



HEALTH INFORMATION AND DATA SHARING Fact Sheet

Summary of 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records, Final Rule.


Summary of notable changes to the Part 2 rule

On February 8, 2024, the U.S. Department of Health & Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights announced a final rule modifying the Confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR Part 2 (“Part 2”). The effective date of the new rule is April 16, 2024, and entities have until February 16, 2026, to comply. What follows is a summary of notable changes to the Part 2 Rule. As anticipated, key changes have been made to better align many of Part 2’s provisions with HIPAA’s, specifically those concerning consent, civil money penalties, and how breaches are to be handled. A key new provision grants special treatment for “SUD counseling notes”, which is akin to HIPAA’s treatment of psychotherapy notes. Of particular interest to public health authorities will be the adoption of HIPAA’s deidentification standards that will now permit Part 2 programs to disclose de-identified data to public health authorities.

To put these changes in context, the intent of 42 CFR Part 2 regulations is *“to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable by reason of the availability of their record than an individual with a substance use disorder who does not seek treatment.”* 42 CFR §2.2(b)(2)

Highlights of the 42 CFR Part 2 Final Rule Related to Consent (some changes underlined for emphasis)

- **Consent requirements better aligned.** Aligns the content requirements for Part 2 written consent to use or disclose Part 2 records with most of the content requirements for a valid HIPAA authorization.
- **Single consent for TPO.** A single consent for all future uses and disclosures for Treatment, Payment, or Operations (TPO) is now permitted. Further, unless and until revoked, a recipient Part 2 program, HIPAA covered entity, or business associate receiving Part 2 records under such a consent may use and disclose those records for TPO as permitted by HIPAA. And a covered entity or business associate




(not a Part 2 program) may further disclose those records in accordance with HIPAA regulations. It appears that the Part 2 redisclosure notice still must accompany all disclosures, including these.

- **SUD Counseling Notes:** Adopts a protection analogous to HIPAA's treatment of psychotherapy notes. Creates a new definition for an SUD clinician's notes documenting or analyzing the conversation in an SUD counseling session that the clinician voluntarily maintains separately from the rest of the patient's SUD treatment and medical record and that require specific consent for disclosure from an individual and cannot be used or disclosed based on a broad TPO consent.
- **Separate documents for certain consents.** Permission to use or disclose Part 2 records must be given on separate consent forms as follows. The Rule:
 - prohibits combining patient consent for the use and disclosure of records for civil, criminal, administrative, or legislative proceedings with patient consent for any other use or disclosure.
 - requires a separate patient consent for the use and disclosure of SUD counseling notes.
- **Copy of consent** or a clear explanation of scope of the consent must be provided with the record(s) being disclosed.
- **Broader description of recipient allowed.** Clarifies how recipients (by name or "class of persons", etc.) may be designated in a consent to use and disclose Part 2 records, lightening the earlier stringent requirement that each recipient be specifically listed.
- **Restrictions on records and testimony in more legal settings:** Expands restrictions on the use and disclosure of records and testimony to civil, administrative, and legislative proceedings against patients (previous rule protections were limited to criminal proceedings) absent patient consent or a court's order.
- **Disclosures to Public Health Authorities:** Permits Part 2 programs to disclose to public health authorities (without need for patient consent) deidentified patient information that meets the HIPAA standards for de-identification. The earlier Part 2 rule did not permit de-identified information to be shared with public health authorities.

Other Highlights of the 42 CFR Part 2 Final Rule

- **Segregation of Part 2 Data:** Adds an express statement that a Part 2 program, covered entity, or business associate that receives Part 2 records based on a single consent for all Treatment, Payment, Operations is not required to segregate or segment such records.
- **Notice of Privacy Practices:** Aligns Part 2 Patient Notice requirements with the requirements of the HIPAA Notice of Privacy Practices.
- **Civil Penalties:** Adds civil money penalties for violations of Part 2 (same as HIPAA violations).
- **Breach Notification:** The HIPAA Breach Notification Rule has been adopted and will now apply to Part 2.
- **Use and Disclosure.** Extends application of most Part 2 provisions to the use and disclosure of SUD records (the earlier version generally uses only one or the other of those terms, so it now clearly applies to both uses and disclosures of SUD records).
- **Safe Harbor for Investigative Agencies:** Provided certain conditions are met, the Final Rule creates a limitation on civil and criminal liability (a safe harbor) for investigative agencies and person(s) acting on their behalf that investigate and prosecute Part 2 programs (not patients) and unknowingly receive and disclose records subject to Part 2. The safe harbor requires investigative agencies to take certain "reasonable diligence" steps to be eligible for the safe harbor.

- 
- **Qualified Service Organization.** The QSO definition was modified to include HIPAA business associates in circumstances when the Part 2 program is also a HIPAA covered entity, adding clarity to what legal agreement would be needed between entities to use or disclose Part 2 records.
 - **Definitions added:** Adds new terms and definitions to align with existing HIPAA terms (*Breach, Business associate, Covered entity, Health care operations, HIPAA regulations, Public health authority, Treatment, Unsecured protected health information*) and adds other terms (*Lawful holder, Substance use disorder (SUD) counseling notes, Unsecured protected health information, Unsecured record, Use*)
 - **Definitions modified:** Modified the Part 2 definitions of the following to distinguish them from or align them with similar terms in HIPAA (*Patient, Program, Records, Treating provider relationship, Qualified service organization*) or to clarify them (*Patient Identifying Information*).

Additional resources on data and privacy can be found on the Network’s website and on the Center of Excellence- Protected Health Information site: <https://coephi.org/>

This document was developed by Chris Alibrandi O’Connor, Deputy Director, Mid-States Region. This document is not an exhaustive review of the 42 CFR Part 2 Final Rule. Readers should review the Rule for more details related to the highlighted provisions as well as to others not covered herein. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

March 7, 2024

SUPPORTERS

Support for the Network provided by the Robert Wood Johnson Foundation. The views expressed in this document do not necessarily reflect the views of the Foundation.

