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CONFIDENTIALITY OF SUD RECORDS

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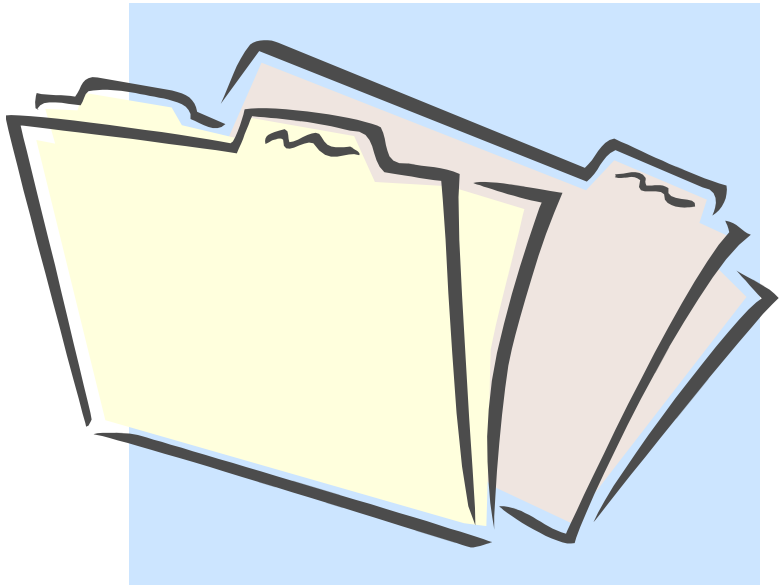
HIPAA and 42 C.F.R. Part 2



Both prohibit the use and disclosure of records or other patient related information.

HIPAA, 42 U.S.C. §1320d-1320d-8

- Health Insurance Portability and Accountability Act of 1996
- 45 C.F.R. Parts 160 and 164
- Rules enacted in 2003

The Basics - Health Insurance Portability and Accountability Act (HIPAA)

- Original Intent:
  - Act passed in 1996 with two main goals:
    1. Ensure individuals would be able to maintain their health insurance between jobs (the "portability" part); and
    2. Ensure the security and confidentiality of patient information and mandate uniform standards for electronic data transmission (the "accountability" part).
  - Act required the Department of Health & Human Services (DHHS) to implement regulations on the specific areas of HIPAA.

- Rules of Primary Concern Here - Privacy & Security Rules:
  - *Privacy Rule:* Sets limits and conditions on the uses and disclosures of protected health information without patient authorization; gives patients rights over their health information (*e.g.*, rights to examine and obtain a copy of their health records, to request corrections).
    - Compliance Deadline: April 2003
  - *Security Rule:* The ability to control access to and prevent information from accidental or intentional disclosure to unauthorized persons and from alteration, destruction or loss.
    - Compliance Deadline: April 2005

The Basics– HIPAA (cont'd)

- **Entities subject to HIPAA ("covered entities"):**
  - Health plans, health care clearinghouses or ***health care providers*** (*e.g.,* hospitals, physicians, etc.) that:
    - transmit health information electronically
    - in connection with "covered transactions" (*e.g.,* billing, transmission of health plan enrollment information).
  - For example, the UC Student Health & Counseling Centers (SHCs and SCCs)

- Operational Consequences of Being a Covered Entity
  - Comply with the HIPAA rules for transactions and code sets (*i.e.*, use certain standardized forms of transmitting electronic data)
  - IF the covered entity is using or disclosing Protected Health Information (PHI) → THEN it is required to comply with the HIPAA Privacy Rule (*e.g.*, issue a notice of privacy practices, execute business associate agreements, follow the HIPAA Privacy Rule's restrictions on the use and disclosure of PHI)

- What is PHI?
  - Individually identifiable health information *except for*
    - *"Education records" or "treatment records" of students under FERPA*
  - Even though the SHCs and SCCs are HIPAA covered entities, they are not required to comply with the HIPAA Privacy Rule with respect to student records.

Code of Federal Regulations

- 42 C.F.R. Part 2
- Issued in 1975 revised in 1987
- Federal agency primarily responsible for implementing and interpreting Regulations: **Dept. of Health and Human Services**
- **Frequently being revised, amended by HHS – latest July 2020**

Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule

- The 42 CFR Part 2 regulations (Part 2) serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD). Part 2 has been revised to further facilitate better coordination of care in response to the opioid epidemic while maintaining its confidentiality protections against unauthorized disclosure and use.

Why Privacy Protection?

- Reduction of stigma
- Fostering trust
- Preserving confidentiality
- Encourage people to seek help
- Avoid damaging consequences of disclosure
  - Criminalization
  - Discrimination

SUD is Generally Considered a “Disability”

A covered entity cannot discriminate against someone because of their SUD

- ***Past*** substance use disorder involving illegal use of drugs ***is*** generally considered a “disability”

- ***Current*** substance use disorder involving illegal use of drugs is generally ***NOT*** a “disability”
  - Does not apply to the receipt of health care
  - Does not apply if action is not based on illegal use

Brief Comparison

HIPAA

- Permits but does not mandate disclosure of health information:
- *Permits d*isclosure for w/out consent for payments
- *Requires* patient access to records

42 C.F.R. Part 2

- *Prohibits* all disclosures except those specifically allowed by the regulations
- *Prohibits* disclosure without patient consent
- *Permits* patient access to records

How Does CFR 42 PART II Differ From HIPAA?

Main Differences:

HIPAA:

- **HIPAA was created to protect patient information regarding health records**
- **Patient information protected by HIPAA CAN be exchanged between covered entities (providers, payers, etc) and their business associates for treatment, payment, and health care operation activities without additional patient consent.**

42 CFR Part 2:

- **Created to protect patient information regarding health records as it pertains to substance use disorder (SUD).**
- **Patient information CANNOT be exchanged without patient consent except in limited circumstances.**

Who is Covered?

HIPAA

- "Covered entity":
  - Health Plans
  - Health care clearinghouses
  - Health care providers who transmit health information in electronic form
- Courts are NOT

42 C.F.R. PART 2

- "Program"- any person or organization that in whole or in part provides alcohol or drug abuse diagnosis, treatment or *referral* for treatment or prevention; AND
- "Federally assisted"- receives fed'l funds even if funds do not pay for D/A services

Consent Required to Disclose SUD Treatment Records, 42 C.F.R. Part 2

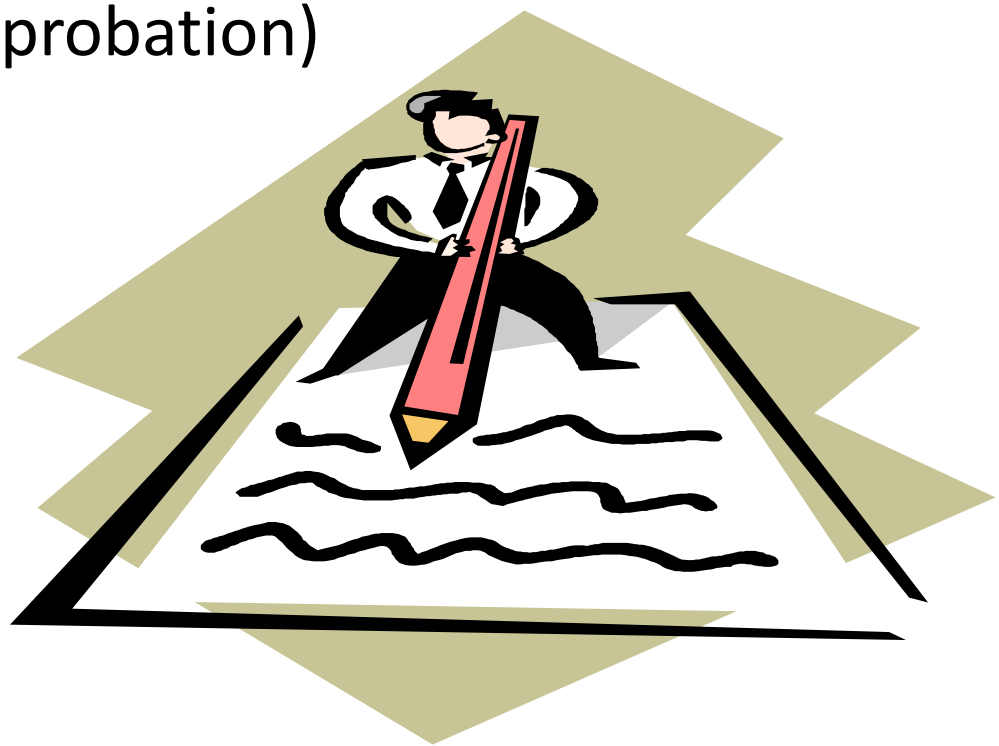
- Disclosure of treatment records content is only permitted in the manner specified by statute, a general release does not suffice.
- Without consent, a specific court order is required
- Order must be for non-criminal purposes, 42 C.F.R. §2.64(a); notice of application to person whose records are sought and opportunity to respond or appear §2.64(b)

42 C.F.R. Part 2:
Elements of Written Consent

1. Name or designation of program making disclosure
2. Name/title of person to whom disclosure is made
3. Name of the patient/client
4. Purpose of the disclosure
5. How much and what kind of info. to disclose
6. Signature of patient/ minor with parent*

Elements of Consent (cont'd)

7. Date consent signed
8. Statement re: revocation
9. Date, event or condition upon which consent expire (e.g. termination of probation)



Prohibition on Redisclosure
42 C.F.R. §2.32

- Written statement that must accompany each disclosure made with the patient's consent
- Informs the recipient of the prohibition on redisclosure and specific release requirement
- Indicates that Federal rules restrict use of information to criminally investigate or prosecute a patient

Disclosure to Criminal Justice System, 42 C.F.R. §2.35

- May be made to those who have made participation a condition of the disposition of a criminal proceeding
- Only to those with a need to monitor progress
- Signed consent of patient
- Redisclosure only to carry out official duties

Subpoena & 42 C.F.R. Part 2

- A subpoena is *insufficient* to overcome the privacy protection of 42 C.F.R. Part 2
- A court must find good cause for ordering release after finding
  1. Other ways not available or not effective
  2. Public interest and need outweigh potential injury to the patient

  See *United States v. Oberle,* 136 F. 3d 1414, 1420 (10th Cir. 1998) finding no good cause for release

What *Has Not* Changed Under the New Part 2 Rule:

The revised rule does not alter the basic framework for confidentiality protection of substance use disorder (SUD) patient records created by federally assisted SUD treatment programs. Part 2 continues to prohibit law enforcement's use of SUD patient records in criminal prosecutions against patients, absent a court order. Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Applicability and Re-Disclosure	Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.	To facilitate coordination of care activities by non-part-2 providers.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Disposition of Records	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.	To ensure that the personal devices of employees will not need to be confiscated or destroyed, in order to sanitize in compliance with Part 2.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Consent Requirements	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.	To allow patients to apply for benefits and resources more easily, for example, when using online applications that do not identify a specific person as the recipient for a disclosure of Part 2 records.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Disclosures Permitted w/ Written Consent	Disclosures for the purpose of "payment and health care operations" are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision.	In order to resolve lingering confusion under Part 2 about what activities count as "payment and health care operations," the list of examples has been moved into the regulation text from the preamble, and expanded to include care coordination and case management activities.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Disclosures to Central Registries and PDMPs	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. OTPs 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.	To prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Medical Emergencies	Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a “bona fide medical emergency,” for the purpose of disclosing SUD records without patient consent under Part 2.	To ensure clinically appropriate communications and access to SUD care, in the context of declared emergencies resulting from natural disasters.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Research	Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).	To facilitate appropriate disclosures for research, by streamlining overlapping requirements under Part 2, the HIPAA Privacy Rule and the Common Rule.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Audit and Evaluation	Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.	To resolve current ambiguity under Part 2 about what activities are covered by the audit and evaluation provision.

What Has Changed Under the New Part 2 Rule:

- The revised rule modifies several major sections of Part 2, as follows:

Provision	What Changed?	Why Was This Changed?
Undercover Agents and Informants	Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.	To address law enforcement concerns that the current policy is overly restrictive to some ongoing investigations of Part 2 programs.

Exceptions to the general rule
42 C.F.R. Part 2

- Written consent
- Internal communications
- No identifying information
- Medical emergency
- Court order
- Crime at program
- Research
- Audit and evaluation
- Child abuse

Mandated reporting of child abuse

- Substance abuse by itself not a condition that must be reported as child abuse or neglect, there must be some reason to suspect actual or imminent harm to a child
- Release only applies to initial reports– subsequent reports require consent or court order.

Patient privacy rights: key points

1

- Check to see if your provider is a “Part 2 program”
- *You can ask – they should be able to tell you!*

2

- Part 2 programs must follow strict privacy rules – they generally need your written consent to share information about your SUD treatment
- *Read consent forms closely and ask questions!*

3

- Know your rights under the laws – and the limits.
- *Information you tell a social worker, police, parole/probation, judge, friend, or family member is not protected by the SUD privacy law*

How confidential is your SUD treatment?

Key Point #1: Check to see if your provider is a "Part 2 program"

- Why is this important?
  - Part 2 programs must follow a very strict privacy law, 42 CFR Part 2
    - *Not all SUD providers are covered – so you should ask!*
  - Non-Part 2 programs are likely still covered by HIPAA, but HIPAA has less privacy protections:
    - Allows more sharing with law enforcement and the legal system
    - Allows sharing SUD information with other healthcare providers, without asking your permission first

What are you being asked to sign?

Key Point #2: Part 2 programs generally need your written consent to share information about your SUD treatment

- <u>What to look for in consent forms:</u>
  - ✓ *Who* is authorized to receive the information
  - ✓ *What* information is being shared
    - You have the right to ask for the *minimum necessary*
  - ✓ *Why* are they getting the information (and *how* can they use it)

What are your privacy rights?

Key Point #3: Know your rights under the laws – and the limits

- HIPAA gives you the right to:
  - ✓See or get a copy of your health record
  - ✓Correct errors in your health record
  - ✓Know who has seen your health information
  - ✓Request that certain information not be shared*
    - *Providers don't have to say yes to this request, but if they do, they must honor it!
  - ✓Ask to be reached somewhere other than home

QUESTIONS?

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