Protecting the Confidentiality of Substance Use Disorder Records

Legal and Practical Challenges

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WoodsRogers

Agenda

1. Key Concepts
    - Key Definitions
    - Patient Consent Requirements
    - Subpoenas & Third-Party Requests
    - Permitted Disclosures
    - and more!
2. Recent Amendments
3. Compliance Challenges and Best Practices

Key Concepts

42 CFR Part 2

History & Policy Goals

- Enacted in 1975 to address concerns that substance use disorder (SUD) information could be used against patients in administrative or criminal hearings, deterring patients from getting treatment
- Protect confidentiality for patients seeking SUD treatment
- Reduce adverse consequences for those seeking treatment
- Reduce stigma around addiction and promote access to treatment

General Overview

- Applies to any information that:
  - Identifies a patient as having a substance use disorder (SUD)
  - Was obtained for the purpose of diagnosing or treating the SUD
- All "Federally Assisted Programs" must comply
  - May not disclose identity of a person receiving SUD services unless an exception exists

“Substance Use Disorder”

- Cluster of cognitive, behavioral, and physiological symptoms indicating the individual continues using the substance despite significant substance related problems
  - For example, impaired control, social impairment, risky use, pharmacological tolerance, and withdrawal
  - **Does not** include tobacco and caffeine use

“Program”

- Individual or entity that “holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment” for alcohol or drug abuse
- Includes:
  - Unit of a general medical facility that holds itself out as providing SUD diagnosis, treatment, or referral for treatment
  - Medical personnel or staff in a medical facility whose “primary function” is providing SUD diagnosis, treatment, or referral for treatment

“Records”

- “Any information, whether recorded or not, created by, received, or acquired by a Part 2 Program relating to a patient”
  - Includes both paper and electronic records
- 2020 Clarification:
  - Information conveyed **orally** by a Part 2 Program to a non-Part 2 healthcare provider **for treatment purposes**, **with the consent of a patient** does not become a “record” merely because the information is written down by the non-Part 2 provider

How is Part 2 different from HIPAA?

HIPAA

- **Applies to**: PHI from Covered Entities and Business Associates
- **Protects**: privacy and security of general health information
- **Purpose**: to protect health data integrity, confidentiality, and accessibility
- **Permits**: disclosures without patient consent for treatment, payment and healthcare operations and as permitted by HIPAA exceptions

PART 2

- **Applies to**: SUD patient records from federally-assisted “Part 2 Programs”
- **Protects**: privacy and security of records identifying individuals as being diagnosed with SUD or seeking / receiving SUD treatment
- **Purpose**: to encourage people to seek SUD treatment and reduce stigma through enhanced confidentiality
- **Prohibits:** disclosures for treatment, payment, and healthcare operations unless a patient consents, with limited exceptions

Hypothetical 1

- Linda is an LPC who focuses on treating individuals with anxiety and depression. As part of the counseling intake process, some patients report histories of substance abuse and Linda documents this their charts. However, Linda does not directly treat or diagnose SUDs. Occasionally she will refer clients to SUD counseling or other SUD-related services offered by the CSB. However, this typically only happens a couple times a year.
- **Is Linda covered by 42 CFR Part 2?**

Hypothetical 1

- **Answer:** No! Linda does not treat or diagnose SUD. Although she occasionally makes referrals for SUD treatment, this is not her “primary function.” She does not hold herself out as providing SUD treatment services.

Enforcement

Penalties for Part 2 Violations

Before 2024 amendments

- Specific Criminal penalties
  - $500 for first offense
  - $5,000 for subsequent offenses
- Could also be liable for HIPAA violations

New → HIPAA penalties apply

- Civil fines**
  - No willful neglect: $141 – $71,162 per violation
  - Willful neglect: $14,232 to $2.1 million per violation
- Criminal fines & possible imprisonment

**Adjusted annually for inflation

Enforcement

- **New → HIPAA enforcement process applies to Part 2 violations**
  - OCR complaints and investigations
  - OCR settlements and agreements
  - OCR civil penalties
- **New → Must self-report breaches in violation of Part 2 disclosure rules**
  - HIPAA Breach Notification Rule
  - See 42 CFR Part 2.16(b)

Confidentiality & Consent Requirements

Release Restrictions

- SUD information may only be released with a **patient's consent** or if an **exception** is met
- Prohibits even acknowledging presence of individual in a facility "publicly identified" as a place where only SUD diagnosis/treatment provided
- Applies to minors if a minor, acting alone, can obtain SUD treatment (See Va. 54.1-2969)
  - Includes provision of patient-identifying information to parent to obtain payment

Consent Requirements

- SUD records can be released pursuant to the **written consent** of the patient
- May be written or electronic
- Must include specific requirements to be valid, including:
  - Explicit description of SUD information to be disclosed
- A HIPAA authorization does not necessarily comply with Part 2

Consent requirements

- **New →**
  - Flexibilities in describing recipients, e.g., can describe recipient as a “class of person” such as “my treating providers” or “health plans” rather than naming specific individuals or entities.
- **New →**
  - Aligns many of the required elements for Part 2 written consents with requirements for HIPAA authorizations

Notice of Prohibition on Re-Disclosure

- Each disclosure made pursuant to a Part 2 Consent must contain one of the two specific required disclosure statements:
- The regulations provide both a long-form and short-form notice that can be included to the recipient of the disclosure.
  - **New language for short and long notices**
  - **New → Disclosures must include a copy of the signed consent or a clear explanation of the scope of the consent provided**

Disclosures without Patient Consent

- Within Part 2 program (need to know basis only)
- To “Qualified Service Organization” if QSO Agreement is in place
- Release pursuant to a specific court order + subpoena
- Medical emergencies
- To law enforcement in narrow circumstances
- To report suspected child abuse or neglect
- Limited disclosures of public health purposes
- Research
- **Updated → Management audits, financial audits and program evaluation**
- **New → Disclosures for public health**

Disclosures to Qualified Service Orgs.

- Part 2 Programs may disclose records to QSOs when the QSO needs those records to provide services to the program
- Similar to Business Associates under HIPAA

Disclosures to Qualified Service Orgs.

Qualified Service Organizations (“QSOs”) are:

(1) Individuals/entities that provide services to the Part 2 Program, such as:

- Data processing
- Bill collecting
- Dosage preparation
- Laboratory analyses
- Legal, accounting, medical, or other professional services
- **NEW → HIPAA business associates of a Part 2 program that is also a covered entity**

Disclosures to Qualified Service Orgs.

- **AND**

- (2) Have entered into a written agreement that acknowledges that QSO will:
- Receive, store, process, or deal with patient records in accordance with 42 CFR Part 2
- Be fully bound by requirements of 42 CFR Part 2
- If necessary, will resist in judicial proceedings any attempt to obtain patient identifying information related to SUD, except as permitted by 42 CFR Part 2

Hypothetical 2

- Jane receives treatment for a substance use disorder at a CSB. During her last appointment with her treating provider, Dr. Jones, she verbally requests that Dr. Jones send her records to her primary care doctor.
- **Question**: Can Dr. Jones send the records to Jane's primary care doctor?

Hypothetical 2 - Answer

- **Answer**: NO!!!
- Jane's request is verbal—not written
- Verbal consent is insufficient under Part 2
- This is a key difference between Part 2 and HIPAA
- **New** → Under the amended regulations, providers can get one single consent at a patient's first appointment that would authorize future disclosures for treatment, payment, and health care operations

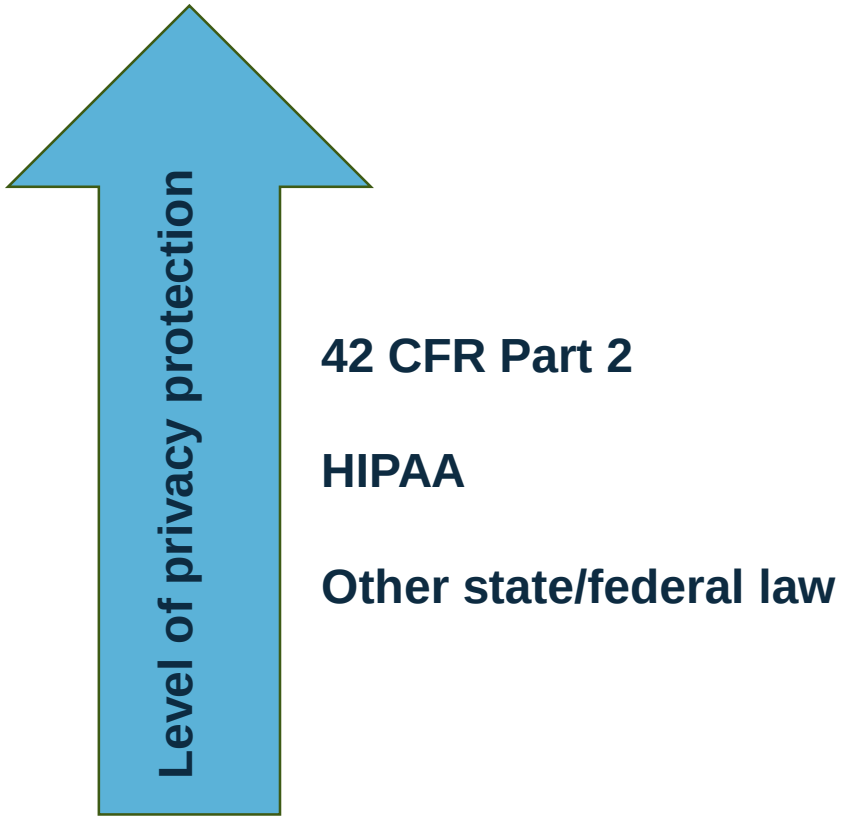
Subpoenas, Law Enforcement Requests & Court Orders

Subpoenas

- A patchwork of state and federal law governs the confidentiality of client information
  - HIPAA – PHI and EPHI
  - 42 CFR Part 2 – Substance Use Disorder Records
  - Virginia Health Records Privacy Act
- Each law has different rules regarding subpoenas

Which law applies?

- Must generally comply with the most restrictive federal or state law
  - Law that gives greater protection to client/patient information
  - Law that gives client/patient more control over their information



Subpoenas

- If a CSB receives a record request about a SUD patient, the CSB cannot acknowledge that an individual is a SUD patient unless:
  - Patient consents
  - Court Order authorizes such disclosure
- CSB can give the requestor a copy of the Part 2 regulations and state that they restrict disclosure of SUD records, but may not affirmatively identify a particular patient as having a SUD

Disclosures in the Judicial System

- Part 2 sets out a specific requirements for a provider to disclose SUD records to the Court:
  - Must have **both** a court order **and** a subpoena to disclose to a court
    - Regulations specify that order compelling disclosure of SUD records may only be entered for **good cause**
  - Subpoena without accompanying order (i.e., attorney-issued) is **not** sufficient
  - A court order without a subpoena is **not** sufficient

Disclosures in the Judicial System (con.)

- Order from a court without jurisdiction over your CSB (i.e., out-of-state court) is **not** a valid order
- Provider cannot disclose records unless the subpoena and court order comply with Part 2 and must challenge non-compliant subpoenas/orders

Contact your Compliance Officer immediately for guidance!

Disclosures to Law Enforcement

- Disclosures permitted if there is an immediate threat to the health or safety of an individual due to a crime on program premises or against program personnel
- Can disclose circumstances of the incident, including suspect's name, address, last known whereabouts, and status as a patient in SUD program

Disclosures to Related to Child Abuse

- Part 2 restrictions on disclosures do not apply to suspected child abuse and neglect reporting requirements under applicable state laws to state or local authorities.
- However, disclosure restrictions still apply to the parent or guardian SUD records and to their disclosure in connection with any court proceeding that results.

Contact your Compliance Officer for guidance!

Disclosures to Medical Personnel

- Disclosures permitted to medical personnel if a medical emergency exists, i.e., there is an immediate threat to the health of any individual that requires immediate medical intervention.
- Medical personnel treating an individual during a medical emergency may redisclose Part 2 information for treatment purposes as needed.
- Providers must document these disclosures in the patient's record: (1) name of recipient; (2) name of person making disclosure; (3) date and time of disclosure; (4) nature of emergency.

Hypothetical 3

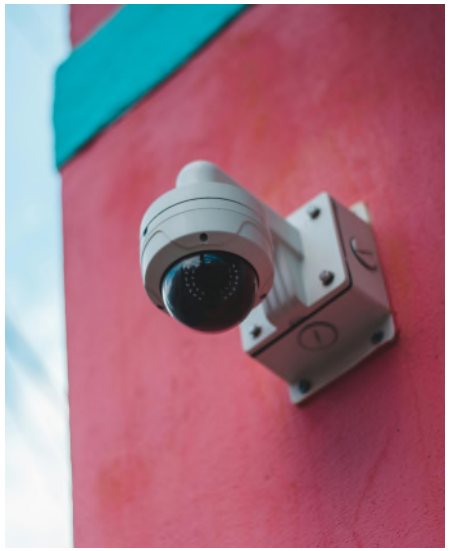
- Compliance Officer Carla receives a clerk-issued subpoena duces tecum commanding the CSB to produce records for Gus, a patient receiving SUD treatment at the CSB, in connection with a criminal case.
- **Question**: Can Carla produce Gus's records to the Commonwealth's Attorney?

Hypothetical 3 - Answer

- **Answer**: NO!!!
- To produce any SUD records, Carla must have **BOTH** a subpoena **AND** a court order. Even when the subpoena is clerk-issued and not just attorney-issued, any production of Part 2 records must also pursuant to a Court order that complies with the requirements of Part 2.

Hypothetical 4

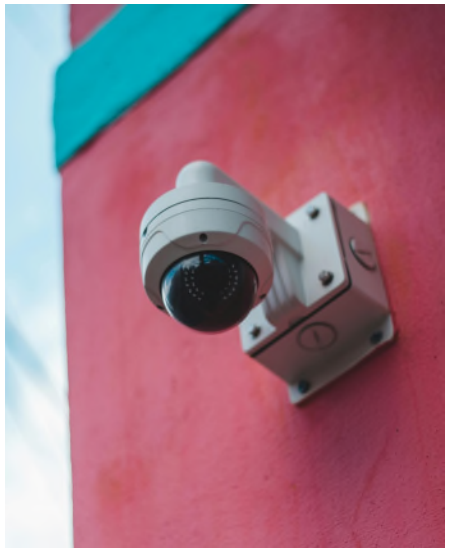
- Officer Jones shows up to a CSB facility and requests a copy of security footage of the waiting room and building entrance to investigate the theft of a laptop from the facility. The security footage covers areas of the building accessible to patients seeking addiction treatment services, mental health care, and other services. Officer Jones insists he needs the security footage to investigate a crime. He does not have a warrant, subpoena or court order.



- **Can the CSB release the security camera footage to Officer Jones? How should the CBS respond?**

Hypothetical 4 – Answer

- **Can the CSB release the security camera footage to the officer?**
  - No! The security camera footage contains PHI and SUD information that could be used to identify patients.
  - A court order and warrant or subpoena is required. This does not fall into the limited exception for disclosures to law enforcement due to an “immediate threat to the health or safety” of an individual due to a crime on program premises.



Hypothetical 5

- Luna Heddleston and Ruby Wood enter the Woods Rogers Annual Cutest Pet Competition.

- **Question:** Which pet will be named the cutest pet of all?

Hypothetical 5 - Answer

- **Answer:** BOTH OF THEM!!! Both are 110% cute and therefore there is no other option but for them both to win the top prize! How could you ever choose?

Recent Amendments

42 CFR Part 2

Final Rule – Feb. 16, 2024 Amendments

- Compliance date – **February 16, 2026**
- Purpose of amendments:
  - Better align Part 2 with HIPAA requirements (as required under the CARES Act)
  - Increase coordination among providers for treating SUD
  - Increase protections for patients concerning records disclosure to avoid discrimination in treatment

Three Categories of Changes

Consent

- Single consent for TPO & redisclosure
- Consent regarding legal proceedings
- Consent regarding SUD counseling notes

Patient Rights

- Notice with disclosures
- Accounting of disclosures
- Right to request restriction
- Patient notice of privacy practices

Breaches

- Complaints, penalties
- Enforcement process
- Breach notification

Patient Consent

Patient Consent for TPO Purposes

- Allows single patient consent given once for all future uses and disclosures for treatment, payment, and health care operations
  - **Recipient**: “my treating providers, health plans, third-party payers, and people helping to operate this program” or similar statement
  - **Purpose**: “treatment, payment or healthcare operations”
  - **Expiration**: “end of treatment” or “none”

Patient Consent for TPO Purposes (Ctd.)

- After patient signs a TPO consent
  - Recipients that are Part 2 programs or HIPAA Covered Entities or Business Associates can use and disclose records for TPO purposes
  - Recipients that are HIPAA Covered Entities or Business Associates can further disclose those records in accordance with HIPAA regulations
    - **EXCEPT** uses and disclosures for civil, criminal, administrative and legislative proceedings against the patient

Patient Consent for TPO Purposes

- TPO consent form must include required statement on redisclosure
  - Potential for records to be redisclosed by the recipient and no longer protected by Part 2
- TPO consent form must include statement on consequences to patient who refuses to sign

Hypothetical 6

- Patient Paula receives SUD treatment at Virginia CSB for alcoholism. Paula signs a TPO consent form during her initial intake. Paula is admitted to Virgina Hospital for a psychiatric inpatient stay and Virginia Hospital requests Paula's SUD records for treatment purposes. Virginia CSB disclosures Paula's SUD records to the Hospital.
- Virginia CSB and the Hospital receive a subpoena requesting all of Paula's health records (include SUD records) for proceedings against Paula related to child custody.
- **Can Virginia CSB release those records?**
- **Can Hospital release those records?**

Hypothetical 6

- **Answer – No to both, but for different reasons.**
- **Virginia CSB** – Paula's records are protected by 42 CFR Part 2. They cannot be disclosed absent patient consent or a court order + subpoena that complies with Part 2.
- **Virginia Hospital –** Received Paula's SUD records for treatment purposes under the TPO consent.
  - Virginia Hospital can use and share Paula's records for purposes permitted under HIPAA, **except for legal proceedings against Paula.**

Hypothetical 7

- Parker is a patient at Virginia CSB where he receives SUD treatment for an opioid addiction. Parker signs a consent form authorizing Virginia CSB to share his SUD records with is primary care doctor for treatment purposes.
- In which circumstances can Parker's primary care doctor re-disclose his SUD records?
  - **A.** Only as permitted by 42 CFR Part 2.
  - **B.** For purposes permitted by HIPAA, except for uses and disclosures in legal proceedings against Parker.

Hypothetical 7

Answer – Under which circumstances can Parker's primary care doctor re-disclose his records?

- **A.** Only as permitted by 42 CFR Part 2.
- **B.** For purposes permitted by HIPAA, except for uses and disclosures in legal proceedings against Parker.

Lawful Holder

- "Lawful holder": entity that is bound by Part 2 because they have received SUD information through:
  - Patient's written consent plus notice of disclosure alerting them to Part 2 requirements
  - Part 2 exception allowing disclosure without written consent
- Lawful holders may redisclose SUD information under limited circumstances depending on whether they are a Part 2 entity, covered entity or business associate under HIPAA

SUD counseling notes

- Heighted protection
- Consents authorizing disclosure of SUD counseling notes cannot be combined with other consents

Substance use disorder (SUD) counseling notes means notes recorded (in any medium) by a part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private SUD counseling session or a group, joint, or family SUD counseling session and that are separated from the rest of the patient's SUD and medical record. *SUD counseling notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

SUD Counseling Notes

- Part 2 program must obtain consent for any use or disclosure of SUD counseling notes, except:
- Certain TPO purposes
  - Originator of notes can use notes for treatment
  - Part 2 program can use or disclose notes internally for training providers
- As required by HHS-OCR to investigate Part 2 compliance
- As permitted by limited exceptions for mandated reports of child abuse/neglect, deceased patients, oversight activities and court orders

Consent re legal proceedings

- Consents where patient is authorizing disclosure of SUD records for legal proceedings cannot be combined with other consent forms

Patient Rights

Patient Rights

- Right to request privacy protection for Part 2 records
- Right to an accounting of disclosures
- Right to discuss notice of patient rights
- Right to opt out of fundraising communications
- Right to file a complaint with Part 2 program

Notice to Patients re Confidentiality

(b) ***Content of notice.*** In addition to the communication required in paragraph (a) of this section, a part 2 program shall provide notice, written in plain language, of the program's legal duties and privacy practices, as specified in this paragraph (b).

(1) ***Required elements.*** The notice must include the following content:

(i) ***Header.*** The notice must contain the following statement as a header or otherwise prominently displayed.

> Notice of Privacy Practices of [Name of Part 2 Program]
>
> *This notice describes:*
> • HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED
> • YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION
> • HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION
> YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER NAME OR TITLE] AT [PHONE AND EMAIL] IF YOU HAVE ANY QUESTIONS.

Notice to Patients re Confidentiality

- **Summary of Content Requirements**
  - Permitted or required uses and disclosures of SUD records without patient consent
  - Description of uses and disclosures that requires patient consent + examples
  - Statement that patient may provide single consent for all future uses or disclosures for TPO purposes
  - Statement that Part 2 program will make uses and disclosures not described in Notice only with patient consent
  - Statement that patient may revoke written consent

Notice to Patients re Confidentiality

- **Summary of Content Requirements (Ctd.)**
  - Statements regarding requirements for disclosing SUD information in legal proceedings (i.e., requirements for patient consent or court order + subpoena)
  - Other requirements re TPO and fundraising communications Patient rights
  - Duties of Part 2 program
  - Complaint process
  - Contact info for Part 2 program + right to discuss notice of patient rights
  - Effective Date

Patient Rights

- Right to request restrictions on disclosures
  - Part 2 program must permit a patient to request a restriction on uses or dislcosures of Part 2 Records carry out TPO.
    - Policies are not sufficient; programs must make a concerted effort to evaluate how they can reasonably accommodate patients' requests
  - If the Part program agrees, it **must** honor the restriction unless there is an emergency
  - Part 2 program **must** agree only when patient requests restriction on disclosure to health plan for services in which patient has paid in full

Patient Rights

- Right to accounting of certain disclosures made by Part 2 program with patient's consent over past **3 years**
  - Accounting of TPO disclosures only for disclosures through electronic health record
  - Subject to HIPAA standards
- Note yet in effect; Compliance date delayed

Complaint Process & Non-retaliation

- Part 2 program must provide a process to receive complaints concerning the program's compliance with 42 CFR Part 2
- Part 2 program may not retaliate against any patient for making a complaint or otherwise exercising their rights under Part 2
  - Part 2 program may not require patients to waive right to file a complaint

Compliance Tips & Best Practices

42 CFR Part 2

Compliance Tips

Compliance date: February 16, 2026

- **Next steps**
  - Update consent forms
    - Develop standard consent form for TPO disclosures
    - Update notices prohibiting redisclosure for disclosures based on patient's written consent
    - Update process for include consent form with disclosure

Compliance Tips

- **Next Steps**
  - Review and update Notice of Privacy Practices
  - Update policies and procedures
  - Staff Training
    - Especially staff describing new consent forms to patients
  - Patient education
    - Understand different between types of consent (TPO, SUD counseling notes, etc.)
    - New patient rights

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