information.²⁰

CONCLUSION

For substance use disorder treatment providers, the most recent amendments to Part 2 will not greatly affect existing practices for protecting patient confidentiality. However, LAC encourages Part 2 programs and other lawful holders that adopt the abbreviated notice of prohibition of redisclosure to follow SAMHSA’s recommendation and discuss Part 2’s protections and requirements with third parties prior to disclosing protected information. LAC also encourages Part 2 programs, after reading the regulations, to alert their patients to the ways that information may be shared with contractors, subcontractors, and legal representatives of the entities to whom a patient discloses information pursuant to written consent.

¹⁸ 83 Fed. Reg. at 240 (preamble to the Final Rule).

¹⁹ Confidentiality of Substance Use Disorder Patient Records – Notice of Public Meeting, 83 Fed. Reg. 1041 (Jan. 9, 2018). Registration to attend the listening session in-person closes on January 22, 2018 at 12:00 p.m. ET. Registration to attend via teleconference/webcast closes on January 31, 2018 at 8:30 a.m. ET.

²⁰ 83 Fed. Reg. at 1041-1042. SAMHSA must receive comments by February 28, 2018, at 5:00 p.m. ET.