42 CFR part 2



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Idaho Primary Care Ass'n

(3/19)



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Written Materials

- IC 37-3101 et seq.
- 42 CFR part 2
- SAMHSA Fact Sheet: Does Part 2 Apply to Me?
- SAMHSA Fact Sheet: *How Do I Exchange Part 2 Data?*
- SAMHSA FAQs: Applying the Substance Abuse Confidentiality Regulations



Applicable Laws

- Records of Substance Use Disorder Programs, 42 CFR part 2
- Health Insurance Portability and Accountability Act, 45 CFR part 164
- Records of Drug Treatment or Rehab, IC 37-3102
- Standards for Nonhospital, Medically Monitored Detox/Mental Health Diversion Units, IDAPA 16.07.50.261





Comply with Most Restrictive Law

42 CFR part 2

HIPAA

Other state or federal law

- Must generally comply with the most restrictive federal or state law, i.e.,
 - The law that gives greater protection to patient info, or
 - The law that gives greater control of their info to the patient.

(42 CFR 2.21)

➤ Must comply with HIPAA and other applicable laws as well as 42 CFR Part 2



Drug Treatment and Rehab, IC 37-3102

- A person may request treatment and rehabilitation for addiction or dependency to any drug, as defined in section 37-3101, from a physician qualified to administer such treatment under the provisions of this act; and such physician or any employee or person acting under his direction or supervision shall not report or disclose the name of such person or the fact that treatment was requested or has been undertaken to any law enforcement officer or agency; nor shall such information be admissible as evidence in any court, grand jury, or administrative proceeding unless authorized by the person seeking treatment.
- Limited to government proceedings.



Licensed Detox/Mental Health Units, IDAPA 16.07.50.261

Standards for Nonhospital, Medically Monitored Detoxification/Mental Health Diversion Units, Access to Client Records

- "Each detox/mental health diversion unit must ensure that client records are protected against loss, tampering, or unauthorized disclosure of information under the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 160 and 164, 42 U.S.C. Sections 290 dd-3 and ee-3, and 42 C.F.R., Part 2. Only authorized personnel may have access to client records."
- "No release of medical information can be made without written consent of the client, guardian, by court order, or as authorized by federal or state law."
- Additional rules concerning:
 - Removal of records.
 - Retention of records.
 - Electronic records.
 - Security measures.



HIPAA Privacy and Security Rules, 45 CFR part 164

- Generally may not use or disclose protected health information ("PHI") without the patient's written authorization unless exception applies.
- Must implement specified security safeguards.
- Patient has certain rights to their PHI.
- Must self-report breaches of unsecured PHI.



Substance Use Disorder Programs, 42 CFR Part 2

 Part 2 revised 1/18/17 and 1/3/18.



- ➤ In general, Part 2 programs may not disclose any info that would identify a person as having or having had a substance use disorder unless the person provides written consent or an exception applies.
- Certain entities to whom program discloses info must comply with Part 2.



Penalties

- Enforced by Dept. of Justice ("DOJ")
- Criminal penalty
 - \$500 for first offense
- + \$5000 for subsequent offenses(42 CFR 2.3)
- Also subject to HIPAA penalties
 - Up to \$58,000 per violation
- Must self-report breaches of unsecured PHI (45 CFR 160.401)
- Might be subject to private lawsuit, e.g.,
 - Common law privacy tort.
 - Negligence per se



Likely No FTCA Coverage

• FTCA applies to claims "for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by [FQHC providers] while acting within the scope of his office or employment..."

(42 USC 233(a), (g))



Likely No FTCA Coverage

- "The Federally Supported Health Centers Assistance Act ... granted medical malpractice liability protection through the Federal Tort Claims Act (FTCA) to HRSA-supported health centers." (https://bphc.hrsa.gov/ftca/about/index.html)
- "What services are covered under the FTCA Program? "Deemed Health Center Program grantees are immune from medical malpractice lawsuits resulting from the performance of medical, surgical, dental, or related functions within the approved scope of project."
 - (https://bphc.hrsa.gov/ftca/healthcenters/ftcahcfaqs.html)
- Criminal claims are not for "damages for personal injury."
- Criminal actions are generally outside course and scope of employment.
- But you can always submit claim and try...



Applicability

- Generally prohibits use or disclosure of info without patient consent if:
 - Info identifies a patient as having or having had a substance use disorder ("SUD"); and
 - Is SUD info created, obtained, or maintained by a federally assisted drug or alcohol abuse program.

(42 CFR 2.12(a))

- Prohibition applies even if:
 - Person seeking the info already has it or may obtain it elsewhere;
 - Info sought by law enforcement or any other government agency; or
 - Use or disclosure is for a civil, criminal, administrative or legislative proceedings by any federal, state or local authority.

(42 CFR 2.13(a))



Applicability: Substance Use Disorder

 "SUD" = cluster of cognitive, behavioral and physiological symptoms indicating that the patient continues using substance despite significant substance-related problems such as impaired control, social impairment, risky use, tolerance and withdrawal.

(42 CFR 2.11)

- Applies if patient:
 - Has SUD now
 - Had SUD in the past
 - Referred or seen for SUD treatment



Applicability: SUD Patient Information

Applies to:

- Any info created by a Part 2 program that would identify the patient as having or having had a SUD, including records indicating that patient was diagnosed with, or received or was referred for treatment of a SUD, either directly or indirectly.
- Identifying info includes name, address, SSN, fingerprints, photos, or similar info by which identity of patient can be determined.

Does not apply to:

- Diagnosis made solely for purpose of providing evidence for use by law enforcement, or
- Diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual does <u>not</u> have a SUD (e.g., involuntary ingestion of drugs or reaction to prescribed dosage).
- De-identified SUD info.

(42 CFR 2.12(a), (e))



Applicability: "Federally Assisted" Program

- "Federally assisted" =
 - Carried out under license or authorization granted by U.S. department or agency (e.g., participating in Medicare, DEA registration, etc.);
 - Supported by funds provided by a U.S. department or agency (e.g., receiving federal financial assistance, grants, etc.);
 - Program is tax-exempt or claims tax deductions relating to program; or
 - Conducted directly or by contract or otherwise by any dept or agency of the United States (but see rules re VA or armed forces).
- NOT purely private pay programs. (42 CFR 2.12(b))
- ➤ Most clinics are "federally assisted".



Applicability: Federally Assisted "Program"

- "Program" =
 - Individual or entity (other than general medical facility*) who holds itself out as providing and provides SUD diagnosis, treatment or referral.
 - Identified unit in a general medical facility* that holds itself out as providing and provides SUD diagnosis, treatment or referral.
 - Medical personnel in a general medical facility* whose primary function is providing SUD diagnosis, treatment or referral and who are identified as such providers.

(42 CFR 2.11; 2.12(e))

* "General medical facilities" = hospitals, trauma centers, and FQHCs. (SAMHSA FAQ 10, https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)



Applicability: Federally Assisted "Program"

Individual or Entity; Not General Medical Facility	General Medical Facility	
	Identified Unit	Medical Personnel or Staff
 Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, and Provides SUD diagnosis, treatment, or referral for treatment 	 Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, and Provides SUD diagnosis, treatment, or referral for treatment 	 Primary function is to provide SUD diagnosis, treatment or referral for treatment, and Identified as such providers

Applicability: Federally Assisted "Program"

 "Hold self out" = activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, e.g., through advertising or marketing.

(42 CFR 2.11; 2.12(e))

 May include state licensing procedures, advertising or posting notices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-"program" practitioners, information presented to patients or families, etc.

(SAMHSA FAQ 10, at https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)



Applicability: Federally Assisted Program

General Medical Facility, e.g., FQHC

Part 2
Program =

1. Identified unit that holds out and provides SUD.

2. Individual whose

2. Individual whose primary function is and identified as providing SUD.

Rest of FQHC not Part 2 Program

- Only the SUD unit/personnel are the "program".
- Program must comply with Part 2 in disclosing SUD info outside the program, e.g.,
 - Per consent
 - To administrative control
 - To qualified service organization
 - Other exception
- Program must have administrative controls in place to share SUD info.



Entities That Must Comply

- Prohibition against disclosure applies to:
 - Part 2 program.
 - Third party payers who receive info from Part 2 programs.
 - Entities having direct administrative control over the program.
 - "Lawful holders", e.g., persons who:
 - Receive SUD info from a program, and
 - Receive required notice prohibiting redisclosure.

(42 CFR 2.12(d)(2))



Responding to Requests about Patient

- May not acknowledge patient's presence if facility is publicly identified as place where SUD diagnosis, treatment or referral for treatment is provided.
- May acknowledge person's presence if facility is not publicly identified as only a SUD facility, and if acknowledgement does not reveal the patient has a SUD.
- Any answer to request for SUD records must be made in way that will not affirmatively reveal the patient has been or is being diagnosed or treated for SUD.
- May give the requester a copy of Part 2 regulations and state that they restrict disclosure of SUD records, but may not affirmatively state that the regulations prohibit disclosure of the records of an identified patient.

(42 CFR 2.13(c))





Federally Assisted Program Disclosure of SUD Info

Without patient's written consent

- Within part 2 program if need to know
- To those with administrative control over program
- Qualified service organization if have agreement
- Medical emergency
- Report to law enforcement if crime on premises or threat against program personnel
- Report child abuse
- Research subject to conditions
- Audits and investigations subject to conditions
- Per compliant order + subpoena

With patient's written consent

- Consent must contain required elements
 - Patient's name
 - Persons authorized to disclose
 - Info to be disclosed
 - To whom info may be disclosed
 - Purpose of disclosure
 - Statement re revocation
 - Expiration date, event or condition
 - Patient's or surrogate's signature
 - Date of signature
- Must include notice prohibiting redisclosure



Permitted Disclosure Without Patient Consent

- Communications within program based on need to know.
- Communications between program and entity with direct administrative control over the program.
- Communications with a qualified service organization ("QSO").
 - Must have agreement with QSO ("QSOA").
- Medical emergency where patient cannot consent.
 - Program must document disclosure in medical record, including name of medical personnel to whom disclosure made, their affiliation with facility, person making disclosure, date and time of disclosure, nature of emergency.

(42 CFR 2.12(c))



Permitted Disclosure Without Patient Consent (cont.)

- Report to law enforcement crime or threats (i) on program premises or (ii) against program personnel.
 - Limit info to circumstances of incident, patient status, whereabouts, etc.
- Report child abuse or neglect per state law.
 - May not disclose SUD records.
- Research.
 - Subject to conditions.
- Audit of program by govt, payer, or other lawful holder.
 - Subject to conditions.



Consent for Disclosure: Required Elements

- Patient's name.
- Specific names or general designation of program(s), entity(ies), or individuals authorized to disclose.
- How much and what kind of info may be disclosed, including explicit description of SUD info to be disclosed.
- Purpose of the disclosure.
 - Info must be limited to that which is necessary to fulfill stated purpose.

HOLLAND&HART.

Consent for Disclosure: Required Elements (cont.)

- Name(s) of individual recipient(s) of disclosure; or
- If recipient is third party payer entity, include name of payer.
- If recipient entity has treating provider relationship with patient (e.g., hospital, clinic, or practice), include name of the recipient.
- If recipient entity has no treatment relationship (e.g., health info exchange or research), include name(s) of recipient(s) plus
 - Name of individual participant(s); or
 - Name of entity participant(s) with treating provider relationship to patient; or
 - General designation of individual or entity participant(s) or class of participants that must be limited to participants who have a treating provider relationship with patient.
 - Must notify patient of right to request list of disclosures.

HOLLAND&HART

To whom disclosure to be made (i.e., recipient)	Treating provider to patient?	Primary designation	Additional designation
Individual	No	Name of individual (e.g., Jane Doe)	
Individual	Yes	Name of individual (e.g., John Doe, MD)	
Entity	Yes	Name of Entity (e.g., Lakeview Hospital)	
Third party payer	No	Name of entity (e.g., Medicare)	
Entity that is not a third-party payer		Name of entity (e.g., Health Info Exchange, or ACO) lust include notice of right to obtain list of disclosures	 At least one of following: Name of individual recipient (e.g., Jane Doe MD) Name of entity recipient with treating provider relationship (e.g., Lakeview Hospital) General designation of individual or entity limited to treating providers (e.g., my current/future treating providers)
(42 CFR 2.31(a)(4))			

Consent for Disclosure: Required Elements (cont.)

- Statement that consent may be revoked at anytime unless program or lawful holder has relied on it (e.g., providing treatment in reliance on consent to disclose to third party payer).
- Expiration date, event or condition, which can be no longer than necessary to serve the purpose of consent.
- Signed by patient or surrogate.
- Date of signature.

(42 CFR 2.31)

Consent may be paper or electronic.



Consent for Disclosure

- Disclosure per consent must be limited to info that is necessary to carry out stated purpose.
- May not rely on consent that has expired, is facially defective or false, or has been revoked.

(42 CFR 2.31)

- No redisclosure without consent or other exception.
- Must provide notice of redisclosure.



Notice of Redisclosure

- If disclose with written consent, must include one of these notices with the records produced to the recipient:
 - "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"; or
 - "42 CFR part 2 prohibits unauthorized disclosure of these records."

(42 CFR 2.32, as amended)



List of Disclosures

- Patient who has consented to disclosure and identified treating provider recipients through general designation (i.e., "my past/current/future healthcare providers") has right to receive a list of disclosures to such entities.
- Patient must submit written request.
- Intermediary (e.g., data exchange or ACO, not Part 2 program) must:
 - Respond within 30 days; and
 - Provide list of names, dates, and description of disclosures.
- Only required to list disclosures for prior 2 years. (42 CFR 2.13(d))



Qualified Service Organizations

- Program may disclose to qualified service organizations ("QSOs")
 - Provides services to Part 2 program, e.g., data processing, collections, dosage prep, lab analyses, legal, accounting, or other professional services.
- Must have written agreement between program and QSO ("QSOA").

(42 CFR 2.11; 2.12(c)(4))

- QSO may redisclose to its contract agents helping to perform QSO function per QSOA.
- QSO may generally not redisclose to other third parties.



QSO Agreements

- Acknowledge that it is bound by Part 2 in receiving, storing, processing or dealing with patient records from Part 2.
- If necessary, resist judicial proceedings to obtain access to patient identifying info related to SUD unless exception applies.
- Cannot redisclose except as necessary to its duties.
 (42 CFR 2.11)
- QSOA authorizes communication between the program and QSO, and between QSO and its contract agent to carry out QSOA.
- QSOA does <u>not</u> authorize QSO to communicate with third parties unless allowed by patient consent or another Part 2 exception.

(SAMHSA FAQ 14, https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs).



Lawful Holders and Agreements

- If consent allows disclosures to lawful holders:
 - for payment or healthcare operations: lawful holders may redisclose SUD info to contractors, subs and legal representatives to carry out purposes if:
 - Have contract by which contractor is bound by Part 2.
 - Furnish notice of non-redisclosure.
 - Require appropriate safeguards to protect info.
 - Require report of violations.
 - for other purposes, including treatment: lawful holders may <u>not</u> redisclose SUD info to contractors, subs and legal representatives without consent.

(42 CFR 2.33(b)-(c))



Sharing SUD Info within FHQC

General Medical Facility, e.g., FQHC

Part 2
Program =

1. Identified unit that holds out and provides SUD.

2. Individual whose

primary function is and identified as providing SUD.

Rest of FQHC not Part 2 Program

- Only the SUD unit/personnel are the "program".
- Program must comply with Part 2 in disclosing SUD info outside the program, e.g.,
 - Per consent
 - To administrative control
 - To qualified service organization
 - Other exception
- Program must have administrative controls in place to share SUD info.



Sharing SUD Info within FQHC

 "[P]atient consent is not required when information is exchanged within a Part 2 program or between a Part 2 program and an entity that has direct administrative control over the program. 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."

(SAMHSA FAQ 5, https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf)





Federally Assisted Program Disclosure of SUD Info

Without patient's written consent

- Within part 2 program if need to know
- To those with administrative control over program
- Qualified service organization if have agreement
- Medical emergency
- Report to law enforcement if crime on premises or threat against program personnel
- Report child abuse
- Research subject to conditions
- Audits and investigations subject to conditions
- Per compliant order + subpoena

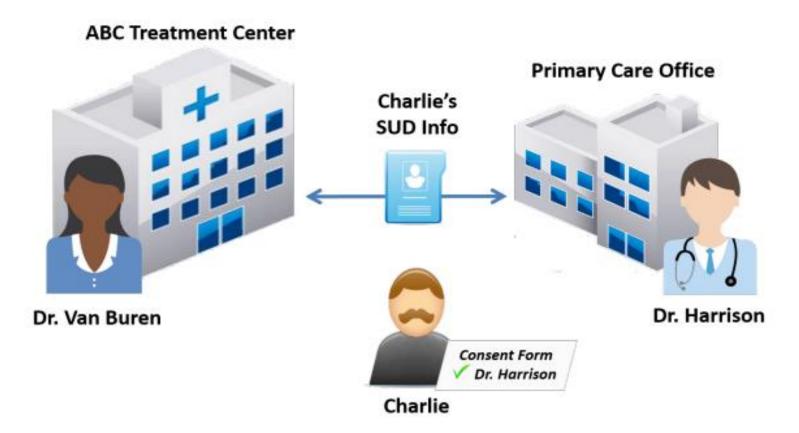
With patient's written consent

- Consent must contain required elements
 - Patient's name
 - Persons authorized to disclose
 - Info to be disclosed
 - To whom info may be disclosed
 - Purpose of disclosure
 - Statement re revocation
 - Expiration date, event or condition
 - Patient's or surrogate's signature
 - Date of signature
- Must include notice prohibiting redisclosure



Scenario: Treatment Program

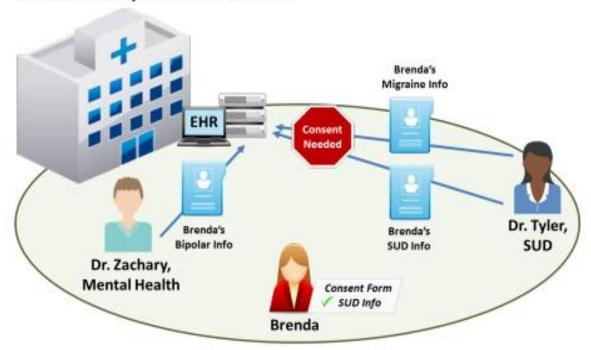
SCENARIO 1: OPIOID TREATMENT PROGRAM



Scenario: General Medical Facility

SCENARIO 2: MIXED-USE FACILITY

Acme Community Mental Health Center





Scenario: Integrated Care Setting

SCENARIO 4: INTEGRATED CARE SETTING



Blue Mountain Physician Group

- Primary care, integrated setting
- Does not advertise SUD treatment



Dr. Pierce

- DEA registration
- SAMSHA waiver
- SUD not primary function

Brooke



Minors

- Under Idaho law minors may consent to their own care if:
 - Emergency
 - Emancipated
 - Statute allows minor to consent, e.g.,
 - Minors may generally consent to treatment for drug rehab.
 - If patient is 16 or older, the fact that such person sought or is receiving treatment shall <u>not</u> be reported or disclosed to parents or legal guardian without patient's consent.
 - Must counsel patient as to the benefits of involving parents or legal guardian in treatment or rehab.

(IC 37-3102)



Minors

- If minor may consent to care under state law, minor controls disclosure of their SUD info.
 - Program may not disclose SUD info to parent/guardian without minor's consent, including disclosures to obtain payment.
 - Program may refuse to provide care unless consent is given.
- If minor may <u>not</u> consent to care under state law:
 - Cannot disclose minor's request for treatment to parent/guardian without minor's written consent unless minor not rational.
 - Any consent for disclosure to others must be signed by minor and parent/guardian.
- May disclose facts to parent/guardian if:
 - Disclosure may reduce substantial threat to well-being of minor or other person; and
 - Minor lacks capacity to make rational decision due to age or mental or physical condition.



Other than Minors

- If patient has been adjudicated as incompetent, consent for disclosure may be given by surrogate authorized by state law, e.g.,
 - Legal guardian
 - Agent in durable power of attorney for healthcare
 - Spouse
 - Adult children
 - Parent
 - Other relatives
- If patient has <u>not</u> been adjudicated as incompetent but suffers from medical condition that prevents knowing or acting, program director may consent for sole purpose of obtaining third party payment.

(42 CFR 2.15(a))



Deceased Patients

- Prohibition on disclosures for SUD info generally applies to deceased persons.
- May disclose cause of death consistent with state laws for reporting vital statistics.
- Written consent for other disclosures of SUD info may be given by:
 - Personal representative of estate, or if none:
 - Spouse, or if none:
 - Any responsible family member.

(42 CFR 2.15(b))



Disclosures to Criminal Justice System that Have Referred Patient

- If patient referred by criminal justice system as condition in criminal proceeding or parole, program may disclose info about patient to individuals in justice system if:
 - Disclosure limited to officers with duty to monitor, and
 - Patient signs written consent that satisfies certain elements.
- Person in criminal justice system may only use and redisclose info to carry out duties regarding patient's conditional release or parole.

(42 CFR 2.35)



Use in Criminal Proceedings

- No one can use any SUD info to:
 - Initiate or substantiate criminal charges against a patient, or
 - Conduct a criminal investigation of patient unless have qualifying court order.
- Cannot place undercover agents or informants in program, or use SUD info obtained from undercover agent or informant to investigate or prosecute criminal actions against the patient.

(42 CFR 2.12(d), 2.17)



Subpoenas and Orders

May disclose SUD info if have:

- Subpoena + court order authorizing disclosure.
 - Protect life or serious bodily injury.
 - Extremely serious crime committed by patient.
 - Criminal prosecution.
 - Investigate Part 2 program.
- Process for obtaining order, including notice to holder of record.

(42 CFR 2.61-2.67)

- May need to seek compliant order for certain disclosures.
- > Must challenge non-compliant subpoena or order.



Disclosures to Prevent Multiple Enrollments

- Part 2 program may disclose records to central registry or withdrawal management or treatment program < 200 miles to prevent multiple enrollments if:
 - Have patient consent that names registry or programs, except may generally refer to programs < 200 miles.
 - Disclosure is made when patient accepted treatment, drug changed, treatment interrupted, resumed or terminated.
 - Disclosure limited to certain info.
- Registry or withdrawal program may communicate to avoid multiple enrollments.

(42 CFR 2.34)



Identification Cards

- Away from program premises, program may not require patient to carry ID cards or other object that would identify the patient has having a SUD.
- On the program premises, may require patient to use or carry ID cards.

(42 CFR 2.18)



Notice of Confidentiality Protections

Upon admission (or if patient lacks capacity at the time as soon as patient gains capacity) program must:

- Communicate federal laws and regulations protecting SUD info.
- Give patient written summary of federal laws and regulations, including:
 - Description of limited situations in which program may acknowledge that patient is present or disclose that patient has SUD.
 - State that violation of law is a crime + contact info for making reports.
 - State that info related to patients' commission of crime on the Part 2 premises or against Part 2 personnel is not protected.
 - State that reports of child abuse and neglect made under state law are not protected.
 - Cite federal regs.

(42 CFR 2.22)



Patient Access to Records

- May provide a patient with a copy of or access to the patient's own records.
- No written consent is required to disclose the patient's info to the patient.

(42 CFR 2.23)



Security

- Programs and entities receiving SUD info must have formal policies and procedures protecting against unauthorized use or disclosure of paper and electronic SUD info or threats to security of SUD info.
- Policies and procedures must address:
 - Transfer and removing records.
 - Destroying records, including sanitizing media.
 - Maintaining records in secure room, locked file cabinet, safe, or similar container or storage facility when not in use.
 - Using and accessing workstations, secure rooms, locked file cabinets, safes, or similar containers or storage facilities.
 - De-identification of records.

(42 CFR 2.16)



Disposition of Records

- If program discontinues operations or is taken over or acquired by another program, it must de-identify or destroy records unless:
 - Patient gives written consent to transfer of records; or
 - Applicable law requires records to be retained for specified period that extends beyond acquisition or discontinuation of program.
 - Must comply with specific requirements concerning how paper or electronic records are maintained.
 - Must destroy records upon expiration of retention period.

(42 CFR 2.19)

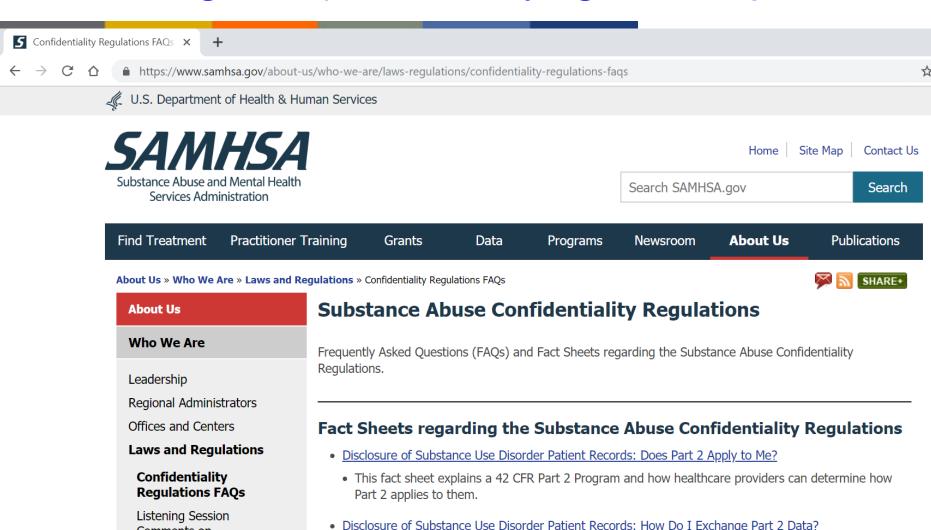


Additional Resources





https://www.samhsa.gov/about-us/who-we-are/lawsregulations/confidentiality-regulations-faqs



with a Part 2 Program.

• This fact sheet describes how 42 CFR Part 2 applies to the electronic exchange of healthcare records

Comments on Substance Abuse

Confidentiality

Treatment

https://www.hollandhart.com/healthcare#overview





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