Changes to 42 CFR Part 2 take effect on August 14, 2020. Final rule is available here: <https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records>

The changes include the following:

1. If a patient in a part 2 program gives permission to share their information **orally** with a non-part 2 provider for treatment purposes, the record at the non-part 2 provider does not become a record subject to part 2 regulations merely because that part 2 information is added to the patient’s record by that non-part 2 provider.

2. The recording of information regarding SUD and its treatment by a non-part 2 provider does not, by itself, make the record subject to part 2. However, any records the non-part 2 provider receives from a part 2 program remain subject to part 2. The non-part 2 provider must segregate the Part 2 patient records to ensure that new records created by a non-Part 2 provider will not become subject to Part 2.

3. Non-part 2 providers do not need to redact information in a non-part 2 record regarding SUD and may re-disclose the patient records if expressly permitted by written consent of the patient (or permitted under part 2 regulations).

4. An SUD patient may consent to disclosure of the patient’s Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.

5. Patients of a part 2 program may consent to the disclosure of their information to a wide range of entities for “health care operations”. This is allowed for 18 types of payment and health care operational activities:

(1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing, and/or related health care data processing;

(2) Clinical professional support services (*e.g.,* QI/QA; utilization review; management);

(3) Patient safety activities;

(4) Activities pertaining to:

(i) The training of student trainees and health care professionals;

(ii) The assessment of practitioner competencies;

(iii) The assessment of provider or health plan performance; and/or

(iv) Training of non-health care professionals;

(5) Accreditation, certification, licensing, or credentialing activities;

(6) Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;

(7) Third-party liability coverage;

(8) Activities related to addressing fraud, waste and/or abuse;

(9) Conducting or arranging for medical review, legal services, and/or auditing functions;

(10) Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;

(11) Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;

(12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;

(13) Resolution of internal grievances;

(14) The sale, transfer, merger, consolidation, or dissolution of an organization;

(15) Determinations of eligibility or coverage (*e.g.,* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(18) Care coordination and/or case management services in support of payment or health care operations; and/or

(19) Other payment/health care operations activities not expressly prohibited in this provision.

6. Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.  
  
7. Opioid treatment programs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.

8. If there is a state or federally-declared natural and/or major disaster, there is a Medical Emergencies exception authorizing disclosures of patient information to another part 2 program or other SUD treatment provider.

9. Changes to the research requirements permit research disclosures of part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research. This final rule also permits research disclosures to recipients who are covered by Food and Drug Administration (FDA) regulations for the protection of human subjects in clinical investigations

10. Changes to audit and evaluation clarifies that federal, state and local governmental agencies and third-party payers may conduct audits and evaluations to identify needed actions at the agency or payer level to improve care; that audits and evaluations may include reviews of appropriateness of medical care, medical necessity, and utilization of services; and that auditors may include QA organizations as well as entities with direct administrative control over a part 2 program or lawful holder. There are also updates related to QIOs to allow for patient identifying information to be disclosed to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by statute or regulation.

11. Orders authorizing use of undercover agents and informants amends the period for court-ordered placement of an undercover agent and informant within a part 2 program to 12 months and clarifies that the 12-month time period starts when an undercover agent or informant is placed in the part 2 program.

12. There is now clarification of what’s supposed to happen if an SUD patient sends a text or email to the personal device of an employee, volunteer, or trainee of a Part 2 program. When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for “sanitizing” the device by deleting that message.

From the final rule: “In the case that patient contact is made through an employee's (or volunteer's or trainee's) personal email or cell phone account which he or she does not use in the regular course of business for that part 2 program, the employee should immediately delete this information from his or her personal account and only respond via an authorized channel provided by the part 2 program, unless responding directly from the employee's account is required in order to protect the best interest of the patient.If the email or text contains patient identifying information, the employee should forward this information to such authorized channel and then delete the email or text from any personal account. These authorized channels are then subject to the normal standards of sanitization under §§ 2.16 and 2.19 and any other applicable federal and state laws. SAMHSA believes that this process will both protect the employee's personal property and the confidentiality of the patient's records if the patient makes such unauthorized contact.”