

Summary of 42 CFR Part 2 Changes Effective August 14, 2020

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). On March 27, 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act, which prompted the Department of Health and Human Services (HHS) to amend Part 2 on July 15, 2020. The amendment is intended to facilitate better coordination of care in response to the opioid epidemic while maintaining confidentiality protections against unauthorized disclosure and use. The amendment is effective August 14, 2020.

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.

Providers should also note that HHS anticipates another round of Part 2 changes, effective March 27, 2021.

Resources:

- HHS summary of the changes:
<https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html>
- The amendment itself:
<https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf#page=52>

Main Changes Impacting SUD Providers:

Consent Requirements: An SUD patient may now consent to the disclosure of their Part 2 records to an entity without naming a specific person as the recipient of the disclosure. For example, Part 2 programs may now accept a Consent form ("ROI") that lists 'San Diego County Probation Department' without the specific name of the Probation Officer.

2.31(a)(4)(i) General requirement for designating recipients. The name(s) of the individual(s) or the name(s) of the entity(-ies) to which to whom a disclosure is to be made.

Prohibition on Re-Disclosure: Previously Part 2 Programs had to ensure one of two statements was included on each disclosure. The lengthier statement has been revised. The shorter statement remains unchanged.

2.32(a)(1) This information record which has been disclosed to you is from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65;

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Medical Emergencies: Declared states of emergency resulting from disasters (e.g., COVID-19) may be considered a medical emergency, for the purpose of disclosing Part 2 records without patient consent.

2.51(a)(2) Meet a bona fide medical emergency in which a part 2 program is closed and unable to provide services or obtain the prior written consent of the patient, during a temporary state of emergency declared by a state or federal authority as the result of a natural or major disaster, until such time that the part 2 program resumes operations.

Audit and Evaluation: Clarifies the ability to perform audit and evaluation of Part 2 records, including records viewed onsite, taken offsite, copied, downloaded, or forwarded, if the review is on behalf of a controlling entity.

2.53(a)(1) (iii) An entity with direct administrative control over the part 2 program or lawful holder

Summary of Other Salient Changes:

2.11 **Definition of Records:** Certain oral communications to a non-Part 2 program now excluded from Part 2.

2.12(d)(2)(ii) **Applicability:** SUD treatment records created by non-Part 2 programs based on their own patient encounter(s) now excluded from Part 2, unless Part 2 records previously received are incorporated into such records.

2.31 (4)(ii) **Consent Requirements:** New consent requirements for health information and research institutions.

2.33(b) **Disclosures Permitted with Written Consent:** Clarified disclosures for payment and health care operations.

2.34(b) and (d) **Disclosures to Prevent Multiple Enrollments:** Expanded to include non-opioid treatment programs and non-central registry treating providers as eligible to query a central registry to coordinate care, inform prescriber decision making, or prevent multiple enrollments.

2.36 **Disclosures to Prescription Drug Monitoring Programs:** Allowed if required by state law; not applicable in California.

2.52 **Research:** Disclosures now permitted by a HIPAA-covered entity or business associate to researchers who are neither HIPAA covered entities, nor subject to the Common Rule re: Research on Human Subjects.

2.53(c)(d) and (g) **Audit and Evaluation:** Expands on allowable disclosures for audit and evaluation mandated by law.

2.67(d)(2) **Undercover Agents and Informants** – Expands court ordered placement of such persons within a Part 2 program from 6 months to 12 months and allows courts to extend further.

HHS also issued guidance, not regulation, which can be found in the above links, related to staff's use of personal email or cell phone to communicate with clients. Although HHS does not encourage patient communication through such personal devices, if an SUD patient sends an incidental message to an employee's personal device, the employee may fulfill Part 2 sanitization requirements by deleting the message.

For more information about Part 2 rules, contact the Agency Compliance Office at 619-338-2808 or email PrivacyOfficer.HHSA@SDCounty.ca.gov