42 CFR Part 2 2024 Final Rule

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Purpose

- *In general, Part 2 programs may not disclose information that would identify someone as a current patient, including by providing a referral, without written patient consent.*
- Aims to prevent a patient being made "more vulnerable by reason of the availability of their patient record than an individual who does not seek treatment"
- Intended to ensure that patients are not discouraged from seeking treatment for substance use disorders (SUD)
- Particularly concerned with preventing treatment records from being used in criminal proceedings

What Is Covered

- Clinical programs covered by 42 CFR Part 2 protections are defined as:
  - Federally assisted (receipt of any federal funding, tax exempt status, or dispensing controlled SUD treatment medications such as methadone)

    and

  - Organization is primarily "held out as" SUD treatment provider

    or

  - Within a mixed-use facility, an identified unit or identified individual medical personnel/staff whose primary function is provision of SUD treatment
- Note that Part 2 occurs at the clinical program/provider level, **not the patient level**

How It's Different from HIPAA

- Disclosures for the purpose of "payment and health care operations" are permitted **with written consent.**
  - **Part 2 (previously) required a named recipient (organization or individual) on the consent.**
  - Part 2 also requires that recipients of the patient's SUD treatment records be notified that they are **prohibited from re-disclosing the records** without written consent from the patient.
- Requires a Qualified Service Organization Agreement (QSOA) to act as the equivalent of a business associate under HIPAA.

Data Segmentation

"Data segmentation" is the term often used to describe the electronic labeling or tagging of a patient's health information in a way that allows patients or providers to electronically share parts, but not all, of a patient record.

Data segmentation helps providers comply with specific state and federal laws, helping to keep the "sensitive" portions of a patient's electronic record private. For example, mental health counseling, Human Immunodeficiency Virus (HIV) status, substance abuse treatment, and other types of sensitive topics may need to be treated differently than other parts of a patient's record depending on the applicable laws.

Granular consent = patient consent process

Data segmentation = technical requirements to enable granular consent

Source: https://archive.healthit.gov/providers-professionals/data-segmentation-overview

2024 Final Rule

- Prompted by the CARES Act Section 3221 which directed SAMHSA to bring Part 2 more in line with HIPAA.
- **Effective date 4/16/2024.**
- Also required rules to be promulgated that broadly prohibit discrimination based on information in SUD treatment records (not yet addressed by SAMHSA in rulemaking).
- Does many other things I will not be discussing today…

Final rule available here: https://www.federalregister.gov/documents/2024/02/16/2024-02544/confidentiality-of-substance-use-disorder-sud-patient-records

Major Changes

- Patient Consent
  - Allows for 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 re-disclose the records in accordance with HIPAA.
- Other Uses and Disclosures
  - Permits disclosure of patient records without consent to public health authorities, provided that the records are deidentified in accordance with HIPAA Privacy Rule. Once de-identified, no longer considered covered by Part 2.

Patient Consent Changes

- 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 operate this program” or a similar statement.
- Each disclosure or re-disclosure under HIPAA TPO must be accompanied by a written statement that it is covered by Part 2 and must be accompanied by a copy of the consent or a clear explanation of the scope of the consent.
- Information obtained orally by a non-Part 2 program regarding SUD treatment with patient consent (whether from patient or provider) which is written into a record does not become covered by Part 2.

Differences in Final Rule vs. NPRM

- **Added express statement that segregating or segmenting Part 2 records is not required by covered entities or business associates.**
  - However, some means to ensure that records are used and disclosed according to the scope of the consent will be needed.
- Established SUD counseling notes as analogous to psychotherapy notes under HIPAA and therefore exempt from disclosures when they are held apart from the rest of the record.
- Requires that each disclosure made with patient consent includes a copy of the consent itself or a clear explanation of the scope of the consent.

HIT Implications

- All changes are “permissible but not mandatory”. Providers can choose which aspects to adopt and may remain more restrictive.
- These changes will implement the CARES Act consent provisions by permitting HIEs that are business associates to receive part 2 records under a broad TPO consent and redisclose them consistent with the HIPAA regulations.
    - Patient has a right to receive an accounting of disclosures made, including electronically.
    - The notice accompanying the record that it is covered by Part 2 is also required for electronic exchanges. An abbreviated (80 character) notice is suggested by SAMHSA for EHR use.

RI State Mental Health Law

Only applies to inpatient psychiatric units and to community mental health centers as licensed by BHDDH.

http://webserver.rilin.state.ri.us/Statutes/TITLE40.1/40.1-5/40.1-5-26.htm

§ 40.1-5-26. Disclosure of confidential information and records.

(a) The fact of admission or certification, and all information and records compiled, obtained, or maintained in the course of providing services to persons under this chapter, shall be confidential.

(b) Information and records may be disclosed only:

(1) To any person, with the written consent of the patient, or the patient's guardian.

(2) In communications among medical or mental health professionals for the provision of services, or to make appropriate referrals for diagnosis, treatment, and/or transitions of care.

[…]

(14) To any vendor, agent, contractor, or designee who operates an electronic health record, health information exchange, or clinical management system to fulfill one of the purposes specified in subsection (b) of this section.