Part 3: Substance Use Disorder and Confidentiality for 42 CFR, Part 2

Presented by: Susan Clarke, Health Care Information Security and Privacy Practitioner

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An overview of Part 2, the federal regulations for heightened confidentiality requirements for SUD and the recent changes. Discuss ways to determine if your facility or providers are considered a Part 2 program and overlap with HIPAA.

Exercise 1 will follow this presentation.
Title 42 of the Code of Federal Regulations (CFR) \textit{Part 2}: Confidentiality of Substance Use Disorder Patient Records (\textit{Part 2}) was first promulgated in 1975 to address concerns about the potential use of Substance Use Disorder (SUD) information in non-treatment based settings such as administrative or criminal hearings related to the patient.
42 CFR Part 2 are the federal substance use disorder (SUD) confidentiality regulations issued by the Department of Health & Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). These regulations protect the confidentiality of SUD treatment records. The Part 2 rules were recently amended with the first substantial update to the Confidentiality of Alcohol and Drug Abuse Patient Records (Part 2) regulations since 1987. Final rule was published Jan. 18, 2017, then on Jan. 3, 2018, another final rule issued.
Why did Part 2 Change?

✓ To encourage care integration and information exchange
✓ To address healthcare technology changes
✓ To address prohibition against redisclosures and accounting for disclosures
✓ To address research uses of data
✓ To address security of records

“SAMHSA wants to ensure that patients with substance use disorders have the ability to participate in and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards.”
The purpose of Part 2 is to protect patients from any unintended bias associated with substance use disorders. The additional confidentiality protections of Part 2 protect SUD patients who seek treatment from the potentially harmful consequences of having their patient records available to others who do not need access to them. The goal is to encourage people to seek SUD treatment, rather than not, because they can do so without fear of their information being shared.

To accomplish this, Part 2 prohibits the disclosure and use of SUD patient records except with the patient’s specific written consent or under certain limited exceptions. The lawful recipient of SUD records is also prohibited from redisclosing the information except with written patient consent or when another Part 2 exception applies.
Why increased awareness?

1) More treating providers have access to confidential SUD treatment records to provide services.

2) The opioid crisis has focused on the need for treatment and services, and the need for more integrated care for patients.
A “program” is defined as any “individual” or “entity” that “holds itself out as providing education, treatment or prevention to individuals in need of alcohol or drug abuse treatment.”
Part 1 of Part 2
The Individual or Entity

A Medical personnel or staff member who:
- Holds themselves out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
- Practices in a general medical facility whose primary function is SUD treatment, diagnosis, or referral for treatment and is identified as such; or
- Is a NH Licensed Alcohol and Drug Counselor (LADC) providing LADC services.

Examples of Part 2:
An entity (other than a general medical facility) that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
A unit within a general medical facility that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment.
Part 2 of Part 2
AND Federally Assisted

• Recipients of federal financial assistance
• Federal financial assistance is assistance of any kind, even if it does not directly fund the SUD treatment, diagnosis, or referral for treatment services
• Licensed, certified, registered, or authorized by the federal government to conduct business
• Tax-exempt through the IRS
• Conducted by the federal government or a state or local government that receives federal funds, which could be used for SUD programs

Exception: Part 2 does not apply to the Department of Veterans Affairs or Armed Forces
Yes and Maybe Examples

An internist who provides occasional advice about substance abuse to patients as part of their primary care practice

**NO:** Internist does not “hold himself/herself out” as providing specialized substance abuse treatment services

A Community health clinic that is not licensed as a substance abuse treatment provider but advertises its expertise in serving patients with substance abuse disorders

**PROBABLY:** If the clinic promotes its substance abuse treatment services capacity and provides or makes referrals for substance abuse services, probably subject to Part 2
HIPAA versus Part 2

HIPAA

• Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Additional protections for psychotherapy notes
• Business Associate Agreements, BAA
• Require specific protections to safeguard electronic health information

Part 2

• Protects the confidentiality of substance use disorder (SUD) patient records from disclosure without express patient consent
• Qualified Service Organizations (QSO)
• Require specific protections to safeguard electronic health information
Qualified Service Organizations (QSO)

• Under Part 2 a qualified service organization (QSO) is an individual or entity providing a service to Part 2 treatment programs pursuant to a written agreement

• QSO services include EHR vendor, Health Information Exchange, network data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting or other professional services

• QSOs are exempt from Part 2 restrictions on disclosure of SUD information, however, QSOs agree in their contract with the provider to be bound by Part 2 requirements
The QSO must enter into a written agreement with the Part 2 program and the agreement must acknowledge the QSO’s obligations to comply with the Part 2 regulations.

The Part 2 program can then share necessary information with the QSO. This means the Part 2 restrictions on disclosures do not apply to communications between a Part 2 program and a QSO, but only to the extent the information disclosed is necessary for the QSO to provide agreed-upon services to the Part 2 program.
Part 2 Impact to third party

Previously, Part 2 did not permit a patient to authorize disclosure to a class of organizations. Previously, lawful holders, such as other treating providers or HIEs, struggled with whether they had the ability to further disclose Part 2 information to their contractors.

Now they may do so for limited purposes.
The new Final Rule allows the patient to consent to disclosure to a Health Information Exchange (HIE) or Accountable Care Organization (ACO) network generally, so long as the “To Whom” section of the consent designates a general description of individuals or entities with a treatment relationship with the patient.
Example third party consent

The Patient may consent to disclosure on the Consent form to a third-party entity with whom the patient does not have a treating provider relationship (e.g., a health information exchange) and,

On the same consent form, the patient can permit this third-party entity to redisclose his or her Part 2 information to other named individuals or entities with whom the patient does have a treating provider relationship:

(e.g., “I consent to disclosure of my Part 2 information to the Western Frontier Information Exchange, and agree to permit the HIE to redisclose my information to my current provider and all future providers with whom I have a treating provider relationship.”).
Catch 22 is a paradoxical form which we cannot escape because of contradictory rules.

Additional provisions in the new rule continue to make the exchange of Part 2 information difficult, and in some cases, impossible, such as:

• Third-party entities without a treating provider relationship with the patient that have redisclosed Part 2 information pursuant to a “general designation” on a consent form, including health information exchanges, will need to be able to provide this list of disclosures to the patient before the entity can begin accepting and acting based on a “general designation” consent form.

• A patient is entitled to receive a list of all entities to which his or her information has been disclosed pursuant to a general designation. Upon written request by the patient, the intermediary must provide, within 30 days of the request:
  ✓ A list of entities to whom information was disclosed
  ✓ Descriptions of what information was disclosed and when
  ✓ Dating back for the last 2 years
Example QSO Agreement is signed

Monument (Part 2 Program) and the HIE could sign a QSOA acknowledging that the HIE is providing information exchange services to Monument and is bound by the requirements of Part 2. Because the HIE is considered a QSO, Part 2 Programs at Monument would not need patient consent to disclose patient information to the HIE. However, providers participating in the HIE would need Thomas’s (SUD patient) consent to view his SUD patient records. The HIE would be restricted from re-disclosing patient identifying information to participating providers without Thomas’s consent.
If Monument and the HIE did not sign a QSOA, Dr. Madison (Part 2 program) could have her patients fill out a consent form to disclose their SUD treatment records to other health care providers through the HIE. Health care providers listed on the patient’s consent form could access the HIE to view the patient’s records. The consent form would need to include the name of the HIE, as well as the (1) name of a specific individual and/or organization participating in the HIE, or (2) a general designation of individuals/entities that have a treating provider relationship with the patient. The consent form would also have to fulfill all other requirements as specified by Part 2.
Part 2 requires that a **notice prohibiting redisclosure** accompany disclosures of Part 2 information.

Under the 2018 Final Rule, SAMHSA has adopted an **abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems**.

It reads “**Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records.**”
1. Part 2 programs should update their patient consent forms to address the release of SUD Information for payment and health care operations purposes.

2. Part 2 should evaluate whether to update their patient consent forms to include the abbreviated notice regarding re-disclosure and, if they do, they should consider how to assure that their Subcontractors are aware of the scope of re-disclosure restrictions.

3. Part 2 programs, health systems, ACOs and other integrated care models treating Part 2 patients will need to carefully evaluate their relationships with Subcontractors (third party) to determine what information may be shared with each of them, and they then must amend or enter into appropriate contracts with each applicable Subcontractor (third party) no later than February 2, 2020.
Conclusion

SAMHSA is trying to balance between making SUD Information available to those who need it for legitimate purposes to enable individuals who seek treatment for SUDs to participate in and benefit from ACOs, health information exchanges, and other innovative care models, while safeguarding that information from improper uses and disclosures that may result in reputational harm or adverse legal consequences to patients.
Please let me know how I can help?

For assistance please contact:

Susan Clarke: sclarke@mpqhf.org, (307) 248-8179
Questions