

## Summary of 42 CFR Part 2 Changes Effective April 16, 2024

### **Background:**

The 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records regulations (Part 2) serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD). In December 2022, the Department of Health and Human Services (DHHS) issued a Notice of Proposed Rule Making (NPRM) to modify several Part II regulations to implement the confidentiality provisions of the 2020 CARES Act. The amendment is intended to align certain aspects of Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) rules and those of Health Information Technology for Economic and Clinical Health Act (HITECH). The amendment is effective April 16, 2024.

This document is intended to outline the Part 2 changes most impactful to County of San Diego contracted SUD providers. However, providers should confer with their own legal counsel for official guidance as to whether they are a 'Part 2 Program' and, if so, how the Part 2 changes impact them. This document is NOT intended as a comprehensive list of requirements, nor as legal advice.

### **Resources:**

- HHS summary of the changes:  
[Fact Sheet 42 CFR Part 2 Final Rule | HHS.gov](#)
- The amendment itself:  
[2024-02544.pdf \(govinfo.gov\)](#)

**Main Changes Impacting SUD Providers:** Below is a summary of the main updates to Part 2. Actual edits to the regulation language are in [blue](#).

**Single consent for treatment, payment and health care operations:** An SUD client may now sign a single consent for all future uses and disclosures for treatment, payment and health care operations (TPO) without the need to obtain a new consent for each entity and/or each purpose. It is important to note that while the new rule makes the consent process less burdensome, it does not eliminate the need to obtain a consent for TPO purposes.

2.31(a)(4)(i) **General requirement for designating recipients.** The name(s) of the person(s) or the name(s) of the class of persons to which a disclosure is to be made (recipient(s)). [For a single consent for all future uses and disclosures for treatment, payment, and health care operations, the recipient may be described as “my treating providers, health plans, third party payers, and people helping to operation this program” or a similar statement.](#)

**Redisclosures pursuant to a consent:** Allows providers who have received information through a TPO consent to redisclose the records in accordance with HIPAA regulations. *Note, there is an exemption for SUD information that can be used in a legal proceeding against the individual. Such information cannot be disclosed or redisclosed under a TPO consent and requires a separate consent.*

2.33(a)(2) **Uses and Disclosures Permitted with Written Consent.** The entirety of the previous section 2.33(b) was removed and section 2.33(a)(2) was added which includes: [When the consent provided is a single consent for all future uses and disclosures for treatment, payment and health care operations, a Part 2 program...may use and disclose those records for treatment, payment and health care operations as permitted by the HIPAA regulations, until such a time as the patient revokes such consent in writing.](#)

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Notice of Privacy Practices. Prior to the Final Rule, Section 2.22(a) required a Part 2 program to “communicate to the patient that federal laws and regulations protect the confidentiality of substance use disorder patient records.” The Final Rule **adds** section 2.22(b) Content of notice. In addition to the communication required in paragraph (a) of this section, a part 2 program shall provide notice, written in plain language, of the program’s legal duties and privacy practices, as specified in this paragraph. The remainder of sections (b) and (c) describe requirements and implementation specifications for the Notice of Privacy Practices (NPP) that align with HIPAA, including a requirement that Part 2 programs allow an individual to opt-out of receiving fundraising communications.

Notification of breaches. Section 2.16 **added** paragraph (b) which states, The provisions of 45 CFR part 160 and subpart D of 45 CFR part 164 shall apply to part 2 programs with respect to breaches of unsecured records in the same manner as those provisions apply to a covered entity with respect to breaches of unsecured protected health information.

Individual’s right to receive an accounting of disclosures: The Final Rule **adds** section 2.25 which requires Part 2 programs to provide an individual with an accounting of disclosures that were made pursuant to a consent if requested by the individual. The accounting must meet the requirements under HIPAA (45 CFR 164.525(a)(2) and (b) through (d). Whereas HIPAA requires the accounting to include disclosures made during the previous six years, Part 2 disclosures are only required for the previous three years. However, unlike HIPAA, disclosures made for TPO purposes must be included in the accounting if they were made through an electronic health record.

Individual’s right to request privacy protections for records: The Final Rule **adds** section 2.26 which requires a Part 2 program to permit an individual to request that the Part 2 program restrict uses or disclosures of records about the individual to carry out treatment, payment or health care operations, including when the individual has signed a consent.

### Summary of Other Salient Changes:

- **Other Uses and Disclosures**
  - Permits disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the standards established in the HIPAA Privacy Rule.
  - Restricts the use of records and testimony in civil, criminal, administrative, and legislative proceedings against patients, absent patient consent or a court order.
  - Requires recipients of SUD data to receive the signed consent or a summary thereof.
- **Segregation** of SUD records is no longer required.
- **Penalties:** Aligns Part 2 penalties with HIPAA by replacing criminal penalties currently in Part 2 with civil and criminal enforcement authorities that also apply to HIPAA violations.
- **Safe Harbor:** Creates a limit on civil or criminal liability for investigative agencies that act with reasonable diligence to determine whether a provider is subject to Part 2 before making a demand for records in the course of an investigation. The safe harbor requires investigative agencies to take certain steps in the event they discover they received Part 2 records without having first obtained the requisite court order.
- **SUD Counseling Notes:** creates a definition of and identifies consent and disclosure requirements for SUD counseling notes that is analogous to the definition of Psychotherapy Notes under HIPAA.

For more information about Part 2 rules, contact Business Assurance and Compliance at 619-338-2808 or email [PrivacyOfficer.HHSA@SDCounty.ca.gov](mailto:PrivacyOfficer.HHSA@SDCounty.ca.gov)