Confidentiality of Substance Use Disorder Patient Records
42 C.F.R. Part 2

Kendri M. M. Cesar, Partner
Sonosky, Chambers, Sachse, Miller & Monkman, LLP

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Governing Laws

- Health Insurance Portability and Accountability Act (HIPAA)
- Health Information Technology for Economic and Clinical Health (HITECH)
- 42 C.F.R. Part 2 (Part 2)– the Confidentiality of Substance Use Disorder Patient Records
- The Privacy Act, 5 U.S.C. Section 552a (b)

42 C.F.R. Part 2

- Regulations issued in 1975, revised in 1987, then in 2017 and 2018. Notice of proposed rulemaking issued August 2019.
- Purpose: to ensure privacy for individuals seeking help for drug or alcohol problems, who might otherwise be deterred from accessing services.
- Prohibits all disclosures without consent, except those specifically outlined by the regulations.
- Preempts state law which would permit or require a disclosure otherwise prohibited by Part 2. But stricter laws control.

Substance Use Disorder

- New term expanded protections beyond drug and alcohol services.
- This term means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.

TREATMENT

- This term means the care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.
- Does not exclusively mean care provided by medical personnel or under a medical model.

Who Must Comply?

Federally-assisted "programs"

- Can be a stand-alone facility
- Can be a person, unit of a facility, or organization (other than a general medical care facility) that "holds itself out as providing, and provides, substance use disorder diagnosis, treatment, referral for treatment or prevention." 42 C.F.R. § 2.11.
- Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment, and who are identified as such providers.

Holds Itself Out:

Any activity that reasonably indicates the program provides SUD services:

- Advertising
- Certifications in addition treatment, etc.
- State licensing procedures
- Statements to the community
- Listing in SUD treatment registries

Application in Tribal Health

- BH Departments which provide both behavioral health services and treatment for substance use disorders.
- Standalone programs or facilities:
  - Tanana Chiefs Conference: Graf Rheenerhanjii (Youth Treatment Facility)
  - SouthCentral Foundation Detox (formerly known as Ernie Turner Center Detox)

Not Treated as a Part 2 Program:

- The Emergency Department, including when providing emergency detox services.
- A primary care physician, even if providing certain substance use disorder treatment services.
- Must “hold themselves out” as providing such services.

Individuals As Programs

- Primary function must be SUD services
- Term "primary function" not defined by the regs
- But must be *identified* as a provider whose primary function is SUD services
- Example: A doctor works in a primary care practice, and specializes in patients with opioid use disorder. The primary care practice advertises that she is authorized to prescribe buprenorphine, and she is listed on SAMHSA's buprenorphine treatment practitioner locator. She prescribes buprenorphine to approximately 75%-95% of his patients.

Individuals As Programs

- Factors to consider:
  - % of time spent providing SUD services.
  - Whether other services provided are closely related or intertwined with the provision of SUD services.
  - Whether the individual's job title or position indicates that SUD services are their primary function.
  - Whether the individual is closely affiliated with a unit or a program of the facility that provides SUD services.

Patient Identifying Information

- Any information, oral or written, which would directly or indirectly reveal a person's status as a current or former patient of a Part 2 program.
- Name, address, SSN, fingerprints, photograph, or similar info by which the identity can be determined with reasonable accuracy either directly or w/reference to other info.
- Doesn't include a number assigned to a patient by the program from the program's internal use, if it doesn't otherwise use any patient identifying information (for example, the number includes the SSN).

Patient Identifying Information

- Protects patients who have applied for an interview, counseling, diagnosis, treatment, or referral for treatment – doesn't matter if they showed up for an appointment.
- Protects an individual who, after arrest on a criminal charge, is identified as an individual with a SUD in order to determine that individual's eligibility to participate in a Part 2 program.

Application to Behavioral Health

- BH staff that provide, in whole or in part, SUD services must comply with Part 2 when dealing with the records of SUD service patients, even if they primarily provide other therapeutic services.
- A diagnosis alone does not trigger Part 2. To trigger Part 2, diagnosis must be made for the purpose of treatment or referral for treatment.
- Example: A psychiatrist who is treating an individual for depression may determine that the person is abusing alcohol. If the psychiatrist does not use this determination to treat or refer the client to SUD services, the info is protected by HIPAA but not by Part 2.

Screening, Brief Intervention and Referral to Treatment

"A comprehensive, integrated, public health approach to the screening and identification of individuals who are practicing risky alcohol and drug use, and the timely delivery of brief interventions to these people in order to reduce risk use which, if not successful, leads to their timely referral to more intensive substance abuse interventions."

- Provided in many different settings
- Protected only if the provider or entity is considered a Part 2 "program".
- EXAMPLE: A patient admitted to the ER receives SBIRT services from a provider whose primary function is *not* the provision of substance use disorder treatment services, so the SBIRT records are not protected by Part 2.

Lawful Holder

- A “lawful holder” of information protected by Part 2 is an individual or entity who has received such information as a result of written patient consent. or one of the exceptions to Part 2’s consent requirements, and who is therefore required to comply with Part 2.
- ANTHC is a lawful holder when it receives Part 2 info from other health care organizations.
- When primary care receives Part 2 info from a behavioral health department pursuant to a valid consent, it is also a lawful holder.

Prohibition on Redisclosure

This information has been disclosed to you from records protected by federal confidentiality rules (42 C.F.R. 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 or as otherwise permitted by 42 C.F.R. 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.

- 42 C.F.R. Part 2 prohibits unauthorized disclosure of these records.

Limitations on Access/Disclosure

- Requires any disclosure to be "limited to the information which is necessary to carry out the purpose of the disclosure" except disclosures made to patients. 42 C.F.R. § 2.13(a).
- Compare to "minimum necessary" requirement, which does not apply to uses or disclosures for treatment purposes. 45 C.F.R. § 164.502(b)(1).
- Must review requests for disclosures on an individual basis. But can rely on the requestor's representations as to what is "necessary to carry out the purpose of the disclosure," in the exercise of professional judgment.
- Must follow HIPAA's requirement that a program identify those workforce members who need access to carry out their duties in furtherance of Part 2 services. Access must be restricted for others.

Segregation of Records

- Segregation is necessary to ensure you protect covered records in compliance with Part 2.
- Part 2 does not require a particular method of segregation.
- Evaluate what your options, whether using a paper or electronic recordkeeping system.
- EHRs might be able to provide a separate SUD record, or mechanisms for restricting access to certain records.
- Consult with your vendor. Additional expense to “build” a facility for these records may be necessary.

Permitted Disclosures

Much more limited than HIPAA:

1) Written consent
2) Internal communications
3) No patient-identifying information
4) Medical emergency
5) Court order
6) Crime at program/against program personnel
7) Research
8) Audit and evaluation
9) Child abuse
10) Qualified Service Organization Agreement

Internal Program Communications

- Program staff may disclose information to other staff *within the program* – or to "an entity having direct administrative control over that program" – if the recipient needs the information in connection with the duties that arise out of the provision of substance use disorder diagnosis, treatment, or referral for treatment.
- Example: disclosures for administrative purposes such as to central billing or record-keeping departments, as necessary to provide substance use disorder services.
- This does not allow disclosure to primary care for treatment purposes, without specific patient consent, even if medically necessary to other types of treatment by primary care. It's important to get signed consent up front to avoid problems.

Written Consent

- A general medical release is not sufficient.
- Patient must get copies of signed consent forms.
- No general designations for disclosures to entities/individuals that do not have treating provider relationship with patient.
  - Ex: Sonosky Chambers AND Kendri Cesar, Dick Monkman, etc.
- Treating provider relationship – name of entity
  - Ex: Alaska Native Medical Center
- Minor's consent is always required.

Consent For Disclosure to HIE

- Access to Part 2 info on the HIE cannot be provided to other health care entities without patient consent.
- Must name the entities with a treating provider relationship to the patient who are authorized to access the Part 2 info or use a general designation:
  - Ex: All my treating providers participating in the ABC HIE
  - OR: ABC's HIE and South Hanover Clinic and Dr. Phil
- Other entities participating in the HIE, who do not have a treating provider relationship with the patient, must restricted from accessing that patient's Part 2 info in the HIE.
- List of Disclosures

COURT-ORDERED DISCLOSURES

- **CIVIL: Judge must make specific findings**
  - **PRIOR notice and opportunity to object – patient and provider**
    - "Good cause" for the disclosure, meaning the public interest and need for disclosure outweigh any adverse effect that the disclosure will have on the patient, the doctor-patient relationship, and the effectiveness of the program's services.
    - Other ways obtaining the information are not available or would not be effective.
  - **"Confidential Communications"**
    - Necessary to protect against a threat to life or of serious bodily injury; or
    - Is necessary to investigate or prosecute an extremely serious crime; or
    - Is in connection with a proceeding in which the patient has already presented evidence re: the confidential communication.

Part 2 Violations

- Reported to the U.S. Attorney's office in the judicial district where the violation occurs.
- Can also report to the agency in your state that regulates alcohol or drug programs, if any.
- Violations are a crime: fines are not more than $500 for the first offense; no more than $5000 for each subsequent offense.
- Will also constitute a violation of HIPAA subjecting the violator to either civil or criminal penalties.

HIPAA Fines

- The fine for a first time infringement by someone who did not know they violated HIPAA could be as low as $100 or as high as $50,000.
- Where there was reasonable cause to know of a violation, the fine could be between $1,000 and up to $50,000.
- The fine for a violation due to willful neglect, but corrected within the required time period, is a minimum of $10,000 per violation with a maximum of $50,000.
- The fine when the willful neglect violation is not corrected increases from $10,000 to $50,000.

Questions?

Kendri M. M. Cesar
kendri@sonosky.net