

42 CFR PART 2: RECIPIENTS OF SUD RECORDS



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(3.26)

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Overview

REQUIREMENTS FOR FEDERALLY ASSISTED SUBSTANCE USE DISORDER (SUD) PROGRAMS

- See Webinar, *The New 42 CFR part 2 (9/25)*, available at <https://hhhealthlawblog.com/2025-webinar-recordings/>

TODAY: REQUIREMENTS FOR **RECIPIENTS** OF SUD RECORDS

- Enforcement and penalties
- HIPAA v. part 2
- When part 2 applies
 - “Lawful holders”
 - Others
- Confidentiality requirements
- Security requirements
- Notice of privacy practices

Overview



- Recent changes were intended to more closely coordinate part 2 rules with HIPAA per the CARES Act.
- Regulations poorly written.
 - Convoluted.
 - Some terms are not defined.
 - In many cases the rule is ambiguous, e.g., which rules or exceptions apply to recipients

Additional Resources

- Powerpoint slides
- 42 CFR part 2, <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2>
- OCR, *Fact Sheet 42 CFR part 2 Final Rule*, <https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html>
- Article, *Do the New Substance Use Disorder Record Rules Apply to You?*, <https://www.hollandhart.com/do-the-new-substance-use-disorder-record-rules-apply-to-you>
- Article, *Update Your HIPAA Notice of Privacy Practices by February 16, 2026*, <https://www.hollandhart.com/update-your-hipaa-notice-of-privacy-practices-by-february-16-2026>
- If you did not receive a copy of the powerpoint slides, please contact Sophie at SLericksonViereck@hollandhart.com.
- If you have questions, please submit them
 - Using chat feature, or
 - E-mail me at KCStanger@hollandhart.com

42 CFR part 2



42 CFR part 2

PURPOSE

To encourage people to get treatment for substance use disorders (SUD).

RULE

In general, **federally assisted SUD programs** (part 2 programs) and **certain recipients of SUD records** from part 2 programs may not use or disclose info that would identify a person as having, having had, or having been referred for a SUD unless

- The patient or personal rep provides written consent, or
- An exception applies.

(42 CFR 2.12(a))

Enforcement Initiative begins 2/16/26



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Office for Civil Rights Announces Civil Enforcement Program for Confidentiality of Substance Use Disorder Patient Records



“Beginning February 16, 2026, entities and persons subject to the regulation protecting the confidentiality of SUD patient records must comply with all applicable requirements. The penalties for noncompliance align with the penalties available under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules. OCR investigations conducted under the new program may be resolved through a range of civil enforcement mechanisms. These include OCR entering into resolution agreements, securing monetary settlements, obtaining commitments for corrective action, or imposing civil money penalties for the failure to comply.”

FOR IMMEDIATE RELEASE
February 13, 2026

Contact: HHS Press Office

202-690-6343

[Submit a Request for Comment](#)

Office for Civil Rights Announces Civil Enforcement Program for Confidentiality of Substance Use Disorder Patient Records

Landmark Enforcement Program for Substance Use Disorder Records Begins February 16, 2026

WASHINGTON— February 13, 2026 —The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) today announced a new program to implement and enforce statutory and regulatory requirements that protect the confidentiality of substance use disorder (SUD) patient records. This program marks the first time civil enforcement mechanisms will be available to protect the confidentiality of SUD patient records by covered SUD programs.

Enforcement

Effective 2/16/26

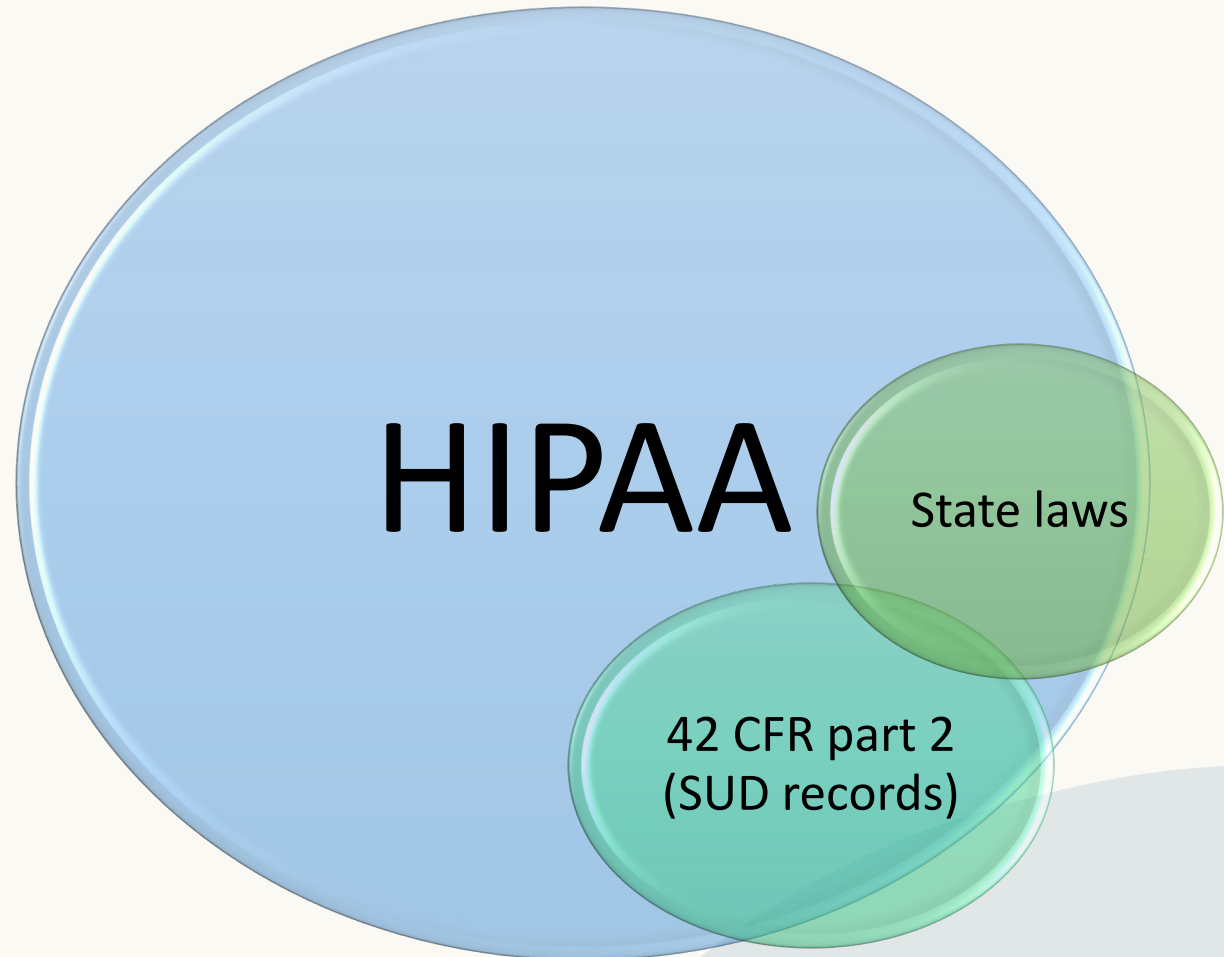
- Government enforcing 42 CFR part 2.
(<https://www.hhs.gov/press-room/hhs-announce-civil-enforcement-program-sud-patient-records.html>).
- Applies to:
 - Part 2 programs, and
 - Certain recipients of SUD records.

Penalties: same as HIPAA

- Civil fines:
 - \$145 to \$2,190,294 per violation, depending on *mens rea*.
(42 USC 1320d-5; 42 CFR 2.2(6); 45 CFR 160.404 and -102.3)
- Criminal penalties:
 - \$50,000 to \$250,000
 - 1 to 10 years in prison
(42 USC 1320d-6)
- OCR complaints and investigations
- Must self-report breaches

Part 2 + HIPAA + State Laws

- When dealing with SUD records, most providers will have to comply with—
 - 42 CFR part 2
 - HIPAA
 - Relevant state laws
- If there is conflict or gap, comply with more restrictive law, e.g.,
 - Part 2: restrictions on use or disclosure of SUD records.
 - HIPAA: patient rights concerning SUD records.
 - State law?



HIPAA v. Part 2

HIPAA

- Applies to protected health info (PHI).
- Applies to*
 - Covered entities, and
 - Business associates.
- *Requirements depend on entity type.*

* Exception: criminal penalties apply to anyone.

42 CFR PART 2

- Applies to SUD records.
- Applies to
 - Federally assisted SUD programs, and
 - Certain recipients of SUD programs.
- *Requirements follow the records.*

Does Part 2 Apply?

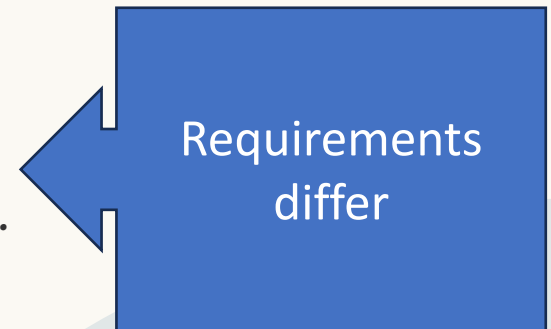


Substance Use Disorder Records

- **Substance Use Disorder (SUD)** = “means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems ... For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use.”
- **SUD record** = any patient identifying information (recorded or not)
 - Created, received, or acquired by a federally assisted SUD program; and
 - Indicating that the person has, had, or has been referred to for SUD.

(42 CFR 2.11)

- Applies to both
 - Federally assisted SUD program (part 2 program) and
 - Certain recipients of SUD records that came from a part 2 program.



“Federally Assisted” SUD Program (Part 2 Program)

A program is considered to be **federally assisted** if:

- 1) It is conducted in whole or in part by any department or agency of the United States.
- 2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to: (i) participating provider in the Medicare program; (ii) authorization to conduct maintenance treatment or withdrawal management; or (iii) registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of SUDs;
- 3) It is supported by funds provided by any department or agency of the United States by being: (i) a recipient of federal financial assistance in any form; or (ii) conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, receives federal funds which could be spent for the SUD program; or
- 4) It is assisted by the IRS through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(42 CFR 2.12(b))

Federally Assisted SUD “Program”

- A SUD program means:
 - 1) A person (other than a general medical facility) that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or
 - 2) An identified unit within a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or
 - 3) Medical personnel or other staff in a general medical facility whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment and who are identified as such providers.

(42 CFR 2.11)

- “General medical facilities” = hospitals, trauma centers, FQHCs, maybe primary care practice, etc.

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

Federally Assisted SUD “Program”

Individual or Entity; <u>Not</u> General Medical Facility	General Medical Facility	
	Identified Unit	Medical Personnel or Staff
<ol style="list-style-type: none"> 1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, <i>and</i> 2. Provides SUD diagnosis, treatment, or referral for treatment 	<ol style="list-style-type: none"> 1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, <i>and</i> 2. Provides SUD diagnosis, treatment, or referral for treatment 	<ol style="list-style-type: none"> 1. Primary function is to provide SUD diagnosis, treatment or referral for treatment, <i>and</i> 2. Identified as such providers

(42 CFR 2.11)

Federally Assisted SUD “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, info presented to patients or families, *etc.*

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

Not Federally Assisted “SUD Program”

- Part 2 program is not:
 - Emergency room personnel or other persons in a general medical facility who provide SUD care unless
 - Their primary function is to diagnose, treat or refer for SUD care, or
 - Defined unit in facility holds itself out to the community as a provider of such SUD services.
 - Providers outside general medical facility who may provide SUD care but who do not hold themselves out as providing SUD treatment.

(42 CFR 2.12(e)(1); SAMHSA FAQ 10, at <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>)

Part 2 Programs

- Part 2 programs generally may not disclose SUD info to others unless:
 - Exception allows disclosure of SUD info without patient consent, or
 - Have patient’s written consent, in which case part 2 program must provide the following with the SUD records:
 - Copy of written consent per 42 CFR 2.31.
 - Written notice per 42 CFR 2.32.

“Lawful Holder”
must comply with
part 2 confidentiality
rules.

“Lawful Holder”

Lawful holder = a person who is bound by part 2 because they have received records as the result of one of the following:

- 1) Written consent in accordance with § 2.31 + accompanying notice of disclosure; or
- 2) One of the exceptions to the written consent requirements in part 2, e.g.,
 - Entities with direct administrative control over part 2 program.
 - Qualified service organization (QSO).

And potentially

- *Medical personnel treating the patient in a bona fide emergency.*
- *Entities conducting permitted research.*
- *Federal, state, or local government agencies or third-party payers conducting audits.*
- *Any person receiving SUD info in any civil, criminal, administrative or legal proceeding against the patient if such info was obtained from a part 2 program, covered entity, business associate, intermediary, or other lawful holder.*

(See 42 CFR 2.11 and subpart D)

Check regulations for specific conditions and requirements.

Qualified Service Organization (QSO)

- Part 2 program may disclose SUD info to a QSO without the patient's consent.
- **QSO** = entity that:
 - 1) Provides services to a part 2 program, such as data processing, bill collecting, lab analyses, or legal, accounting, medical staffing, or other professional services, and
 - 2) Has entered into a written agreement (QSOA) with a part 2 program under which that person:
 - a) Acknowledges that in receiving, storing, processing, or dealing with patient records from the part 2 program, it is fully bound by the part 2 regulations; and
 - b) If necessary, will resist in any efforts to access patient identifying info related to SUD diagnosis, treatment, or referral for treatment except as permitted by 42 CFR part 2.
 - 3) Includes business associates of a part 2 program if the part 2 program is a covered entity under HIPAA.
 - *Ensure your business associate agreements (BAAs) comply.*

(42 CFR 2.11 and 2.12(c))

SUD Records Accompanied By Consent + Notice

- When SUD records are disclosed pursuant to the patient's written consent, the records must be accompanied by:
 - A copy of the consent or a clear explanation of the scope of the consent, and
 - Written notice that satisfies 42 CFR 2.32.
 - Long form
 - Short form

These notify the recipient that:

- *Records are covered by part 2 and must be kept confidential; and*
- *Permissible scope of use per consent.*

(42 CFR 2.32)

Notice Accompanying Disclosure of SUD Records with Consent

- **Statement 1.** “This record which has been disclosed to you is protected by Federal confidentiality rules (42 CFR part 2). These rules prohibit you from using or disclosing this record, or testimony that describes the information contained in this record, in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient, unless authorized by the consent of the patient, except as provided at 42 CFR 2.12(c)(5) or as authorized by a court in accordance with 42 CFR 2.64 or 2.65. In addition, the Federal rules prohibit you from making any other use or disclosure of this record unless at least one of the following applies:
 - (i) Further use or disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or as otherwise permitted by 42 CFR part 2.
 - (ii) You are a covered entity or business associate and have received the record for treatment, payment, or health care operations, or
 - (iii) You have received the record from a covered entity or business associate as permitted by 45 CFR part 164, subparts A and E.A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31).”
- **Statement 2:** “42 CFR part 2 prohibits unauthorized use or disclosure of these records.”
(42 CFR 2.32(a))

Confidentiality



Confidentiality of SUD Records

- Generally, cannot use or disclosure of SUD info without patient consent if info:
 - Is created, obtained, or maintained by a part 2 program, and
 - Identifies a patient as having, having had, or referred for a SUD.
 - Not de-identified info.

(42 CFR 2.12(a); 2.13(a))

- Any use or disclosure of SUD info must be limited to that info which is necessary to carry out the purpose of the use or disclosure.

(42 CFR 2.13(a))

- Confidentiality requirements apply even if:
 - Person seeking the info already has it or may obtain it elsewhere;
 - Info is sought by law enforcement or 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(b))

Responding to Inquiries about Patient

- May not acknowledge patient is in a facility if the facility is publicly identified as place where SUD diagnosis, treatment or referral for treatment is provided unless:
 - Patient consents, or
 - Obtain authorizing court order per part 2.
- May acknowledge person's presence if:
 - Facility is not publicly identified as only a SUD facility, and
 - Acknowledgement does not reveal patient has a SUD.
- Any answer to request for SUD info 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 regs and state that they restrict disclosure of SUD info but may not affirmatively state that regs prohibit disclosure of patient's records.

(42 CFR 2.13(c))

Disclosure of SUD Records

WITH PATIENT'S CONSENT

- For treatment, payment or healthcare operations (TPO); one consent may apply to all future uses.
 - For other purposes specified in consent.
 - *Consent must contain required elements.*
 - *Must also provide notice prohibiting redisclosure.*
- (42 CFR 2.31-2.33)

WITHOUT PATIENT'S CONSENT

- Within part 2 program if need to know.
 - Between part 2 program and those with direct administrative control.
 - To QSO if have QSOA.
 - Report to law enforcement of a crime on part 2 program premises or threat against program personnel.
 - Report suspected child abuse or neglect.
- (42 CFR 2.12(c))
- Disclosure of de-identified info for public health purposes.
 - Medical emergency.
 - Scientific research subject to conditions.
 - Audits and investigations subject to conditions.
 - Per compliant judicial order + subpoena.
- (42 CFR 2.51-2.67)

Check regulatory requirements

Consent Requirements

- Patient's name.
- Names or specific identification of persons or class of persons authorized to use or disclose the SUD info.
- Description of SUD info to be used or disclosed that identifies the info in specific and meaningful way.
- Recipients (see next slide).
- Description of each purpose for disclosure.
 - “at the request of the patient” if patient initiated the request.
 - “for treatment, payment and health care operations” if consent given once for all such future uses.
- Patient's right to revoke consent in writing and how patient may revoke.
 - Exception: if part 2 program or lawful holder has acted in reliance on the consent.
- Expiration date or event that relates to the patient or purpose of use or disclosure.
- Signature or e-signature of patient and/or person authorized to give consent per 42 CFR 2.14 or 2.15.
- Date of signature.

(42 CFR 2.31(a))

Consent Requirements

Designate recipients of SUD info:

- In general, include name(s) or class(es) of persons receiving SUD info.
- For a single consent for all future uses and disclosures for TPO, the recipient may be described as “my treating providers, health plans, third-party payers, and people helping to operate this program” or a similar descriptions.
- For intermediaries,* must also include:
 - Name(s) of the intermediary(ies) and:
 - Name(s) of member participants in the intermediary or general designation of participant(s), which must be limited to participants who have a treating provider relationship with the patient.
- If the recipient is a covered entity or business associate to whom SUD info is disclosed for purposes of TPO, must also include a statement that the patient’s SUD info may be redisclosed in accordance with HIPAA regs except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient.

(42 CFR 2.31(a)(4))

* *Intermediary* = a person, other than a part 2 program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient, e.g., a health data exchange, ACO, etc. (42 CFR 2.11)

Consent Requirements: For Legal Proceedings

- Generally, may not use or disclose SUD records in any civil, criminal, administrative, or legislative investigation or proceeding against the patient without:
 - Patient’s written consent, or
 - Part 2 order from court.
 - See process in 42 CFR 2.61 *et seq.*
- Patient consent for use or disclosure of SUD records in any civil, criminal, administrative, or legislative proceeding may not be combined with a consent for any other purpose.

(42 CFR 2.31(d))

Consent Requirements: Ineffective Consents

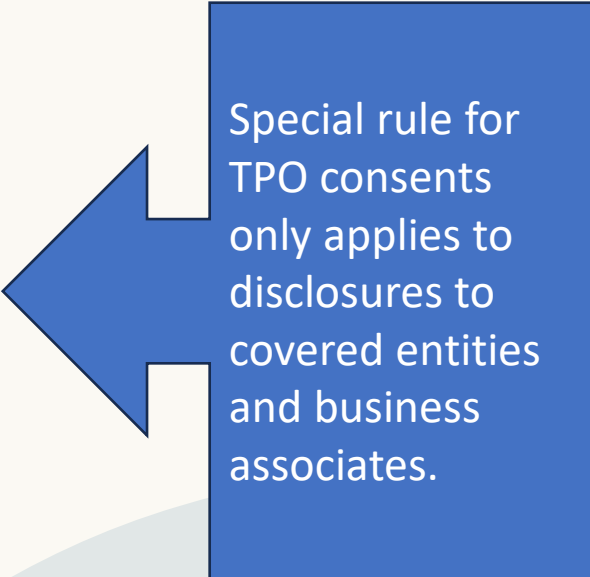
- May not rely on consent which:
 - Has expired;
 - On its face substantially fails to conform to any of the consent requirements;
 - Is known to have been revoked; or
 - Is known, or through reasonable diligence could be known, by the person holding the records to be materially false.

(42 CFR 2.31(c))

Disclosures with Written Consent

- **Specific Consent.** If patient gives a specific written consent, the part 2 program must limit any use or disclosure of the SUD info accordingly.
- **TPO Consent.** If patient gives a single written consent for all future uses and disclosures of SUD info for TPO, a part 2 program, covered entity, or business associate may use and disclose those records for such purposes as permitted by HIPAA until the patient revokes such consent in writing.

(42 CFR 2.33(a))



Special rule for TPO consents only applies to disclosures to covered entities and business associates.

Disclosures with Written Consent: Redisclosure by Recipients

- If patient gives written consent for use or disclosure of their SUD records, the recipient may further disclose such records as follows:

HIPAA
applies

– If disclosed for TPO **to a covered entity or business associate**, recipient may further disclose the records in accordance with HIPAA.

- Not for use or disclose for civil, criminal, or administrative proceedings against patient.

Part 2
applies

– If disclosed for all future TPO activities **to a part 2 program that is not a covered entity or business associate**, the recipient may further disclose those records consistent with the consent.

HIPAA
does not
apply

– If disclosed for payment or health care operations **to a lawful holder that is not a covered entity or business associate**, the recipient may further disclose those records as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or healthcare operations specified in the consent on behalf of such lawful holders if certain conditions satisfied (see next slide...).

(42 CFR 2.33(b))

Disclosures with Written Consent Redisclosure by Recipients (cont.)

- Lawful holders (**other than covered entities and business associates**) who wish to redisclose patient identifying SUD info for payment or healthcare operations must:
 - Have a written contract or similar agreement with subcontractor by which the subcontractor is fully bound by part 2 upon receipt of the SUD info;
 - Provide the notice of part 2 obligations to the subcontractor;
 - Require the subcontractor to implement appropriate safeguards to prevent unauthorized uses and disclosures; and
 - Require the subcontractor to report any unauthorized uses, disclosures, or breaches to the lawful holder.
- The lawful holder may only redisclose info that is necessary for the subcontractor to perform its duties under the contract.
- Contracts may not permit a subcontractor to redisclose info to a third party unless that third party is a contract agent of the subcontractor that is helping them provide services described in the contract, and only as long as the agent only further discloses the info back to the contractor or lawful holder from which the info originated.

(42 CFR 2.33(c))

Recipient Records

- Part 2 provider may disclose part 2 info to non-part 2 provider with patient consent.
 - If SUD info disclosed orally: non-part 2 provider may record info, and part 2 does not apply to non-part 2 provider's records.
 - If SUD info disclosed in writing: written SUD info is still subject to part 2.
 - If non-part 2 provider segregates them, the rest of the non-part 2 provider's records are not subject to part 2.
 - If non-part 2 provider includes them in his/her own records, the non-part 2 provider's records are subject to part 2.

(42 CFR 2.11 and 2.12(d)(2); *but see* (d)(2)(i)(C) re TPO recipients)

➤ *Non-part to providers: segregate part 2 records to avoid having all your records become subject to part 2.*

Minors and Patients Lacking Capacity



Minor Patients

Remember: these rules only apply if they involve SUD records from a part 2 program.

- If minor may consent to SUD care under state law, minor controls disclosure of their SUD info.
 - Only minor may give written consent for use or disclosure of SUD info.
 - May not disclose SUD info to parent/guardian without minor's consent, including disclosures to obtain payment.
 - Part 2 program may refuse to provide care unless consent is given.
- If minor may not consent to SUD care under state law:
 - Any consent for use or disclosure of SUD info must be given by both minor and parent/guardian.
 - May not disclose minor's request for SUD treatment to parent/guardian unless:
 - Minor gives written consent to disclose to parent/guardian, or
 - Minor lacks capacity to make rational decisions.
- May disclose facts relevant to substantial threat to minor or other person to parent/guardian if part 2 program director determines:
 - Minor lacks capacity to make rational decision due to age or mental or physical condition; and
 - Disclosure may reduce substantial threat to well-being of minor or other person.

(42 CFR 2.14)

Adult Patients Who Lack Capacity

Remember: These rules only apply if they involve SUD records from a part 2 program.

- If court has determined that an adult patient lacks capacity to make their own healthcare decisions, consent for use or disclosure of SUD info may be given by the patient's personal representative.*
- If a court has not determined that an adult patient lacks capacity to make their own healthcare decisions, the part 2 program director may consent to disclosure of part 2 info for the sole purpose of obtaining payment from a third-party payer or health plan.

(42 CFR 2.15(a))

* *Personal representative* = person who has authority under applicable law to act on behalf of the patient, but only with respect to records relevant to such personal representation.

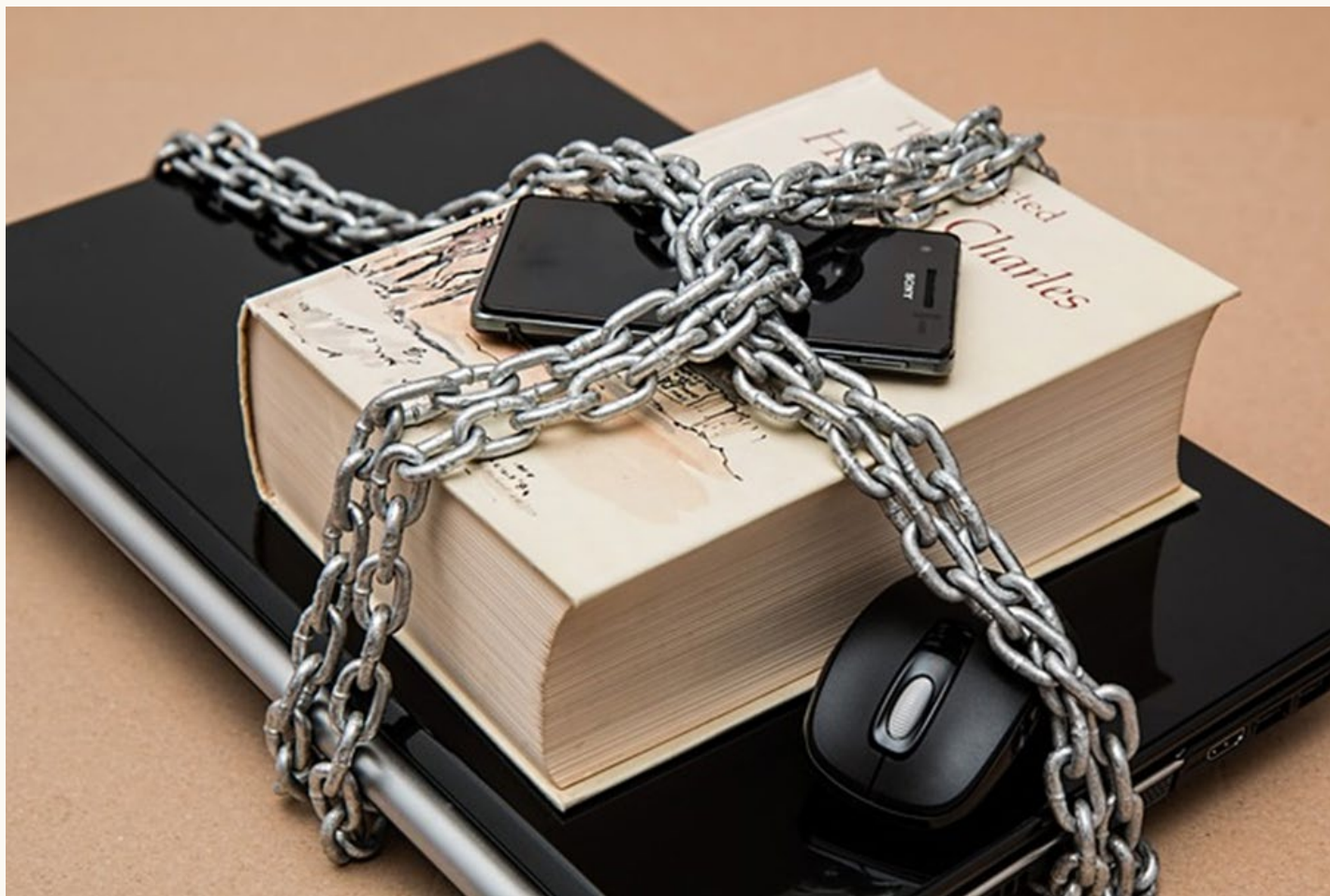
(42 CFR 2.11).

Deceased Patients

- Prohibition on use or disclosures of SUD info generally applies to deceased persons.
- May disclose cause of death consistent with state laws for reporting vital statistics.
- For other uses or disclosures, written consent may be given by the deceased patient's personal representative.

(42 CFR 2.15(b))

Security



Security

- Part 2 programs and lawful holders must have formal policies and procedures to protect against unauthorized use or disclosure of SUD info or threats to security of SUD info.
- Policies and procedures must address all of the following for paper and e-info:
 - Transfer and removing records.
 - Destroying records, including sanitizing media.
 - Maintaining records in secure room, cabinets or facilities.
 - Using and accessing workstations, rooms, cabinets or facilities.
 - De-identifying records consistent with HIPAA standards at 45 CFR 164.514(b).
- These standards do not apply to family, friends, and other informal caregivers who are lawful holders.

(42 CFR 2.16)

Security

Remember...

- HIPAA security rule still applies to e-PHI
 - Periodic risk analysis
 - Safeguards
 - Administrative
 - Physical
 - Technical
 - Business associate agreements
 - Respond to breaches
(45 CFR 164.301 *et seq.*)
- State data privacy laws.



HIPAA Notice of Privacy Practices



HIPAA Notice of Privacy Practices

- Effective 2/16/26, HIPAA covered entities required to update their notice of privacy practices.
 - If covered entity creates or maintains part 2 SUD records, must provide adequate notice of part 2 limits on SUD records.
 - Statement explaining limits on use or disclosure for civil, criminal, administrative or legislative proceedings without patient consent.
 - Describe laws that are more restrictive than HIPAA, including part 2.
 - Statement that info disclosed pursuant to the HIPAA privacy rule is subject to redisclosure and may no longer be protected by HIPAA.
 - If use or disclose SUD records for fundraising, must give patient clear opportunity to elect not to receive fundraising communications.

(45 CFR 164.520)

- Part 2 programs must provide a notice to part 2 patients containing additional items.
 - May be combined with HIPAA notice of privacy practices.

(42 CFR 2.22)

<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html>

- HIPAA Health Care Provider NPP
- HIPAA Health Plan NPP
- Part 2 Patient Notice



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HIPAA for Professionals	
Regulatory Initiatives	
Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	+
Patient Safety	
Covered Entities & Business Associates	+

Model Notices of Privacy Practices

The HIPAA Privacy Rule requires health plans and covered health care providers to develop and distribute a notice that provides a clear, user friendly explanation of individuals' rights with respect to their personal health information and the privacy practices of health plans and health care providers.

As of February 16, 2026, these HIPAA covered entities are required to include information about substance use disorder (SUD) patient records (described in 42 U.S.C. 290dd-2(a) and 42 CFR part 2 ("Part 2")) in their notice of privacy practices (NPP). Additionally, federally assisted SUD treatment programs are required to provide a new patient notice by February 16, 2026, that is aligned more closely with the HIPAA NPP. This page provides options for meeting the requirement to create HIPAA NPPs and Part 2 patient notices.

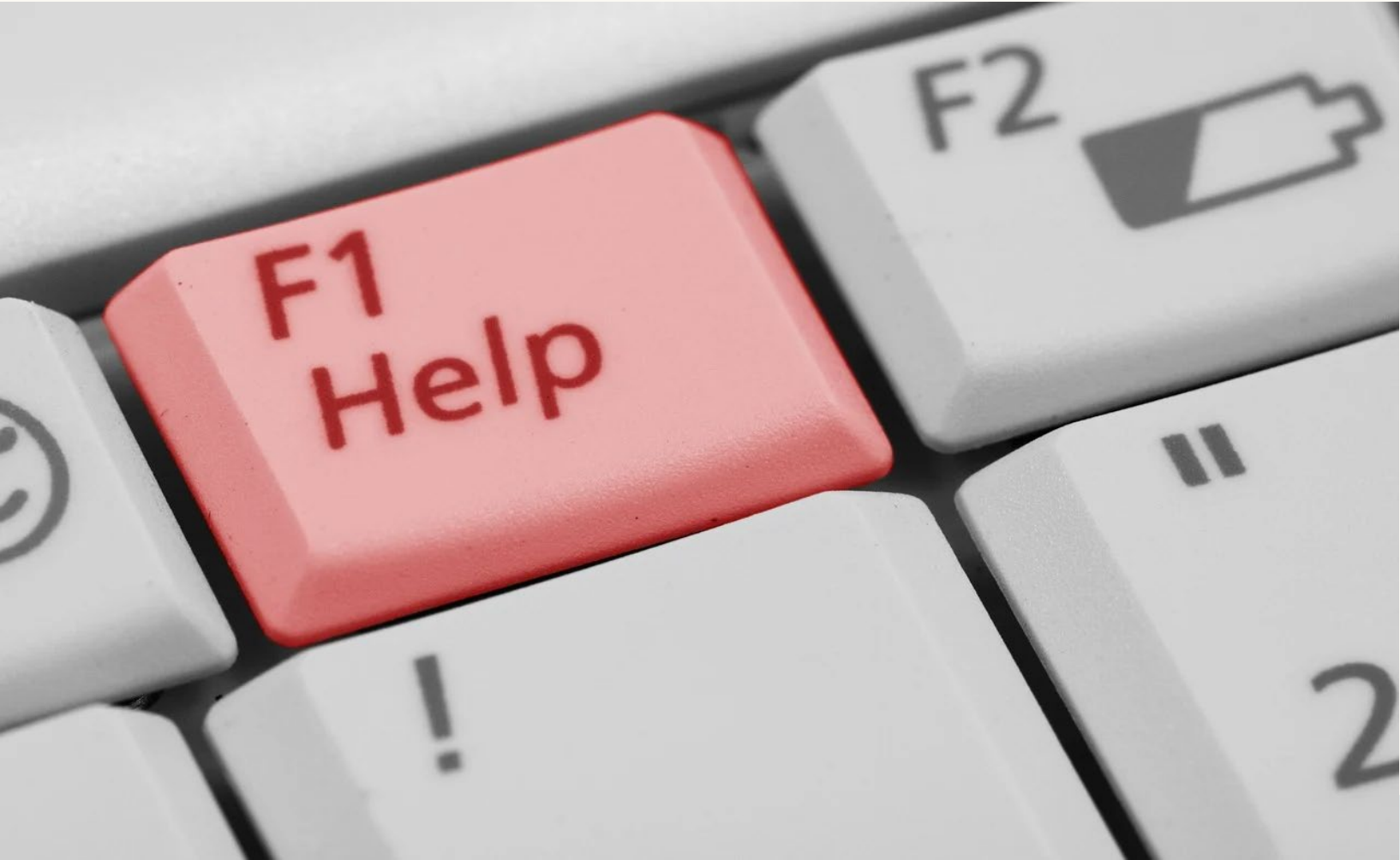
Additional Requirements for Part 2 Programs



Additional Requirements for Part 2 Programs

- Qualified services organization agreements
- Conditions on disclosures without patient consent
- Disposition of records of discontinued programs
- Patient rights
 - Accounting of disclosures
 - Access to records
 - Request additional restrictions on use or disclosure of SUD records
 - Non-retaliation
 - Complaint process
- Notice of patient rights

Additional Resources



OCR/SAMHSA Webinar

<https://www.youtube.com/watch?v=F3ZZgCXpT4k>

OCR and SAMHSA Release Webinar on the New Final Rule Modifying the Confidentiality Provisions for Substance Use Disorder Patient Records

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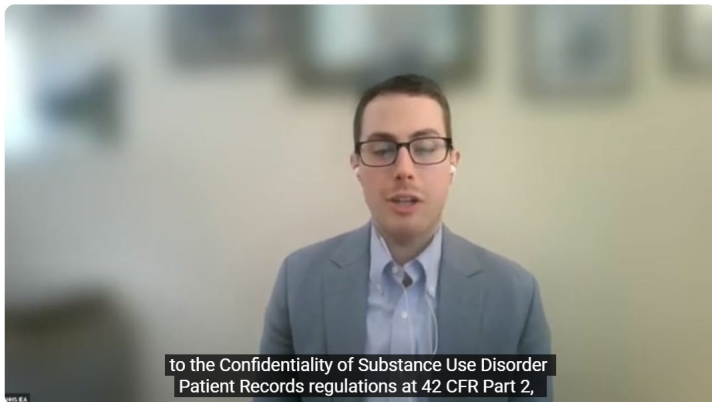
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office for Civil Rights

OCR & SAMHSA Webinar: Part 2 Final Rule Modifying Confidentiality Provisions for SUD Patient Records

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April 16, 2024

OCR and SAMHSA Release Webinar on the New Final Rule Modifying the Confidentiality Provisions for Substance Use Disorder Patient Records

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA) release a webinar recording on the new finalized modifications to the Confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR Part 2 ("Part 2"), which protect the privacy of patients' SUD treatment records.

The new Part 2 Final Rule increases coordination among providers treating patients for SUDs, strengthens patient confidentiality protections through civil enforcement, and enhances integration of behavioral health information with other medical records to improve patient health outcomes.

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

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Substance Use Confidentiality Regulations

The [Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data? \(PDF | 1.6 MB\)](#) fact sheet describes how 42 CFR Part 2 applies to the electronic exchange of healthcare records with a Part 2 Program.

Applying the Substance Use Confidentiality Regulations

Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
42 CFR Part 2 (REVISED)

In 2010, the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) and the HHS Office of the National Coordinator (ONC) published FAQs "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)." The 2010 FAQs are available at [Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange \(HIE\) \(PDF | 381 KB\)](#).

These Frequently Asked Questions (FAQs) are for information purposes only and are not intended as legal advice. Specific questions regarding compliance with federal law should be referred to your legal counsel. State laws may also apply.

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https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html



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Fact Sheet 42 CFR Part 2 Final Rule

Date: February 8, 2024 (Updated January 30, 2026)

On February 8, 2024, the U.S. Department of Health & Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights announced a final rule modifying the Confidentiality of Substance Use Disorder (SUD) Patient Records regulations at 42 CFR part 2 (“Part 2”). With this final rule, HHS is implementing the confidentiality provisions of section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act [PDF, 875 KB]

https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-part-2/index.html



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Understanding Confidentiality of Substance Use Disorder (SUD) Patient Records or “Part 2”

Part 2 is a federal law ([42 U.S.C. 290dd-2](#) and [42 CFR part 2](#)) that protects the confidentiality of patient records for people receiving services for substance use disorders (SUDs). Part 2 confidentiality rules describe when and how SUD patient records may be used and disclosed. These records are called **Part 2 records**.

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