



IMPLEMENTATION FACT SHEET

3 Key Steps for Implementing the Latest Changes to 42 CFR Part 2 (Confidentiality of Substance Use Disorder Patient Records)

Substance use disorder treatment providers at Part 2 programs are required to follow 42 CFR Part 2 (“Part 2”).¹ These providers can take three key steps to implement the changes to Part 2 required by the Department of Health & Human Services (HHS) 2024 Final Rule:

- (1) Update consent forms and required notices
- (2) Revise agency or organization policies and procedures
- (3) Ensure staff knowledge by providing training

What You Need to Know

On February 16, 2024, HHS released a [Final Rule](#) updating 42 CFR Part 2, the federal regulations governing the confidentiality of substance use disorder (SUD) treatment records. The Final Rule implemented changes required by Congress in the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act to align certain aspects of 42 CFR Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

For more information about 42 CFR Part 2, visit the CoE-PHI’s [Resource Library](#).

A Closer Look

The Final Rule changed the confidentiality regulations in ways that will impact patients throughout the country. As Part 2 programs review the Final Rule with an eye to implementation, consider these three steps:

1. Update consent forms and required notices

The Final Rule requires Part 2 Programs to update their consent forms, provide a notice to accompany disclosure, and develop a notice to patients of federal confidentiality requirements.

A. Consent. The 2024 Final Rule modified the required elements for a consent form (2.31) authorizing disclosure of Part 2-protected records, and further aligned many elements with HIPAA's authorization requirements.² At minimum, Part 2 consent forms must be updated to include information about how a patient may revoke consent, which was not previously required on Part 2 consent forms.³ Many programs may also want to update their consent forms' instructions to reflect new flexibilities, like the ability to name "a person or class of persons" as the recipient of the records.⁴ The CoE-PHI will publish a sample template consent form soon that providers can adapt and use consistent with other requirements or policies that may apply; please join our mailing list for updates.

B. Notice to accompany disclosure. Disclosures of Part 2-protected records with a patient's written consent must be accompanied by a notice that the records are protected by federal law (§2.32). The 2024 Final Rule modified both the full and abbreviated versions of this notice.⁵ The short version now reads: "42 CFR Part 2 prohibits unauthorized use or disclosure of these records."⁶ For more information about the notice, see the [CoE-PHI's new resource](#).

C. Notice to patients of federal confidentiality requirements. Even before the Final Rule, Part 2 programs already were required to give patients a notice explaining the federal confidentiality requirements.⁷ The 2024 Final Rule modified Part 2's notice requirements (§2.22) to further align with the HIPAA Privacy Rule's Notice of Privacy Practices (NPP).⁸ The CoE-PHI will publish a sample notice soon that providers can adapt and use; please join [our mailing list](#) for updates.

2. Update policies and procedures

In addition to updating the required forms and notices, Part 2 programs should review and update their policies and procedures to reflect the changes in the 2024 Final Rule. A few examples are highlighted below:

- A. Educating patients about consent.** Patients' consent options have changed in ways that may implicate the privacy protections for their substance use treatment records. It is important for providers to update their policies and procedures to reflect any changes in how patients are educated and counseled about their options regarding completing and signing a consent to share information. For example, providers may want to give additional information to patients so they can make an informed decision if signing a single consent for all future uses for Treatment, Payment and Operations (TPO), a consent for records to be used in legal proceedings against the patient, or a consent for use and disclosure of SUD Counseling Notes (if applicable; not all providers maintain SUD Counseling Notes). Policies and procedures should also reflect the new prohibitions on combining typical consents with those used for SUD counseling notes or legal proceedings against the patient.⁹ See the CoE-PHI's resource: [SUD Counseling Notes](#).
- B. Making disclosures of Part 2 records with consent.** As discussed above, disclosures of Part 2 records with patient consent must be accompanied by an updated notice and a copy of the consent, or a clear explanation of the scope of the consent.¹⁰ Providers must ensure that their policies and procedures have been updated such that all disclosures of Part 2 records are accompanied by the notice and the consent; consent forms can include the required notice, so that sending one form satisfies both requirements.
- C. Implementing new patient rights.** For Part 2 programs that are also [HIPAA covered entities](#), many of the new patient rights in Part 2 may not require as many changes to the program's practices, since these rights already applied under HIPAA. For example, the Final Rule incorporates certain patient rights in the HIPAA Privacy Rule, including a patient's right to request restrictions on disclosures of records otherwise permitted for the purposes of treatment, payment, or healthcare operations.¹¹ The Final Rule also incorporates the HIPAA Breach Notification Rule requirement to notify affected individuals, HHS, and in some cases the media, following a breach.¹² However, Part 2 programs also subject to HIPAA should review both sets of requirements and update their policies and procedures accordingly.

3. Train all staff

Training staff is essential to fully implement the updated policies and procedures. Training is also a good opportunity to refresh and reinforce the basics, including the rationale for the privacy protections, how to discuss concepts of privacy and consenting to share treatment information, the importance of obtaining an individual's informed consent, and where to find updated consent forms, notices prohibiting redisclosure, and patient notices of privacy practices. Looking for more resources and information about how to conduct privacy and compliance trainings? Join our [dedicated mailing list for Privacy, Compliance and Quality Officers](#).

Timing: effective date, compliance date, and implementation

The 2024 amendments to Part 2 went into effect on April 16, 2024, with a compliance date of February 16, 2026, when enforcement may formally begin.¹³ This means that Part 2 programs, lawful holders, and anyone else subject to the rule may start implementing the changes now, and must have fully implemented all required changes by the 2026 compliance date. Remember to coordinate changes in practice with the necessary policies, procedures, and training to implement them and ensure that staff have knowledge of any changes made. As well, programs must maintain compliance with any applicable state-specific statutory and regulatory requirements.

January 2025

This resource was authored by [Jacqueline Seitz, JD.](#)

For More Information

The 2024 42 CFR Part 2 Final Rule

For more information about the Final Rule, including case studies and practical examples, watch the CoE-PHI's recent archived webinar: [42 CFR Part 2 Final Rule – What You Need to Know.](#)

Resources

This resource is one of many that are available within the CoE-PHI's resource library, which can be found at www.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 learning opportunities on our website. Please note that COE-PHI does not provide legal advice.

¹ A Part 2 program is a federally assisted, substance use disorder treatment program that meets the definition in 42 CFR § 2.11. For more resources about when Part 2 applies, visit the CoE-PHI's [Resource Library](#).

² Confidentiality of Substance Use Disorder Patient Records, 89 Fed. Reg. 12,472, 12,541 (Feb. 16, 2024), available at <https://www.federalregister.gov/d/2024-02544/p-977>.

³ See 42 CFR § 2.31(a)(6).

⁴ See 42 CFR § 2.31(a)(4)(i).

⁵ See 42 CFR § 2.32(a).

⁶ 42 CFR § 2.32(a)(2).

⁷ 42 CFR § 2.22.

⁸ 89 Fed. Reg. at 12,597, available at <https://www.federalregister.gov/d/2024-02544/p-797>.

⁹ See 42 CFR §§ 2.31(b)(2) (“A written consent for a use or disclosure of SUD counseling notes may only be combined with another written consent for a use or disclosure of SUD counseling notes.”) and 2.31(d) (“Patient consent for use and disclosure of records (or testimony relaying information contained in a record) in a civil, criminal, administrative, or legislative investigation or proceeding cannot be combined with a consent to use and disclose a record for any other purpose.”).

¹⁰ 42 CFR § 2.32.

¹¹ See 42 USC § 290dd-2(b)(1)(B); 42 CFR § 2.26.

¹² See 42 USC § 290dd-2(j), (k); 42 CFR §§ 2.11, 2.16.

¹³ 89 Fed. Reg. at 12,472, available at <https://www.federalregister.gov/d/2024-02544/p-6>.