

Substance Use Disorder Providers Now Must Align 42 CFR Part 2 SUD Records with HIPAA Standards

For nearly 40 years the confidentiality of patient records created by federally-assisted programs to diagnose or treat substance use disorders have been protected by federal law (42 U.S.C. § 290dd-2) and regulations (42 C.F.R. Part 2). Part 2 requirements predate, and are more stringent than, the requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The inconsistency between HIPAA and Part 2 has created an ongoing source of frustration for providers.

Change has arrived, however, to improve care coordination for both patients and providers. In early February 2024, the U.S. Department of Health & Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), finalized [modifications](#) to Part 2 regulations so that patients' SUD treatment record confidentiality protections are better aligned with aspects of HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH). The changes are effective April 16, 2024. With the exception of the delayed compliance date for accounting of disclosure requirements, the compliance date is Feb. 26, 2026.

The key changes include:

Simplified Part 2 Consent Requirements

Use and disclosure of Part 2 records is now allowed based on a single patient consent given once for all future uses and disclosures for treatment, payment and health care operations (TPO). Previously, a patient had to sign a separate consent for each TPO disclosure and had to name recipients in the consent form.

Once a Part 2 consent is obtained, Part 2 information may be used, disclosed and redisclosed by HIPAA covered entities and their business associates for TPO purposes permitted under HIPAA until the patient revokes consent in writing. This applies to covered entities and business associates even if they are not Part 2 programs but are in possession of a Part 2 record. Each disclosure of a patient record must be accompanied by a copy of the original patient consent form or an explanation of the scope of the consent.

Also, 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

The Final Rule continues to restrict the use of Part 2 records and testimony against patients in civil, criminal, administrative or legislative proceedings without separate patient consent or a court order and subpoena. However, disclosure to public health authorities without consent is permissible provided the records are disclosed and de-identified according to the standards established in HIPAA.

New SUD Counseling Notes and Record Segregation Requirements

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. Similar to the protections HIPAA provides for psychotherapy notes, use and disclosure of SUD counseling notes require separate patient consent and cannot be used or disclosed based on a TPO consent.

Notice of Privacy Practices

Previously, HIPAA and Part 2 required different notices of privacy practices.



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The Final Rule requires Part 2 programs to align their Notice of Privacy Practice (NPP) with that required under HIPAA. Covered entities that have Part 2 records must add the protections to their notices. Part 2 programs are permitted to combine HIPAA, Part 2, and state law notices under a single notice so long as all the required elements are included. This Final Rule only addresses NPPs under Part 2, and HHS intends to publish modifications to the HIPAA NPP requirements in future rulemaking.

Patients’ Right to Accounting of Disclosures and Restriction Requests

Patients of Part 2 programs now 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, although the compliance date on this obligation will be delayed to implement necessary HITECH changes. In addition, patients will have the right to obtain restrictions on certain disclosures to health plans for services paid in full, as well as the ability to opt out of fundraising communications.

Breach Reporting Requirements

Part 2 programs must now report breaches of unsecured Part 2 information according to the requirements in the HIPAA Breach Notification Rule (45 C.F.R. §§ 164.400-414). Therefore, 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.

Qualified Service Organization 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.

Confidentiality Violation Penalties, Right to Complain and Safe Harbor

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). The Final Rule also affords patients 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. In addition, programs cannot require that patients waive their right to file a complaint as a condition of treatment or program eligibility.

Safe harbor requirements were established 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. 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. Additionally, the agency must use reasonable diligence to identify Part 2 records prior to making a demand or seeking the records. 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.

Next Steps

Part 2 programs, and any other entities subject to Part 2, should review related policies and procedures and technology resources for compliance inconsistencies well in advance of the February 2026 deadline to allow time for necessary revisions. Part 2 programs should also:

- update patient consent forms;
- update notice of privacy practices;
- review policies related to maintenance of SUD counseling notes, accountings of disclosures and breach notification;
- train staff on necessary updates to existing operations; and
- develop a plan to communicate changes to patients as necessary.

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