

Changes to Privacy Rules: Intersection of HIPAA and 42 CFR Part 2

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42 CFR Part 2 Basics

- 42 CFR Part 2 is a federal regulation governing substance use disorder program patient records (“SUD Records”)
- Originated in 1975 and implemented in the current form in 1983 (in a paper records world that no longer exist)
- Revised somewhat in 2017-18
- Overall – few meaningful revisions throughout its lifecycle
- Called “Part 2” for short

Part 2 Versus HIPAA

- HIPAA Privacy began in 2003
- HIPAA and Part 2 are not coordinated (even though they often both apply to the same records)
- Part 2 rules require much stricter privacy handling than HIPAA and it can be difficult to blend them operationally
- The new rule assumes too much about providers and insurers understanding of HIPAA and SUD Records rules
- Added confusion: Not all SUD Program providers are governed by HIPAA (today's program focuses mostly on entities that are governed by HIPAA)

Efforts To Align HIPAA and Part 2

- During the COVID-19 pandemic Congress passed the CARES Act
- CARES Act includes requirements for HHS to better align HIPAA and Part 2
- NEW rules published in the federal register February 16, 2024: very detailed and very long (160 pages of tiny type in three column format)
- Deadline for compliance: **February 16, 2026**
 - Many necessary details still need to be filled in!!
 - “Accounting Rule” change on hold, awaiting compliance date

Alignment With HIPAA

- Part 2 will be more like HIPAA -- but ultimately still too different to unify operationally
- Policies, procedures, and new forms will be necessary to comply (whatever you are doing now will need to change)
- Part 2 records will still need to be “tracked” in most circumstances because different or additional rules often apply
- There are different nuances and procedures for non-HIPAA entities for most parts of the rule

Major Updates For Part 2 Privacy

- **Consents:** Disclosures and types of consent
- **Prohibitions:** expansion and clarification of limits of use and disclosures (generally by or to government authorities)
- **Breach and de-identification** rule clarification
- **HIPAA Notice of Privacy Practices** (aka “NPP” or “NOPP”) mandatory changes
- **Restrictions and patient control** clarified
- **Accounting** of disclosures (from HIPAA 45 CFR 164.528)
 - This portion of the rule is on hold awaiting a change to HIPAA

Penalties

- Prior rule had enforcement penalties but were rarely used
- New rule aligns penalties with HIPAA sanction rules
- Range is vast:
 - \$25,000 to \$1,500,000
 - Criminal sanctions fines (\$50-250k) and jail time of 1-10 years in prison
- The inference is the government is more serious about enforcement

Consent Updates

- This is the most complex and lengthy area of changes in the new rule
- Conceptual shift from needing a consent for each purpose and recipient to a consent that can be for all HIPAA “TPO”
- TPO includes the HIPAA designation for Treatment, Payment and Operations
- A single patient consent can be used for multiple, future (some unknown as of yet) purposes

Single Consent For TPO

- Can be a single form for all TPO
- The type and scope of data being release per the consent should be identified in a “specific and meaningful” way (prior rule needed to be exact)
- Covers future uses and disclosures (within TPO)
- Expiration date can be “none”
- Recipients or downstream users identified in the consent can be by class or type
 - E.g.: a health plan or third-party payer; all of my providers

HIPAA Rules On TPO

- A HIPAA covered entity or business associate may use or disclose SUD Records for TPO unless and until patient revokes the single consent
- This does not extend to legal proceedings which would require the patient's specific and separate consent (or a specialized court order)
- Non-HIPAA SUD Programs are confined to the scope of the consent

Segregation Of Records No Longer Required

- Part 2 programs, and HIPAA covered entities or their business associates that receive records through a single consent for treatment, payment or operations (TPO) are not required to segment or segregate the SUD Records from other records
- That sounds a lot better than it is
- Harder to manage in practice because re-release will always need to track the original as SUD Records to ward off inappropriate use in legal proceedings

Prohibited Through Single Consent

- Single consent not allowed for use in a civil, criminal, administrative or legislative proceeding against the patient (needs court order or patient's specific written consent with more details than a single TPO consent)
- This is not a new concept, more a clarification
- It is designed to reduce hesitance to seek treatment due to stigma or fear of reprisal
- This prohibition substantially aligns conceptually with similar changes to the HIPAA Privacy Rule relating to reproductive health privacy that go into effect December 23, 2024

Prohibited Through Single Consent (continued)

- Single consent may not be used for “SUD Counseling Notes” (a new category of protected records similar to HIPAA Psychotherapy note protections)
- This is going to be confusing to implement
- Government assumed providers already understand HIPAA Psychotherapy notes rule
- Very few use the HIPAA psychotherapy notes rule now; that framework is not as illuminating as the SUD Rule makes it sound

Single Consent For TPO & Disclosure Process

- Consent must contain certain “magic words” with various warnings and disclosures to ensure the consent process is transparent for the patient
- Disclosure must be done with a warning to the downstream recipient
- Not clear if the same wording is required for HIPAA covered entities or business associates – but some indication would be needed
- **Intermediaries** have different sharing rules; these are entities that are not subject to HIPAA but access SUD Records (examples: for research or care coordination – but only when **not** a HIPAA covered entity or business associate)

Breach & Deidentification

- HIPAA level deidentification rules apply
- Prior rule had a similar but less clear standard
- Deidentification is very specific under HIPAA – and should be followed carefully
- HIPAA Breach rules apply

Notice Of Privacy Practices

- HIPAA Notice of Privacy Practices (“NPP” or “NOPP”) has more details than the prior Part 2 privacy notice
- Under new rule, HIPAA NOPP can be used for Part 2 compliance
 - **NOTE: HHS still working on examples and clarifications**
- Revised language required to be implemented by providers and others by February 16, 2026
- This is a great opportunity for HIPAA covered entities to revise other NOPP issues that may be lingering
- Specific language is needed in the revised NOPP for Part 2 patients and fundraising (nuanced detail from HIPAA’s current NOPP obligation)

Legal Proceedings

- Prior rule already blocked most uses by authorities for prosecution of the patient or when used against the patient (absent patient's specific consent)
- New rule clarifies and expands those blocking rules to all legal proceedings to include use or disclosure in any civil, criminal, administrative, or legislative proceedings
- Similar in theory to new reproductive health rules for HIPAA privacy
- As with prior rule, effective court orders mandating disclosure are more complicated than under HIPAA; required by law disclosures per HIPAA are **not applicable** to Part 2
- HHS still working on examples and clarifications

Restrictions & Patient Control

- As with prior rule, SUD Records accessed for program oversight or audit cannot be repurposed for proceedings against a patient
- Patient can request restrictions – new rule follows HIPAA restrictions rule (see 45 CFR 164.522 for specific on restrictions to health insurers)
- That should be what HIPAA entities are already doing
- As with prior rule, Part 2 programs have more power to condition treatment on patient consents than a HIPAA entity that is not Part 2 program can require

Accounting – 45 CFR 164.528

- In the last 10 years, there have been multiple (soft) attempts to rework HIPAA’s “Accounting of Disclosures” rule to remove most of the exception categories to create a true audit log of users available for patient review
- Those efforts have never been finalized (providers and health insurers generally oppose the proposed changes)
- Another attempt to modify this rule is pending
- If those pending changes become law, they will also apply to SUD Records

Next Steps

- Identify policies and procedures relating to use, disclosure, and handling of SUD Records and related forms
- Review all consent forms
- Pencil in changes that will be needed
 - Assess whether HHS owes guidance information on those topics before finalizing your changes
- Update breach policies and procedures
- Plan staff training po new rule and policy and forms updates
- Create schedule for completion by February 2026

Key Resources

- HHS resources fact sheet and landing page:
[Fact Sheet 42 CFR Part 2 Final Rule | HHS.gov](#)
- Final rule text in federal register on February 16, 2024:
[2024-02544.pdf](#)
- HIPAA Reproductive Health Privacy Rule update landing page (closer deadline):
[HIPAA and Reproductive Health | HHS.gov](#)

Questions?

Q&A