ECHO IDAHO

Opioids, Pain and Substance Use Disorders

Legislative Updates Surrounding Substance Use in Idaho

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Project ECHO

42 CFR PART 2: NEW RULE

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(5-25)

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Preliminaries

WRITTEN MATERIALS

- Presentation slides.
- Redline showing changes in final rule.
- SAMHSA Fact Sheet *42 CFR Part 2 Final Rule*, available at https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html
- HHS Commentary to Final Rule, 89 FR 12472 (2/16/24), available at https://www.federalregister.gov/documents/2024/02/16/2024-02544/confidentiality-of-substance-use-disorder-sud-patient-records

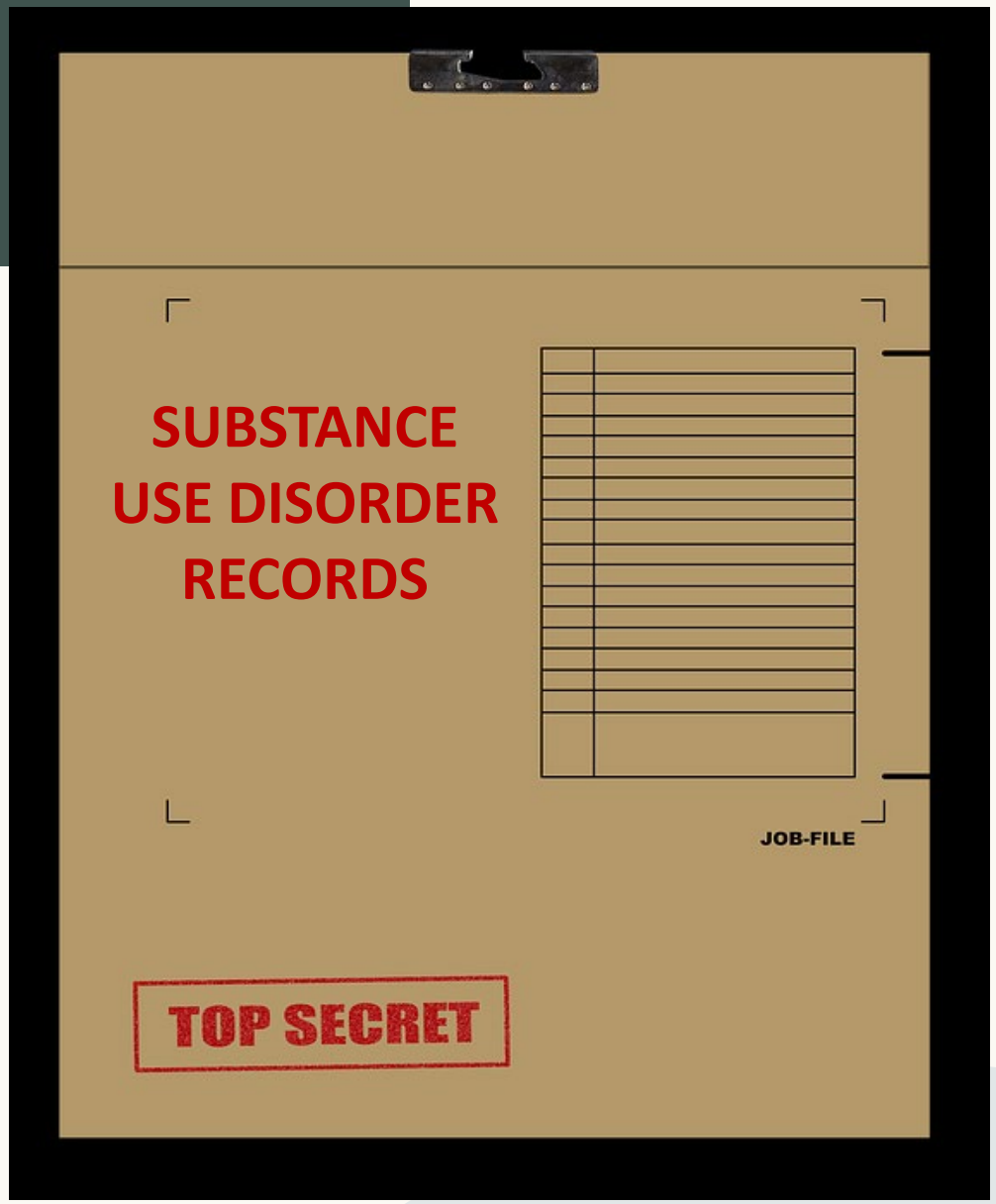
HOUSEKEEPING

- I will focus on application to healthcare providers, not govt agencies.
- Major changes appear in red.

- If you have questions,
  - Submit with chat feature, or
  - E-mail me at kcstanger@hollandhart.com
- Will respond offline.

Applicable Laws

- Confidentiality of substance use disorder ("SUD") records, 42 USC 290dd-2
  - Amended by CARES Act 3221
- SUD confidentiality regulations, 42 CFR part 2 ("Part 2")
- HIPAA privacy and security regulations, 45 CFR part 164 ("HIPAA")
- Information Blocking Rule, 45 CFR part 171
- Other federal and state laws or regs, e.g.,
  - Laws or regs re access or disclosure of SUD records.
  - Laws or regs re data privacy.



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.*,
  - Law that gives greater protection to patient info, or
  - Law that gives greater control of their info to the patient.

(42 CFR 2.20-2.21; 45 CFR 160.203)

Final Rule

- Issued February 8, 2024.
- Effective April 16, 2024.
- Enforced February 16, 2026.

(89 FR 12472)

- Implement CARES Act 3221 (42 USC 290dd-2) to coordinate regs concerning the confidentiality of SUD records with HIPAA.
  - Subpart A: prohibits use or disclosure of SUD records.
  - Subpart B: General provisions, *e.g.*, definitions, applicability, general restrictions, etc.
  - Subpart C: Uses and disclosures with patient consent.
  - Subpart D: Uses and disclosures without patient consent.
  - Subpart E: Court orders authorizing disclosures.

Highlights

- Allows single consent for all future uses and disclosures for treatment, payment and healthcare operations ("TPO").
- Allows HIPAA covered entities and business associates that receive records under such a consent to redisclose the records consistent with HIPAA regs.
- Modifies patient consent requirements.
- Requires copy of consent to be provided along with notice of part 2 obligations to recipients of info.
- Restricts use of records in civil, criminal, and administrative proceedings against patients absent patient consent or a court order.
- Adopts HIPAA penalties and enforcement process.
- Adopts HIPAA breach notification requirements for part 2 violations.
- Requires new patient notice similar to HIPAA notice of privacy practices.
- Adds complaint process.

Confidentiality of SUD Records
42 CFR Part 2

PURPOSE

To encourage persons to obtain treatment for a substance use disorder by limiting disclosure of info relating to their treatment.

REQUIREMENTS

- In general, part 2 programs and certain recipients of SUD records may not use or disclose info that would identify a person as having, having had, or having been referred for a SUD unless (i) the person provides written consent, or (ii) an exception applies.
- May not use or disclose SUD info in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state or local authority.

(42 CFR 2.12(a))

- SUD "record" really means any individually identifiable SUD info whether recorded or not.

(42 CFR 2.11)

Penalties

Old Rule:

- Specific criminal penalties:
  - $500 for first offense
  - $5000 for subsequent offenses

(42 CFR 2.3)

- Could also be liable for a HIPAA violation.

(42 CFR 160.401 *et seq.*)

New Rule: HIPAA penalties apply.

- Criminal penalties
  - $50,000 to $250,000
  - 1 to 10 years in prison

  (42 USC 1320d-6)
- Civil penalties.
  - No willful neglect: $137* to $68,928* per violation.
  - Willful neglect: mandatory penalties of $13,785* to $68,928* per violation.

  (42 USC 1320d-5; 42 CFR 2.2(6); 45 CFR 160.404 and -102.3)

Enforcement

- HIPAA enforcement processes apply to part 2 violations, *e.g.*,
  - OCR complaints and investigations.
  - OCR settlements and agreements.
  - OCR civil penalties.

(42 CFR 2.3(f); *see* 45 CFR 160.401 *et seq.*)

- Must self-report breaches in violation of rules if info was compromised.
  - HIPAA breach reporting rule. (45 CFR 164.402 *et seq.*)
  - Part 2. (42 CFR 2.16(b))

Applicability

Applicability: "SUD" Info

- Generally prohibits use or disclosure of info (whether recorded or not) without patient consent if the info:
  - Identifies a patient as having, having had, or referred for a SUD; and
  - Is created, received, or acquired by a federally assisted SUD program.

(42 CFR 2.11, 2.12(a) and 2.13(a))

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

(42 CFR 2.11)

Applicability: "Federally Assisted"

- "Federally assisted" =
  - Carried out under license or authorization granted by U.S. dept or agency (*e.g.*, participating in Medicare; DEA registration; or authorization to conduct maintenance treatment or withdrawal management).
  - Supported by funds provided by a U.S. department or agency (*e.g.*, receiving federal financial assistance, Medicaid, grants, etc., even if federal money does not pay directly for SUD services);
  - 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.
    - Special rules for VA or armed forces.

(42 CFR 2.12(b))

- *Not purely private pay programs, but HIPAA likely applies.*

Applicability: "Program"

- "Program" =
  - Individual or entity (other than general medical facility*) that 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, FQHCs, maybe primary care practice, *etc.*

(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
1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, *and* 2. Provides SUD diagnosis, treatment, or referral for treatment	1. Holds itself out as providing SUD diagnosis, treatment, or referral for treatment, *and* 2. Provides SUD diagnosis, treatment, or referral for treatment	1. Primary function is to provide SUD diagnosis, treatment or referral for treatment, *and* 2. 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, info presented to patients or families, *etc.*

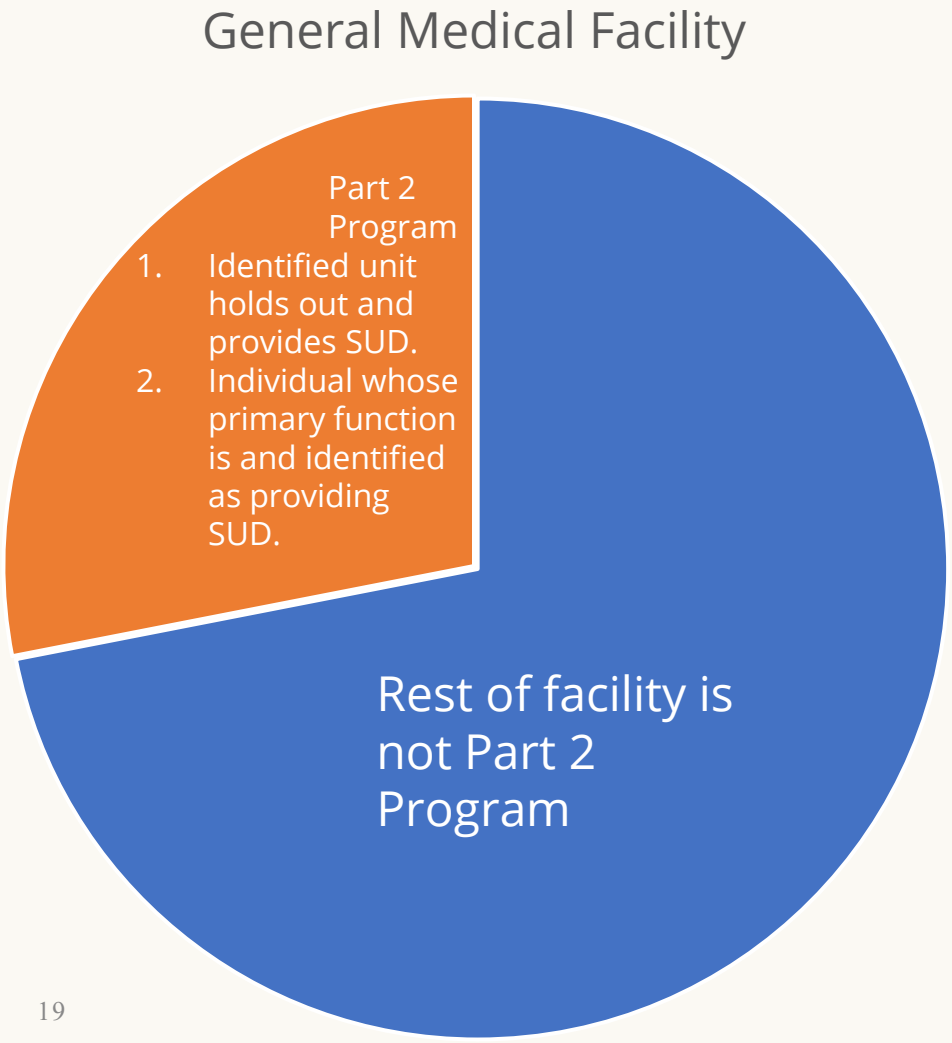
(SAMHSA FAQ 10, at https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)

Applicability:
Federally Assisted "Program"

- Part 2 program is not:
  - Emergency room personnel who treat overdose unless
    - Their primary function is to diagnose, treat or refer for SUD care, or
    - Emergency room has held itself out to the community as a provider of such SUD services.
  - Providers who prescribe controlled substances to treat SUD 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)

Applicability:
Federally Assisted Program



- Only the SUD unit/provider are the "program".
- Program must comply with part 2 in disclosing SUD info outside the program, *e.g.*,
  - Per consent
  - To administrative entity with control
  - To QSO
  - Other exception
- Program must have administrative controls in place to share SUD info.

Recipients Subject to Confidentiality
Restrictions

- Confidentiality requirements generally apply to certain recipients of SUD info, *e.g.*,
  - Entities with direct administrative control over part 2 program.
  - Qualified service organization ("QSO").
  - Lawful holder.
  - Persons receiving part 2 info from part 2 program, covered entity, business associate, intermediary or lawful holder who are notified of prohibited redisclosure per 2.32.
  - Third-party payers to whom records are disclosed by part 2 programs or per patient's written consent.
  - 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.

(42 CFR 2.11 and 2.12(d))

Qualified Service Organization ("QSO")

- Part 2 program may disclose SUD info to QSO.
- "QSO" = entity that:
  - Provides services for part 2 program, *e.g.*, data processing, collections, dosage prep, lab analyses, legal, accounting, or other professional service, medical staffing, population health management, etc.
  - Has written agreement with the part 2 program ("QSOA") to:
    - Comply with part 2 in dealing with SUD info from part 2 program; and
    - If necessary, resist judicial proceedings to obtain SUD info unless allowed by regs.
  - Includes business associates of the part 2 program if the part 2 program is a covered entity under HIPAA.

(42 CFR 2.11 and 2.12(c))

➢ *Similar to HIPAA business associate with business associate agreement ("BAA")*

Lawful Holders

- "Lawful holder" = entity that is bound by part 2 because they have received SUD info as a result of one of the following:
  - Received patient's written consent + notice of disclosure alerting them to part 2 requirements, or
  - One of the exceptions to written consent per part 2 or 42 USC 290dd-2.

(42 CFR 2.11)

- Lawful holders may redisclose SUD info under limited circumstances and depending on whether the holder is a part 2 entity, covered entity or business associate under HIPAA.

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

Non-Part 2 Providers

- 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 2.13(d)(2))

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

Recipients of Info for TPO

- A part 2 program, covered entity, or business associate that receives records based on a single consent for all TPO purposes is not required to segregate or segment such records.

(42 CFR 2.12(d)(2)(i)(C))

➢ *They are already obligated to comply with part 2 and HIPAA.*

Confidentiality

SUD Info

- Generally prohibits use or disclosure of info (whether recorded or not) 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.
    - *E.g.*, name, address, SSN, photos, or other identifiable info.
    - Not de-identified info.

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

Limits on Disclosure

- 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))

➢ *Similar to HIPAA "minimum necessary" standard.*

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

Responding to Inquiries about Patient

- May not acknowledge patient if 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 Info

WITH PATIENT'S CONSENT

- For TPO; one consent may apply to all future uses.
- For other purposes specified in consent.
  - ➢ *Consent must contain required elements.*
  - ➢ *Must include notice prohibiting redisclosure.*

(42 CFR 2.31-2.33)

WITHOUT PATIENT'S CONSENT

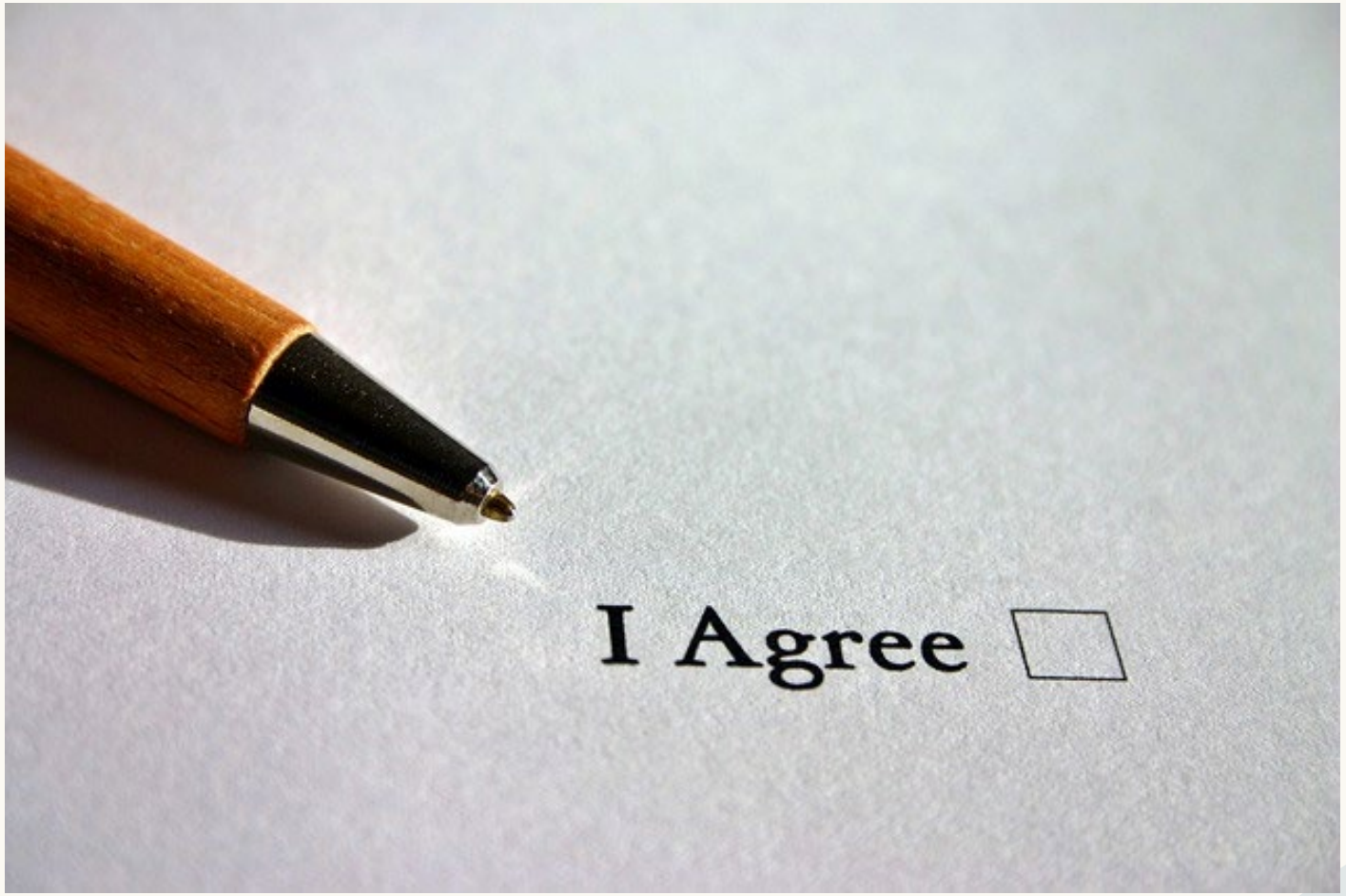
- Within part 2 program if need to know.
- Between part 2 program and those with direct administrative control.
- To QSO if have QSOA.
- Report to law enforcement a crime on part 2 program premises or threat against program personnel.
- Report suspected child abuse or neglect.

(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 order + subpoena.

(42 CFR 2.51-2.67)

Disclosures with Consent



Consent for Use or Disclosure: Requirements

Written consent may be paper or electronic but must contain following elements:

- 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.
- The recipients (see discussion below).
- 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 for Use or Disclosure: 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))

Consent for Use or Disclosure: SUD Counseling Notes

- Part 2 provides special protection for SUD counseling notes.
  - *Similar to "psychotherapy notes" under HIPAA.*

- "SUD counseling notes" = 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 SUD counseling session and that are separated from the rest of the patient's SUD and medical record.
- SUD counseling notes are not 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 diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

(42 CFR 2.11)

Consent for Use or Disclosure: SUD Counseling Notes

- Part 2 program must obtain consent for use or disclosure of SUD counseling notes except:
  - To carry out the following TPO functions:
    - Use by the originator of the SUD counseling notes for treatment;
    - Use or disclosure by part 2 program for its own clinician training programs; or
    - Use or disclosure by part 2 program to defend itself in proceeding brought by the patient.
  - Certain other limited uses or disclosures as specified in the regulations.
  - Written consent for a use or disclosure of SUD counseling notes may not be combined with written consent for disclosures of other records.
- A part 2 program may not condition treatment, payment, enrollment in a health plan, or eligibility for benefits on written consent for a use or disclosure of SUD counseling notes.

(42 CFR 2.31(b))

➢ *Similar to HIPAA rules for psychotherapy notes.*

Consent for Use or Disclosure:
Legal Proceedings

- Generally may not use SUD info in any civil, criminal, administrative, or legislative investigation or proceeding against the patient without:
  - Patient's written consent, or
  - Part 2 order from court.
- Patient consent for use or disclosure of SUD info 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 for Use or Disclosure:
Defective Consent

- 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))

➢ *Similar to HIPAA authorization rules.*

Notice + Copy of Consent

- Each disclosure of SUD info made with patient's written consent must be accompanied by:
  - A copy of the consent or a clear explanation of the scope of the consent.
  - One of two required statements (see next slide).

(42 CFR 2.32)

➢ *Purpose is to notify the recipient of their obligation to maintain the confidentiality of the SUD info.*

Notice + Copy of 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))

Disclosures with Written Consent

- If patient gives a single written consent for all future uses and disclosures 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.
  - *Part 2 program must comply with part 2.*
  - *Covered entity and business associate must comply with HIPAA.*
- If patient gives a specific written consent, the part 2 program must limit any use or disclosure of the SUD info accordingly.
- Disclosures to central registries and in connection with criminal justice referrals must meet the additional requirements of 2.34 and 2.35.

(42 CFR 2.33(a))

Disclosures with Written Consent: Redisclosure by Recipients

- If patient gives written consent for use or disclosure of their records, the recipient may further disclose such records as provided in subpart E of this part, and as follows:
  - If disclosed for TPO to a covered entity or business associate, recipient may further disclose the records in accordance with HIPAA.
    - Exception: may not use or disclose for civil, criminal, administrative, and legislative proceedings against the patient.
  - 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.
  - 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 ("subcontractor") to carry out the payment or healthcare operations specified in the consent on behalf of such lawful holders if certain conditions satisfied.

HIPAA applies

Part 2 applies

HIPAA does not apply

(42 CFR 2.33(b))

Disclosures with Written Consent Redisclosure by Recipients

- 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 info;
  - Provide the notice of part 2 obligations (see 2.32) 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))

Disclosures with Written Consent: Prescription Drug Monitoring Programs

- Part 2 program or lawful holder may report SUD medication prescribed or dispensed by the part 2 program to the state PDMP if:
  - Disclosure required by state law, and
  - Part 2 program or lawful holder obtains patient's written consent prior to reporting the info.

(42 CFR 2.36)

➢ *Include in consent form.*

Disclosures with Written Consent: 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:
  - Patient written 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.
- Central registry or withdrawal program may communicate limited info re prescriptions or to avoid multiple enrollments.

(42 CFR 2.34)

➢ *See specific requirements in regs.*

Disclosures with Written Consent: To Criminal Justice System

- Part 2 program may disclose SUD info to persons in criminal justice system who have made participation in the program a condition in proceedings against patient if:
  - Patient has signed written consent; and
  - Disclosure limited to those with need to know.

(42 CFR 2.35)

➢ *See specific requirements in regs.*

Disclosures without Consent

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Disclosure without Patient Consent

- Communications within part 2 program based on need to know.
- Communications between part 2 program and entity with direct administrative control over the program.
- Communications with a QSO.
  - Must have QSOA.
- Report to law enforcement crime or threats (i) on program premises or (ii) against program personnel.
  - Limit info to circumstances of incident, *e.g.*, patient name and address, patient status, whereabouts, *etc.*
- Report child abuse or neglect per state law.
  - May not disclose SUD records.

(42 CFR 2.12(c))

Disclosure without Patient Consent

- Bona fide medical emergency if
  - Patient's prior written consent cannot be obtained, or
  - Part 2 program is closed and unable to provide services or obtain prior written consent during a temporary state of emergency declared by state or federal authority as a result of natural or major disaster until such time as part 2 program resumes operations.
- Report to FDA if health of individual threatened by error in manufacture, labeling or sale of product.
- Immediately following disclosure, part 2 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, and nature of emergency.

(42 CFR 2.51)

Disclosure without Patient Consent

- Audit of part 2 program or lawful holder on behalf of govt agency, third party payers, QIO, accreditation agency, entity with administrative control.
  - Rules differ depending on whether records are copied or removed from part 2 program.
  - If patient consented to disclosures for healthcare operations:
    - A part 2 program, covered entity, or business associate may disclose info for audits and quality assurance activities; and
    - Recipient may redisclose such records as permitted under HIPAA regulations if the recipient is a covered entity or business associate.

(42 CFR 2.53)

➢ *See specific conditions in regs.*

Use of SUD Records in Criminal, Civil or Administrative Actions

- Cannot use SUD records in any federal or state civil, criminal, or administrative proceeding, investigation, or action unless have either:
  - Patient's consent, or
  - Court order issued per 42 CFR part 2.

(42 CFR 2.12(d))

- Cannot place undercover agent or informant in part 2 program or use any info obtained from them unless satisfy certain conditions.

(42 CFR 2.17 and 2.67)

Subpoenas and Orders

May disclose SUD info if have:

- Court order + subpoena authorizing disclosure if:
  - Protect life or serious bodily injury;
  - Extremely serious crime committed by patient; or
  - Disclosure in connection with proceeding in which patient offers testimony or other evidence pertaining to content of the confidential communications.
- Separate confidential process to obtain order after hearing.
- Order must limit use or disclosure outside the hearing.

➢ *See regs for specific process for obtaining order, including notice to holder of record.*

(42 CFR 2.61-2.67)

Minors and Patients Lacking Capacity

Minor Patients

- If minor may consent to SUD 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 not consent to care under state law:
  - May not disclose minor's request for treatment to parent/guardian unless:
    - Minor gives written consent to disclose to parent/guardian, or
    - Minor lacks capacity to make rational decisions.
  - Any consent for disclosure to others must be given by minor and parent/guardian.
- May disclose facts relevant to substantial threat to minor or other person to parent/guardian if:
  - 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

- 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))

Patient Rights

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Identification Cards

- Away from part 2 program premises, program may not require patient to carry in their immediate possession ID cards or other object that would identify the patient has having a SUD.
- On the part 2 program premises, may require patient to use or carry cards or other identification objects.

(42 CFR 2.18)

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)

But remember:

- HIPAA generally requires "covered entities" to allow patient access to protected health info in a designated set unless exception applies, e.g.,
  - Psychotherapy notes, or
  - Disclosure would result in harm to patient, but decision subject to review

  (45 CFR 164.524)
- Information Blocking Rule prohibits "actors" from unreasonably blocking access to electronic health info unless exceptions apply. (45 CFR part 171)

Restrict Use or Disclosure for TPO

- Patient may but is not required to consent to uses or disclosures for TPO.
- Patient may request that part 2 program restrict uses or disclosures for TPO to which they have consented.
- Part 2 program is not required to consent to restrictions.
  - Exception: if disclosure is to a health plan re service for which patient or other person has paid in full and disclosure is not otherwise required by law.
- If part 2 program agrees to restriction, it must comply with agreement.
  - Exception: part 2 program may disclose info if the patient requires emergency treatment, but program must ask recipient not further use or disclose the info.
- Part 2 program may terminate the restriction prospectively upon notice to patient.

(42 CFR 2.26)

Accounting of Disclosures

- General rule:
  - Upon request, part 2 program must provide the patient with an accounting of all disclosures made with consent under § 2.31 in prior 3 years or a shorter time period chosen by the patient.
  - The accounting must meet the requirements of 45 CFR 164.528(a)(2) and (b) through (d), e.g.,
    - Include date, name of recipient, description of info, and basis for disclosure.
    - Provide no later than 60 days after request.
    - No charge for first request within 12-month period.
    - Maintain documentation to enable entity to provide accounting if requested.
- Disclosures for TPO:
  - If disclosures are made through an electronic health record, Part 2 program must provide a patient with an accounting of disclosures for TPO made during the prior 3 years.
    - *However, this provision is tolled until HHS issues new HIPAA regulations.*

(42 CFR 2.25)

List of Disclosures by Intermediaries

- "Intermediary" = 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.*, health info database.

(42 CFR 2.11)

- Upon request, intermediary must provide patients with a list of persons to whom the patient's records have been disclosed within last 3 years.
  - *See regs for specific requirements.*

(42 CFR 2.24)

Complaints

- Part 2 program must provide a process for receiving complaints.
- Person may file a complaint with HHS in the same manner that a person may file a HIPAA complaint.
- Part 2 program may not intimidate, threaten, coerce, discriminate or retaliate against a patient for asserting part 2 rights, including filing a complaint.
- Part 2 program may not require patients to waive right to file a complaint.

(42 CFR 2.4)

Notice to Patient

Upon admission or when patient gains capacity, part 2 program must:

- Inform the patient that federal law protects confidentiality of SUD info.
- Give patient written notice of the program's duties and privacy practices as specified in the regulations.

(42 CFR 2.22)

➢ *HHS plans to modify HIPAA requirements for notice of privacy practices to align with part 2 notice requirements.*

Notice to Patient:
Header

- Notice must contain the following 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.

(42 CFR 2.22(c)(4))

Notice to Patient:
Uses and Disclosures

- Describe uses and disclosures:
  - Each purpose for which part 2 program may disclose SUD records without the patient's written authorization.
  - Description + at least one example of uses and disclosures that require written consent.
  - Patient may provide a single consent for all future uses or disclosures for TPO.
  - Part 2 program will make uses or disclosures not described in this notice only with patient's written consent.
  - Patient may revoke written consent as provided in 42 CFR 2.31 and 2.35.

(42 CFR 2.22(b)(1)(ii))

Notice to Patient:
Uses and Disclosures

- Describe uses and disclosures (cont.):
  - Records or testimony relaying the content of SUD records shall not be used or disclosed in any civil, administrative, criminal, or legislative proceedings against the patient unless based on specific written consent or a court order.
  - Records shall only be used or disclosed based on a court order after notice and an opportunity to be heard is provided to the patient or the holder of the record where required by 42 U.S.C. 290dd-2 and this part.
  - A court order authorizing use or disclosure must be accompanied by a subpoena or other similar legal mandate compelling disclosure before the record is used or disclosed.

(42 CFR 2.22(b)(1)(ii))

Notice to Patient:
Uses and Disclosures

- Describe uses and disclosures (cont.):
  if part 2 program intends to engage in following activities--
  - Records that are disclosed to a part 2 program, covered entity, or business associate pursuant to the patient's written consent for TPO may be further disclosed by that part 2 program, covered entity, or business associate, without the patient's written consent, to the extent the HIPAA regulations permit such disclosure.
  - A part 2 program may use or disclose records to fundraise for the benefit of the part 2 program only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications.

(42 CFR 2.22(b)(1)(iii))

Notice to Patient:
Patient Rights

- Describe patient rights:
  - Right to request restrictions of disclosures w/consent for TPO.
  - Right to restrict disclosures to health plan if patient paid for services in full per 45 CFR 164.522.
  - Right to an accounting of disclosures of electronic records for the past 3 years.
  - Right to an accounting of disclosures per 45 CFR 164.528 for other disclosures made with consent.
  - Right to a list of disclosures by an intermediary for the past 3 years.
  - Right to obtain a paper or electronic copy of the notice upon request.
  - Right to discuss the notice with a designated contact person or office.
  - Right to elect not to receive fundraising communications.

(42 CFR 2.22(b)(1)(iv))

Notice to Patient:
Part 2 Program Duties

- Describe part 2 program's duties:
  - Part 2 program is required by law
    - to maintain the privacy of records,
    - to provide patients with notice of its legal duties and privacy practices, and
    - to notify affected patients following a breach of unsecured records.
  - Part 2 program is required to abide by the terms of the notice currently in effect; and
  - If the part 2 program wants to apply a change in the privacy practices to records created or received before issuing revised notice, the program reserves the right to do.
  - How the program will provide patients with a revised notice.

(42 CFR 2.22(b)(1)(v))

Notice to Patient:
Additional Items

- Explain rights to file a complaint, i.e.,
  - Patient may complain to the part 2 program and to the Secretary if they believe their privacy rights have been violated,
  - How the patient may file a complaint with the program,
  - Patient will not be retaliated against for filing a complaint.
- Name, or title, telephone number, and email address of a person or office to contact for further information about the notice.
- Effective date of the notice, which may not be earlier than the date on which the notice is printed or otherwise published.

(42 CFR 2.22(b)(vi-viii)

Notice to Patient:
Additional Items

- Explain rights to file a complaint, i.e.,
  - Patient may complain to part 2 program and HHS if their rights have been violated,
  - How the patient may file a complaint with the program, and
  - No retaliation for filing a complaint.
- Name or title, telephone number, and email address of contact person for more info.
- Effective date of notice, which may not be earlier than date on which notice is printed or published.
- Part 2 program must promptly revise and distribute notice if material change in practices or duties.
- Part 2 program may not implement changes before distributing new notice except if law requires otherwise.

(42 CFR 2.22(b)(vi-viii)

Notice to Patient:
Implementation

- Make notice available to any person or patient upon request.
- Provide notice:
  - No later than first service delivery, including e-service.
  - In emergency, ASAP after emergency.
- If maintain physical delivery site:
  - Have notice available for patients to take with them.
  - Post notice in prominent location without identifying person as a patient.
- If maintain website, post on website and make available through website.
- May provide notice by e-mail if patient agrees.
- Provide paper copy if patient requests.

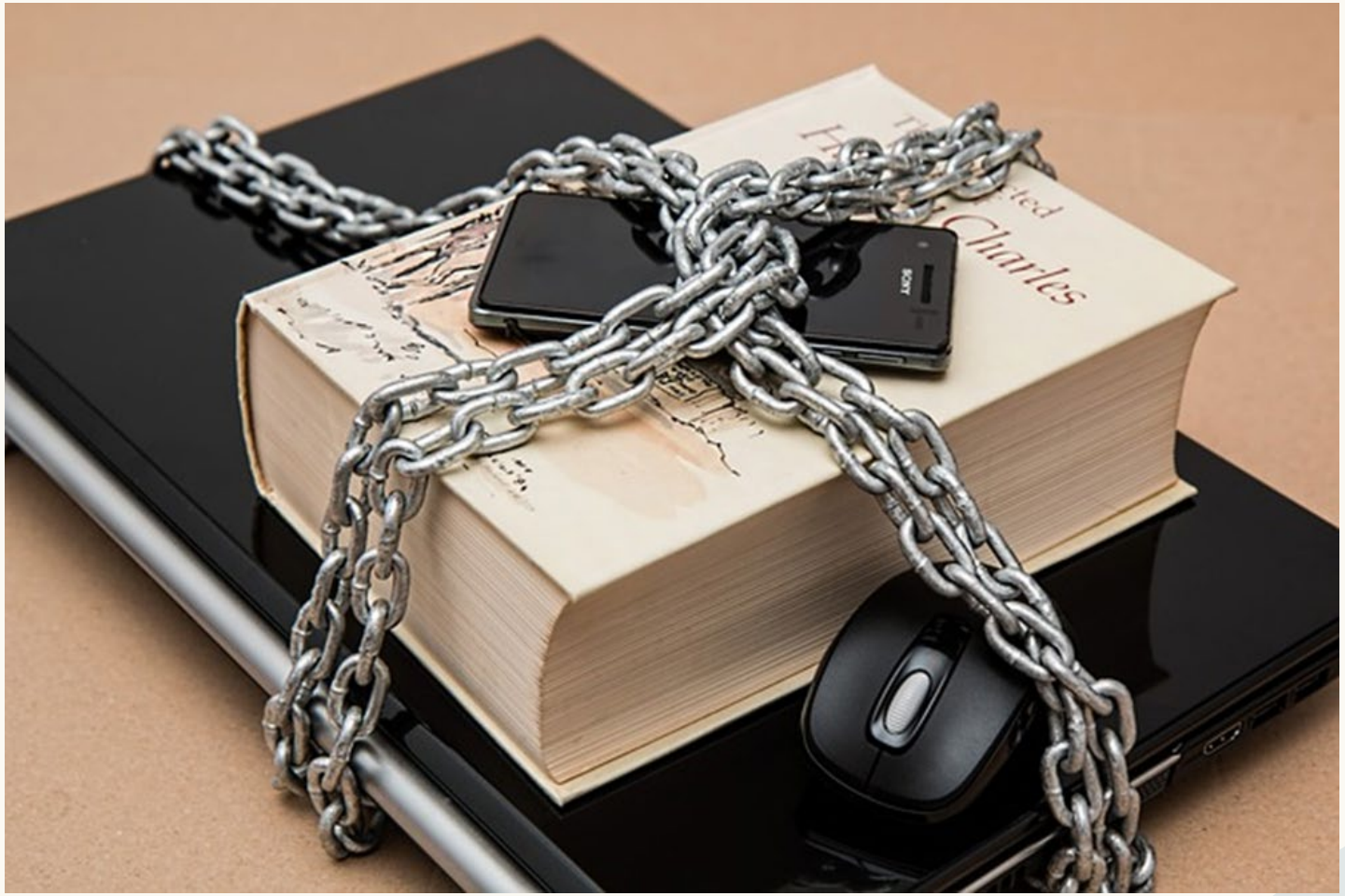
(42 CFR 2.22(b)(vi-viii)

Anti-Discrimination

- No entity shall discriminate against a person based on SUD info re:
  - admission, access to, or treatment for health care;
  - hiring, firing, or terms of employment, or receipt of worker's compensation;
  - the sale, rental, or continued rental of housing;
  - access to Federal, State, or local courts; or
  - access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.
- No recipient of federal funds shall discriminate against a person based on SUD info in affording access to services.

(CARES Act 3221(g), amending 42 USC 290dd-2)

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.

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Breach Notification

- Part 2 program must notify individual and HHS if there is a breach of unsecured SUD info to same extent a covered entity must provide notification of breach under HIPAA.

(42 CFR 2.16(b))

- Must report breach of unsecured PHI in violation of privacy rule which compromises the security or privacy of PHI.
  - Notice to individual.
  - Notice to HHS.
  - For business associates, notice to the covered entity.

(45 CFR 164.401 *et seq.*)

Disposition of Records

- If a part 2 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 records to new entity; or
  - Applicable law requires records to be retained for specified period that extends beyond acquisition or discontinuation of program.
    - Must comply with specific requirements set forth in the regs concerning how paper or electronic records are maintained.
    - Must destroy records upon expiration of retention period.

(42 CFR 2.19)

To Do by February 26, 2026

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To Do

- Remember: you still have obligation to comply—
  - HIPAA
  - Current part 2 rules
  - More restrictive state laws
    - May want to review existing laws to confirm which is more stringent.
  - ➢ *Don't put off compliance.*
- Determine if and to what extent you are a part 2 program, QSO, lawful holder or otherwise covered by part 2.
- Determine if and to what extent you have relationships with QSOs, intermediaries, lawful holders, and other entities that must be considered.

To Do

- Review and, if needed, modify processes for disclosures of SUD info within and outside your organization.
- Identify, draft and execute QSOAs with:
  - QSOs
  - Business associates
  - *Likely review and modify existing HIPAA business associate agreements.*
- May require review, negotiation, training, and/or termination of current business relationships.
  - Check termination and notice provisions.
  - May be justified in terminating due to public policy or impossibility of performance.

To Do

- Review and, if necessary, update your security risk assessment.
  - See https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool
- Review and update your privacy and security policies.
  - Ensure compliance with part 2 policy requirements, including disposal of SUD info.
    - *Likely modify existing HIPAA privacy and security policies.*
- Ensure you have effective cybersecurity protections.

To Do

- Draft and implement new patient consent forms.
  - Ensure it contains required elements.
  - Authorize use and disclosure for TPO.
  - Consider having existing patients execute new forms.
- Review and update notice to recipients that accompanies disclosures.
  - *See updated statement.*
- Draft new patient notice of confidentiality rights.
  - Ensure it contains required elements.
  - ➢ *Likely modify existing HIPAA Notice of Privacy Practices.*
  - Publish it shortly before enforcement date.

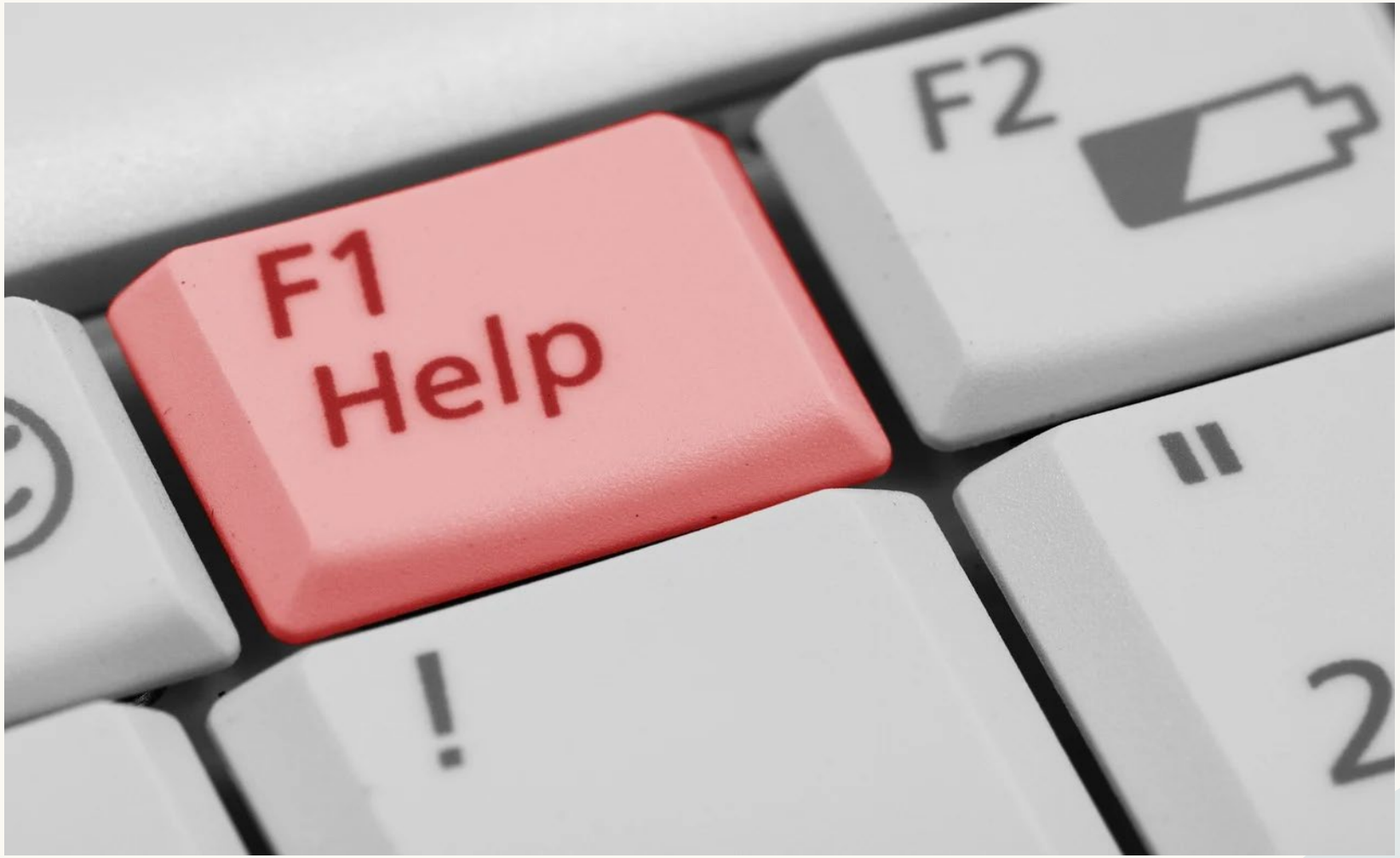
To Do

- Review, draft, and implement policies concerning patient rights.
  - Complaint processes.
  - Access to info.
  - Request for restrictions on uses and disclosures for TPO.
  - Accounting of disclosures, especially if you have electronic record systems.
  - ➢ *Likely may update existing HIPAA policies.*

To Do

- Train staff and document training.
  - New policies and procedures.
  - Use and disclosure rules.
  - Use of consents and other forms.
  - Distribution of consent + notice to lawful holders.
  - Distribution of and compliance with patient notice.
  - Common scenarios and exceptions to use or disclosure rules.
  - Other.

Additional Resources



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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

OO OCR HIPAA Security Rule information distribution <OCR-SECURITY-LIST@LIST.NIH.GOV> on behalf of OS OCR SecurityList, OCR (HHS/OS) <OCRSecurityList@HHS

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

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

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.

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

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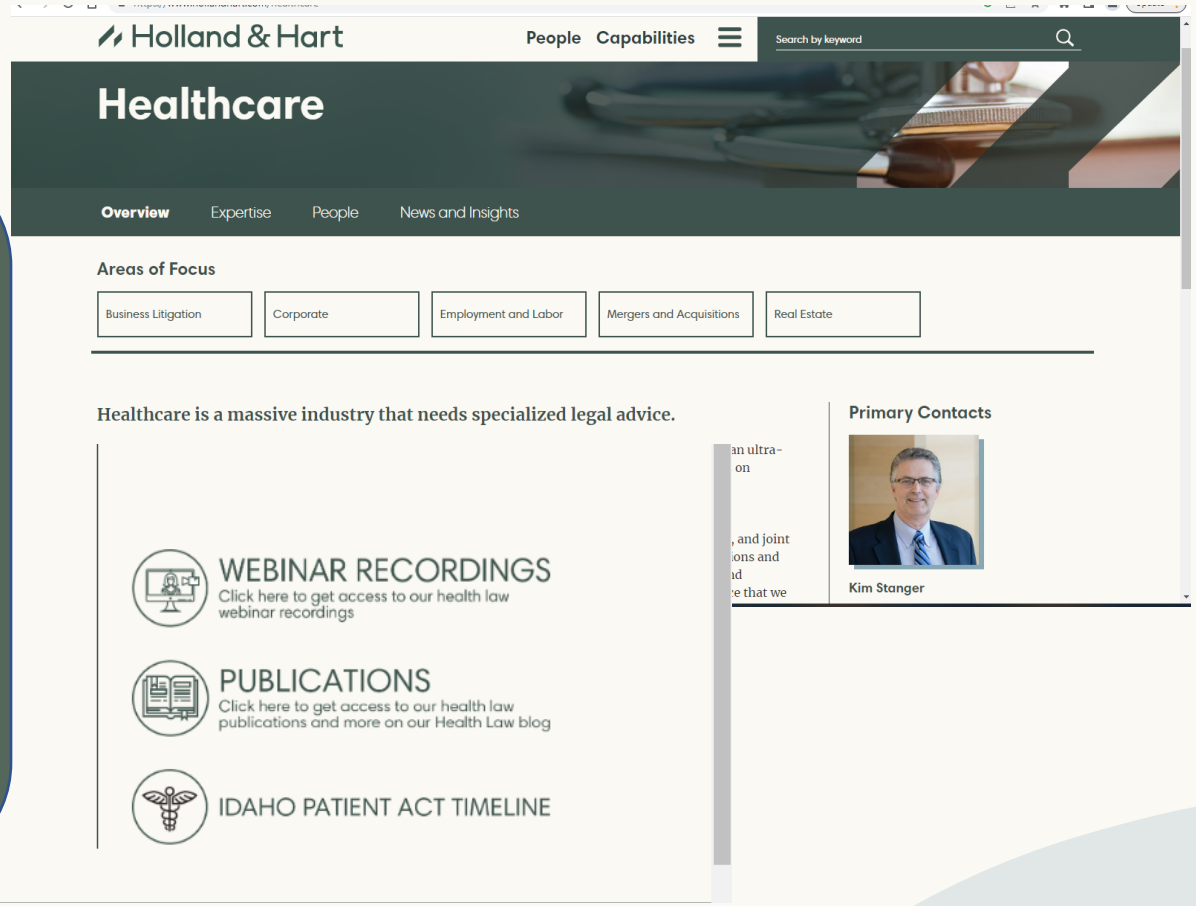

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Questions?

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