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Confidentiality of Substance Use Disorder Patient Records Final Rule (42 CFR Part 2)

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Disclaimer

- This presentation is not intended to constitute legal advice. Any examples discussed are for illustrative purposes only. All questions about compliance with 42 CFR Part 2, HIPAA and other applicable state and federal laws and requirements should be directed to individual, agency or organization legal counsel.

Background: 42 CFR Part 2-History

- Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. §1175) and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. §4582) authorized confidentiality for patient records
- Initial Part 2 regulations completed in July 1975
- Substantive revisions: 1987, 2017

Background: Health Privacy Legislation

- Congress noted discrimination associated with substance use disorders (SUDs) and fear of prosecution deterred people from entering treatment
- At that time most treatment provided by specialty providers
- Statute authorizing 42 CFR part 2 intended to ensure an individual's right to privacy and confidentiality.
- Persons with substance use disorders continue to be subject to discrimination in such areas as employment and housing

WHY REVISE 42 CFR PART 2?

- Regulations first promulgated in 1975 and, before last year's revision, were last substantively updated in 1987.
- Significant changes have impacted health care delivery since 1987:
  - New models of integrated care that rely on information sharing to support coordination of patient care
  - Electronic infrastructure for information exchange
  - New focus on performance measurement
  - "Providers who in the past offered only general or specialized health care services (other than substance use disorder services) now, on occasion, provide substance use disorder treatment services, but only as incident to the provision of general health."

Background: Medical Privacy

- Part 2 aligns with HIPAA to extent feasible under its governing statute
- SUD records and information may be subject to both HIPAA and Part 2 and state laws
- If both HIPAA and Part 2 apply, follow the law that is more stringent
- Part 2 (§ 2.20) does not preempt more stringent state laws
- If state law more protective than Part 2, should follow more stringent state law
- State statutes, licensing, facility policies, and accreditation requirements also may reference Part 2

A Framework for Understanding Part 2

- Applicability: Is information protected by Part 2 (§§2.11-2.23)?
- Exceptions: If protected, does it fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?
- Consent: If not, will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?
- Court orders: If no exception/exclusion to Part 2 applies and patient does not consent to disclosure, can a court order be obtained (§§2.61-2.67)?

- Approach adapted from: Dennis Helms, A Guide to the New Federal Rules Governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 4 Contemp. Drug Probs. 259 (1975)

Penalty (§2.3)

- Penalty: Violations to be fined under Title 18 of US Code (Crimes and Criminal Procedure).
- Purpose and Effect (§2.2): Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute
- Penalty is enforced by DOJ, not SAMHSA
- Reports of violations to US Attorney in district where violation occurs
- For opioid treatment program, report to SAMHSA and DOJ
- No enforcement cases to date but due to criminal penalty regulation and statute likely to be "strictly construed" by courts
- While there is no federal private right of action, may be other penalties-accreditation issues, bad public relations, licensing issues for health professionals, perhaps state law claims (e.g., negligence)

Applicability

- Applicability: Is a patient's information protected by Part 2 (§§2.11-2.23)?

Applicability

- These regulations impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of **any part 2 program (§2.2)**
- Regulations apply to any information, whether or not recorded, which "[w]ould identify 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" (§2.12)

APPLICABILITY(§2.12)

What's a part 2 Program?

Applicability to given information is based on whether the entity is *federally assisted and holds itself out as providing SUD diagnosis, treatment and referral*

- ➔ A. Is the program federally assisted?
- ➔ A. Ex. Program carried out under license, certification or registration by federal department or agency

APPLICABILITY(§2.12)

- Program carried out under federal license/certification may include:
- participating in Medicaid or Medicare;
- being authorized to conduct maintenance treatment or withdrawal management (42 CFR Part 8);
- registration under Controlled Substances Act to dispense medication-assisted treatment (e.g. DEA number);
- Federal assistance also means supported by federal funding to states or local governments or directly:
- Being tax-exempt or receiving tax-deductible donations
- Conducted in whole or part, directly or via contract, by federal entity (BUT Veterans Affairs and Armed Forces are exempt from Part 2 by statute and covered by VA and DOD confidentiality provisions)
- Note: In some cases, states may require compliance with Part 2 even if facility is self-pay or private and otherwise would not be considered to be federally assisted

APPLICABILITY(§2.12)

- In addition to considering federal assistance, applicability is based on the definition of *Program,* which did not change except for updating terminology.
- Applicability is fact-specific but key questions include:
- B. Is a unit/entity/individual other than a general medical facility a Part 2 Program
- 1. Do they “hold themselves out” as providing diagnosis/treatment/referral for SUD?
- Ex. Licensed/certified/registered to provide these activities
- Ex. Advertisements, notices or statements about such services
- Ex. Consultation activities about such services

Lawful Holder MOVE

- Not formally defined in regulatory text. However, important concept for Part 2
- “An individual or entity who has received such information as the result of a part 2-compliant patient consent (with a re-disclosure notice) or as a result of one of the limited exceptions to the consent requirements specified in the regulations” and is therefore bound by Part 2 (Final Rule, p. 6997)
- Examples: May include patient's treating provider, a hospital emergency room, an insurance company, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research.
- Providers and entities that are not covered by Part 2 that possess SUD data that did not originate in Part 2 program are not subject to part 2 requirements

Disclosure of Part 2 information

- Exceptions: If information is covered by Part 2, does it fall under one of the exceptions or exclusions(§2.12, §§2.51-2.53)?
- What does it mean to Disclose Part 2 data?

What does it mean to disclose Part 2 info?

- Disclose (§2.11): Many ways to ‘disclose’ such as providing testimony, sharing written records, sharing patient identifying information in a way that the patient to be re-identified, verbal discussions with staff or others outside the SUD treatment program, submitting claims information to a payer (e.g., Medicare)

Disclosure (Exceptions) (§§2.2; 2.12(a); 2.31, 2.51-2.53)

- Some exceptions to consent, each of which has various caveats, qualifications and limitations, include:
- Bona-fide medical emergencies (§2.51)
- Audit and Evaluations (§2.53)
- Research (§2.52)
- Disclosures to prevent multiple enrollments in maintenance or withdrawal programs within 200-mile radius (§2.34)
- Disclosure to patient themselves ((§2.23)
- Disclosure does not identify patient(s) as having or having had an SUD (e.g., anonymous disclosure or no Part 2 information mentioned)
- The individual themselves voluntarily discloses his or her known or suspected substance use disorder

Disclosure (§§2.2; 2.12(a); 2.31, 2.51-2.53)

- **Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program (§2.12)**
- **Qualified Service Organization Agreements (§§2.11; 2.12(c)(4))**
- **Crime on program premises or against program personnel or threat of such activity (§ 2.12)**
- **Disclosures to elements of the criminal justice system which have referred patients (§2.35)**
- **By statute, Part 2 does not apply to SUD information shared within Armed Forces and VA or between Armed Forces and VA. VA has own confidentiality requirements ((§ 2.12)**

- **Two other situations (not exceptions): Patient consents in writing to disclosure; consent includes required elements (§2.13, §2.31, §2.33)**
- **Court orders authorizing disclosure and use (§§2.61-2.67)**

Internal Communications- within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program (§2.12)

- Those with whom information is shared must have "have need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment."
- FAQ guidance, 2010, umbrella organization: "When a substance use disorder unit is a component of a larger behavioral health program or of a general health program, specific information about a patient arising out of that patient's diagnosis, treatment or referral to treatment can be exchanged without patient consent among the Part 2 program personnel and with administrative personnel who, in connection with their duties, need to know information (42 CFR § 2.12(c)(3)). Patient information may not be exchanged among all of the programs and personnel that fall under the umbrella of the entity that has administrative control over the Part 2 program. A QSOA would be required to enable information exchange without patient consent in this situation."

MEDICAL EMERGENCIES (§2.51)

- The final rule revises the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a “bona fide medical emergency” exists.
- Information can be shared by Part 2 program in these circumstances when consent cannot be obtained.
- Treating provider makes determination
- Part 2 program must document following disclosure date/time, medical personnel information shared with, nature of emergency

Qualified Service Organization Agreements (QSOAs)**(§2.11; § 2.12(c)(4))**

- A QSOA is a "two-way agreement between a part 2 program and the entity providing the part 2 program and an individual or entity providing a service to a part 2 program"
- QSOs provide services to a part 2 program under a written agreement (QSOA). Such services include data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy

NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS (§2.22)

- At time of admission to Part 2 program or, if patient incapacitated, at time when patient is capable of rational communication, the program must provide written summary of part 2
- Paper or electronic
- Include description of limited situations when Part 2 program can disclose information
- Notice may include information on state law and program policies that are not inconsistent with Part 2
- Requires statement regarding the reporting of violations and providing contact information for the appropriate authorities.

RESEARCH (§2.52)

- The final rule allows a part 2 program or other lawful holder of patient identifying information to disclose part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule).
- Data must be aggregated/de-identified
- Researchers must agree to resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part.

AUDIT AND EVALUATION (§2.53)

- Permits an audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (including CMS-regulated Qualified Entities)
- Audit and evaluation not defined but can include financial and quality purposes
- If records not copied or removed from premises can be disclosed to individual/entity who agrees to comply with re-disclosure and other requirements and is acting on behalf of government agency/third-party payer
- If forwarded/removed, must comply with record retention requirements
- Information can only be disclosed for audit and evaluation purposes back to program from which it was obtained and not used to prosecute/investigate patients
- Includes provisions for both paper and electronic patient records
- Permits the part 2 program to determine who is qualified to conduct an audit or evaluation

Criminal Justice-**Disclosures to elements of the criminal justice system which have referred patients** (§2.35)

- Part 2 program may disclose information about a patient to those individuals within the criminal justice system who have made participation in the part 2 program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody
- Ex. Drug courts, parole, other programs as a condition of release or participation may require waiver of confidentiality
- Need signed, written consent
- Limited to those who need information (ex. probation/parole officers, prosecuting attorney(s))
- Consent limited in duration taking into account type of proceeding, anticipated length of treatment and other circumstances

Criminal Justice-**Disclosures to elements of the criminal justice system which have referred patients** (§2.35)

- Consent can be revoked based on specific event occurring (e.g., probation ends) or certain amount of time elapsing- this way program can monitor. By contrast, other consents can be revoked at any time (except to degree program already has relied on the consent)(§ 2.31(a)(6))
- Redisclosure only for official purposes and in connection with purpose for which consent was given
- Ex. Parole revocation following drug court 'failure'

Consent

- Consent: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Disclosure (§§2.12(a); 2.31, 2.33)

- If no exceptions/exclusions apply, Part 2 information can only be disclosed with written consent or through court process
- Consent must be in writing and requires certain elements:
- 1. Must include name of patient
- 2. Amount and Kind: How much and what kind of information to be disclosed- should not just say “all my substance use disorder information” or “all of my records”
- Also should be granular options or categories such as diagnostic information, medications, employment information, trauma history, allergies. Can use checkboxes next to categories.
- 3. Purpose of disclosure (e.g., “treatment”)

Disclosure (§§2.12(a); 2.31, 2.33)

- 4. 'From whom': Name of specific entity/individual permitted to make the disclosure
- The final "From Whom" provision of the consent requirements specifies that a written consent to a disclosure of patient identifying information must include the specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.
- 5. 'To Whom' Name of individual(s) to whom disclosure is to be made or name of entity (if treating provider relationship exists)
- If no treating provider relationship, name of third-party payer or name of entity or individual participants with treating provider relationship or general designation
- The final rule requires that, upon request, patients who have included a general designation in the "To Whom" section of the consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures)

Disclosure and consent

TABLE 1—DESIGNATING INDIVIDUALS AND ORGANIZATIONS IN THE "TO WHOM" SECTION OF THE CONSENT FORM

42 CFR 2.31	Individual or entity to whom disclosure is to be made	Treating provider relationship with patient whose information is being disclosed	Primary designation	Required additional designation
(a)(4)(i)	Individual	Yes	Name of individual(s) (*e.g.*, Jane Doe, MD).	None.
(a)(4)(i)	Individual	No	Name of individual(s) (*e.g.*, John Doe)	None.
(a)(4)(ii)	Entity	Yes	Name of entity (*e.g.*, Lakeview County Hospital).	None.
(a)(4)(iii)(A)	Entity	No	Name of entity that is a third-party payer as specified under §2.31(a)(4)(iii)(A) (*e.g.*, Medicare).	None.
(a)(4)(iii)(B)	Entity	No	Name of entity that is not covered by §2.31(a)(4)(iii)(A) (*e.g.*, HIE, or research institution).	At least one of the following: 1. The name(s) of an individual participant(s) (*e.g.*, Jane Doe, MD, or John Doe). 2. The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (*e.g.*, Lakeview County Hospital). 3. A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed (*e.g.*, my current and future treating providers).

What is the Treating Provider Relationship? (new concept in Final)

Treating-provider relationship when:

- A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and;
- The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.
- May not need formal written agreement. Making appointment or telephone consultation may be sufficient. Can exist even if no in-person encounter
- SAMHSA considers an entity to have a treating provider relationship with a patient if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.

CONSENT REQUIREMENTS (§§2.13; 2.31)- To whom

- The final rule:
  - Allows, in certain circumstances, a patient to include a *general designation* in the "To Whom" section of the consent form.
    - Distinction between those with and without a treating provider relationship with the patient.
  - When using a general designation in the "To Whom" section, their right to obtain, upon request, a list of entities to whom their information has been disclosed, pursuant to the general designation (list of disclosures)(see §2.13)
  - Patient's decision whether to use or not use general designation
  - In the final rule, SAMHSA clarified that the entity that serves as an intermediary (e.g., health information exchange), ***NOT the part 2 program***, is responsible for complying with the List of Disclosures requirement

PROHIBITION ON RE-DISCLOSURE (§2.32)

- Information re-disclosed under Part 2 should be accompanied by a notice that information should not be further re-disclosed without written consent
- Such information should not be used for criminal investigation or prosecution
- General authorization for the release of medical or other information is *NOT* sufficient to permit re-disclosure of part 2 information

Court Orders

- To authorize disclosure of Part 2 information to criminally prosecute or investigate patients, person holding records (including state or local agency) must be provided notice, opportunity to appear and be legally represented (§2.65)
- Court must consider if other ways to obtain information, crime 'extremely serious', likelihood records will disclose information of substantial value and whether potential injury to patient, physician-patient relationship and Part 2 program is outweighed by public interest and need for disclosure
- The person holding the records or any law enforcement or prosecutorial officials who are responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws can apply for such orders

*****Criminal investigations*****

- Restriction on the use of any information subject to the regulations in this part to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (§2.12)
- Applies to any person who obtains that information from a part 2 program, regardless of the status of the person obtaining the information or whether the information was obtained in accordance with the regulations (§2.12)
- Cannot use such info as evidence in criminal proceeding or to investigate or prosecute a crime (§2.12)
- Information obtained by patient access to his or her patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation (§2.23)

2017 SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING (SNPRM)

- In addition to the final rule, SAMHSA issued a SNPRM on January 18, 2017 (82 FR 5485)
- Currently under analysis, this is not a final rule.

CLARIFICATIONS

https://www.regulations.gov/document?D=HHS-OS-2016-0005-0378

STAKEHOLDER CONCERNS: USE & DISCLOSURE

- 2016 NPRM comments highlighted varying interpretations of the rule's restrictions on lawful holders and their contractors' and subcontractors' use and disclosure of patient identifying information for purposes of carrying out payment, health care operations, and other health care related activities.
  - Third-party payers, other lawful holders, and their contractors and subcontractors and legal representatives play a critical role in the provision of health care services.

PROHIBITION ON RE-DISCLOSURE (§2.32): ADDED NOTIFICATION?

- SAMHSA did not propose to substantively modify the existing notice at 2.32, *but sought comment on whether it should add an abbreviated notice to accompany re-disclosure for use in certain circumstances where a shorter notice may be warranted.*
  - For example, "Data is subject to 42 CFR part 2. Use/disclose in conformance with part 2."

Disclosures Permitted With Written Consent (§2.33): PII and Contractors & Subcontractors

- SAMHSA proposed new regulatory text under § 2.33(c) *requiring that lawful holders that engage contractors and subcontractors* to carry out payment and health care operations that will entail using or disclosing patient identifying information include specific contract and subcontract provisions *requiring contractors and subcontractors to comply with the provisions of part 2*.
  - Appropriate comparable instrument will suffice in cases involving a legal representative.

PROPOSED PROVISION: § 2.53

- § 2.53 (Audit and Evaluation) - to expressly address **further disclosures** to contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or CHIP audit or evaluation

QUESTIONS OR COMMENTS?

THANK YOU

Questions:

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