2017 and 2018 Revisions to the SUD Record Confidentiality Rules (42 C.F.R. Part 2)

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- This discussion is for information purposes, and is not the provision of legal services.

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Overview

- 42 C.F.R. Part 2 Primer
- 2017 Revisions to Part 2
- 2018 Revisions to Part 2

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42 C.F.R. Part 2 Primer

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What is Part 2?

- Federal regulations that substantially restrict the use and disclosure of substance use disorder patient records held by federally-assisted programs
- Known as “Part 2” from its location at Title 42, Part 2 of the Code of Federal Regulations

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- Purpose of Part 2 is to ensure that someone seeking treatment is not made "more vulnerable" because of their patient record, than one who does not seek treatment. 42 C.F.R. § 2.2(b)(2).
  - Policy goal is to encourage treatment

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- Part 2 is administered by SAMHSA, and enforced by the U.S. Department of Justice.
  - HIPAA by comparison is enforced by the HHS Office of Civil Rights.
  - HIPAA has a more comprehensive enforcement regime.

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- To what patient information does Part 2 apply?
  - Any information which would identify a patient as having or having had a substance use disorder and
  - Is maintained by a federally-assisted program for the purpose of diagnosing or treating a substance use disorder, or for making a referral for treatment. 42 C.F.R. §2.12

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- "Patient" is a person who "applies for or has been given" diagnosis or treatment for substance use disorder at a federally assisted program. 42 C.F.R. § 2.11.
  - Includes those who have been given diagnosis or treatment involuntarily

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Key Unique Provisions

- Record disclosures are allowed with the patient's consent, using a form for consent that is unique to Part 2. 42 C.F.R. § 2.31.
- A general medical consent form is not sufficient to authorize disclosure.

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Key Unique Provisions

- Redisclosure of Part 2 records obtained by consent is prohibited unless the redisclosure complies with Part 2. 42 C.F.R. § 2.32.
- Recipient becomes a "lawful holder" subject to Part 2
- Unlike HIPAA, which does not prohibit redisclosure of records obtained by consent

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Key Unique Provisions

- For disclosure in litigation, a subpoena alone does not authorize disclosure.
- There must also be patient consent or a court order.
- A Part 2 program cannot respond to a subpoena for Part 2 information without a patient consent or a court order. 42 C.F.R. §§ 2.61, 2.64

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2017 Revisions to Part 2

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Effective March 21, 2017

- First update to Part 2 since 1987
- Revisions are more technical and nuanced than substantive
- End result of a multiyear notice and comment period by SAMHSA

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Goals of the 2017 Revisions

- "Modernize the Part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate heath care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder."

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Goals of the 2017 Revisions

- Facilitate greater information exchange but confidentiality still matters.
- Alignment with HIPAA still a work in progress.

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Name Change

- References to "alcohol and drug abuse" in Part 2 were updated to "substance use disorder"
- Full Title of Part 2 is now "Confidentiality of Substance Use Disorder Patient Records"

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Security of Part 2 Records

- Formal policies and procedures are now required relating to the security of Part 2 records in both paper and electronic form
- Prior rule contemplated only paper records (e.g., “locked file cabinet”)

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Security of Part 2 Records

- New rule requires formal policies and procedures to protect against both unauthorized uses and disclosures by program personnel as well as external security threats
- Transfer, maintenance, destruction, sanitization, and use of Part 2 records with computer workstations, must all be addressed
- 42 C.F.R. § 2.16.

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Notice to the Patient of how a Part 2 complaint can be made

- Notice to Patients of Confidentiality Requirements now must include contact information so the patient knows exactly who to call to report a Part 2 violation
- e.g., local U.S. Attorney's Office address and phone number
- 42 C.F.R. § 2.22

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Allows general designations of recipients of Part 2 information

- Permits a patient to include a general designation in the "to whom" section of the consent form
- e.g., "all my health care treatment providers" rather than to a specifically named provider
- 42 C.F.R. § 2.31

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List of Disclosures

- Upon request, a patient who has previously made a general designation in the "to whom" section of the consent must be given a list of those specific entities to whom a disclosure was actually made. 42 C.F.R. § 2.13(d).
- The consent form must notify the patient of the right to obtain a list of disclosures.

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Revisions to consent formalities and procedures (42 C.F.R. § 2.31)

- Prior rule allowed for disclosures with consent to those identified by "name or title of the individual or the name of the organization"
- New rule provides for disclosure to any identified individual but only certain identified entities

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Disclosure with consent to an entity with a treating provider relationship with the patient

- The name of the entity is alone required
- Each person involved with the entity does not have to be individually named

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Disclosure with consent to an entity without a treating provider relationship with the patient

- If the entity is a third party payer, nothing more than the name of the entity is required
- For other entities, the name of the entity plus the name of an "individual participant" must be given
- Intended for health information exchanges, where the "participants" are participants in the exchange

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What about disclosures made to other non-treating provider entities?

- License boards? Employers? Law firms?
- Who is the "individual participant"?
- How does a Part 2 Program disclose records to a state Board of Nursing?

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Prohibition against redisclosure clarified to apply only to patient-identifying SUD information

- e.g., does not apply to deidentified, or non-SUD, information
- 42 C.F.R. § 2.32

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Reports of Part 2 violations by opioid treatment programs are now to be made to either the Department of Justice or SAMHSA (instead of to the FDA).
42 C.F.R. § 2.4

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Definitions consolidated and clarified into one section of Part 2

- 42 C.F.R. § 2.11

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2018 Revisions to Part 2

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2018 Revisions to Part 2

- Became effective on February 2, 2018
- Follow up to the 2017 revisions

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Changes Effective February 2, 2018

- Abbreviated redisclosure notice
- Redisclosure allowed without consent for payment and healthcare operations activities
- Purely technical revisions

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Abbreviated Redisclosure Notice

- Previously, Part 2 Programs had to include the following with disclosures:

- This information has been disclosed to you 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 or 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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Abbreviated Redisclosure Notice

- Effective February 2, 2018, the following alternative notice is permissible:

"42 CFR part 2 prohibits unauthorized disclosure of these records."

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Redisclosure for payment and operations activities

- If a patient consents to disclosure of records for payment and/or health care operations activities, the lawful holder may then in turn redisclose the records without consent to its contractors, subcontractors, and legal representatives

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Redisclosure for payment and operations activities

- Examples of health care operations: claims management, collection, quality control, accreditation, training, business management, provision of legal services

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Purely technical changes

Corrects minor technical defects from the March 21, 2017, revision, such as:

- Incorrect cross references
- Edits to improve readability

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What did not change?

- Disclosures with consent to entities that do not have a treating provider relationship with the patient
- HIPAA inconsistency

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Analyze the extent to which Part 2 impacts you and your organization

- Am I a "Part 2 program"?
- Do I receive records from a Part 2 program? (making you a "lawful holder" subject to Part 2)
- How do I use Part 2 records?
- Are appropriate consent forms in place?

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