

*The Updated Substance Use Disorder
Record Privacy Requirements:*

Opportunity and Risks for Part 2 Providers

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HIPAA



42 CFR Part 2

HIPAA

Applies to:

Covered entities (healthcare providers, health plans, healthcare clearinghouses) and their business associates

Protects privacy and security of general health information

Purpose:

To protect health data integrity, confidentiality, and accessibility

Permits:

Disclosures without patient consent for treatment, payment, and healthcare operations

42 CFR Part 2

Applies to:

SUD patient records from federally-assisted "Part 2 programs"


Protects privacy and security of records identifying individual as seeking/receiving SUD treatment

Purpose:

To encourage people to enter and remain in SUD treatment by guaranteeing confidentiality

Requires:

Patient consent for treatment, payment, and healthcare operations, with limited exceptions



Predates HIPAA and is more strict



Until now, inconsistent rules between HIPAA and Part 2 have created barriers to info sharing by clinicians and patients.



The New Landscape

- Patients' SUD treatment record protections now better aligned with aspects of HIPAA and HITECH
- Inconsistencies have been addressed by HHS through its Substance Abuse and Mental Health Services Administration
- Compliance date Feb.16, 2026

Key Part 2 Changes

Simplified Part 2 Patient Consent

- Allows a single consent for all future uses and disclosures for treatment, payment and health care operations
- Allows HIPAA covered entities and business associates that receive records under this consent to redisclose the records in accordance with HIPAA regulations

- Each patient record disclosure must be accompanied by a copy of the original patient consent form or an explanation of the scope of the consent
- A Part 2 program, covered entity or business associate that receives Part 2 records based on a single consent is **no longer required to segregate or segment such records**

Other Disclosures

- Continues to restrict the use of records and testimony in civil, criminal, administrative and legislative proceedings against patients, absent patient consent or a court order
- Permits disclosure of records to public health authorities without consent provided the disclosed records are de-identified per HIPAA's established standards

Other Disclosures

- Continues to restrict third-party access to the use of patient records, absent patient consent or a court order

SUD Counseling Notes

- Notes of treating clinicians documenting a conversation in a SUD counseling session by a Part 2 program, which are separate from the treatment and medical record, must be maintained separately from a Part 2 record
- Separate patient consent required for use and disclosure of SUD counseling notes

Notice of Privacy Practices

- Part 2 programs are required to align their Notice of Privacy Practice (NPP) with the HIPAA Notice of Privacy Practices requirements
- HIPAA, Part 2 and state law notices are permitted to be combined in a single notice as long as all required elements are included

Accounting of Disclosures and Restriction Requests

- Patients of Part 2 programs have the right to request an accounting of particular disclosures for the prior three years and request restrictions on certain disclosures as also granted by the HIPAA Privacy Rule
 - The compliance date on this obligation will be delayed to implement necessary HITECH changes

Accounting of Disclosures and Restriction Requests

- Patients have the right to obtain restrictions on certain disclosures to health plans for services paid in full
- Patients have new right to opt out of fundraising communications

Breach Reporting Requirements

- The requirements of the HIPAA Breach Notification Rule (45 C.F.R. §§ 164.400-414) now apply to breaches of unsecured Part 2 information

Breach Reporting Requirements

- In the event of a breach, a Part 2 program has no more than 60 calendar days (unless an exception applies) after discovery to notify patients, HHS, and the media, depending on the number of individuals affected

QSO Definition Revised

- The definition of a qualified service organization (QSO) now includes HIPAA business associates of a Part 2 program that is also a HIPAA covered entity

Penalties

- Violators of confidentiality provisions could now be subject to civil monetary penalties in addition to criminal penalties in alignment with the HIPAA Enforcement Rule (45 C.F.R. Part 160, subparts C, D, and E)

Right to Complain

- Patients have the right to file complaints of alleged violations by a program, covered entity, business associate and others directly to the HHS Secretary and the Part 2 program
- Programs cannot require that patients waive their right to file a complaint as a condition of treatment or program eligibility

Safe Harbor

- Creates a safe harbor for persons acting on behalf of investigative agencies that, in the course of investigating or prosecuting a Part 2 program or other person that holds Part 2 records, unknowingly and inadvertently receive Part 2 records without the required court order

Safe Harbor

- Investigative agencies can only rely on this safe harbor if records are obtained for the purpose of investigating a Part 2 program or person holding such records
- It is not available for investigations related to a patient

Safe Harbor

- The agency must use reasonable diligence to identify Part 2 records prior to making a demand or seeking the records

Safe Harbor

- The safe harbor is intended to protect from Part 2 penalties persons acting on behalf of investigative agencies who have otherwise complied with Part 2, but unintentionally violate Part 2 by receiving protected records absent a court order

What Has Not Changed?

- Patients' SUD treatment records cannot be used to investigate or prosecute the patient without written patient consent or court order (42 CFR § 2.67)
- Records obtained in an audit or evaluation of a Part 2 program cannot be used to investigate or prosecute patients, absent written patient consent or court order

Next Steps

In Advance of February 2026

- Update patient consent forms
- Update notice of privacy practices
- Review policies related to maintenance of SUD counseling notes, accountings of disclosures and breach notification

In Advance of February 2026

- Train staff on necessary updates to existing operations
- Develop a plan to communicate changes to patients as necessary





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ATTORNEYS AT LAW

This is provided as an informational service and does not constitute legal counsel or advice, which can only be rendered in the context of specific factual situations.

If a legal issue should arise, please retain the assistance of competent legal counsel.

Thank You



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