

42 CFR PART 2: UPDATE AND OVERVIEW

**SUBSTANCE
USE
DISORDER
RECORDS**



Kim C. Stanger
Holland & Hart
LLP
(2/21)

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COMPLIANCE WEBINAR SERIES

Date	Webinar
2/4/2021	Cybersecurity and Data Privacy
2/9/2021	Information Blocking Rule
2/11/2021	HIPAA
2/16/2021	42 CFR Part 2
2/18/2021	Immunity for Healthcare Entities regarding COVID
2/23/2021	Unique Compliance Concerns Applicable to Utah
2/25/2021	Employment Law Issues
3/4/2021	Interpreters, Translators, and Assistance for Those with Disabilities
3/11/2021	EMTALA
3/18/2021	Creating, Managing and Terminating Patient Relationships
3/25/2021	Antitrust
4/1/2021	FDA Regulatory Issues for Medical Device Companies



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OVERVIEW

- Update re recent amendments
 - Application
 - Part 2 programs
 - SUD records
 - Confidentiality requirements
 - Disclosures
 - Redisclosures
 - Additional requirements
- Program will be recorded.
 - If you have questions:
 - Submit them using chat feature, or
 - E-mail me at KCStanger@hollandhart.com

WRITTEN MATERIALS

- CARES Act § 3221
- 42 CFR part 2 (rev'd 7/15/20)
 - Highlighted changes
- Confidentiality of Substance Use Disorder Patient Records, 85 FR 42986 (7/15/20), <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf>
- SAMHSA Fact Sheet: *Does Part 2 Apply to Me?*, <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>
- SAMHSA Fact Sheet: *How Do I Exchange Part 2 Data?*, <https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf>
- SAMHSA Fact Sheet: *SAMHSA 42 CFR Part 2 Revised Rule*, <https://www.samhsa.gov/newsroom/press-announcements/202007131330>
- SAMHSA FAQs: *Applying the Substance Abuse Confidentiality Regulations*, <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>

APPLICABLE LAWS

- 42 USC 290dd
- CARES Act 3221
- Confidentiality of Substance Use Disorder Patient Records, 42 CFR part 2
- HIPAA privacy and security regulations, 45 CFR part 164
- Other federal and state laws, e.g.
 - Information Blocking Rule
 - State laws re access or disclosure of SUD records



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)

➤ *Must still comply with HIPAA and other applicable laws.*

CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS, 42 CFR PART 2

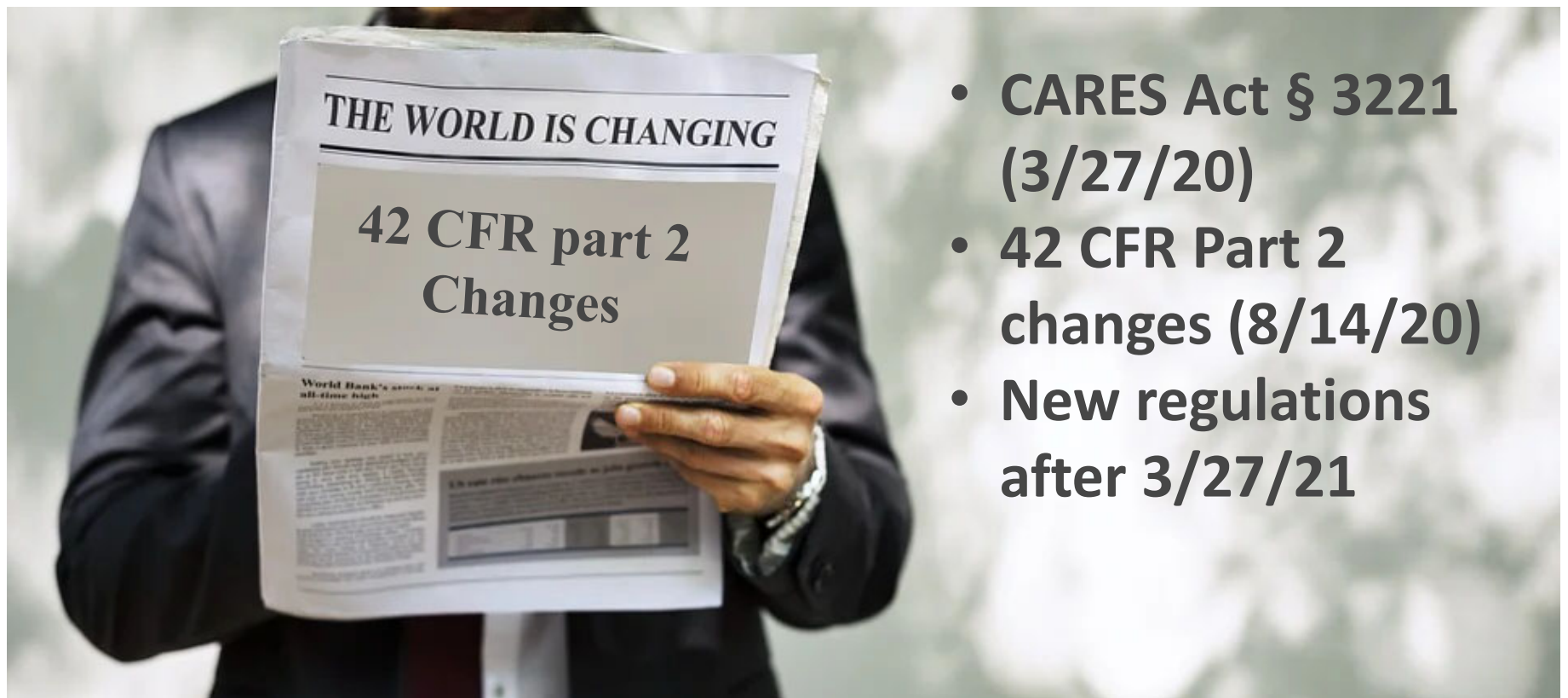
Purpose

- To encourage persons to obtain treatment for a substance use disorder (“SUD”) by limiting disclosure of info relating to their treatment.

Requirements

- In general, part 2 programs may not disclose any info that would identify a person as having, or having had, or being referred to 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.

UPDATE



- CARES Act § 3221 (3/27/20)
- 42 CFR Part 2 changes (8/14/20)
- New regulations after 3/27/21

CARES ACT § 3221

- Allows disclosure of SUD info for treatment, payment or healthcare operations if obtain initial consent.
- May share de-identified info with public health authority
- Limits use of SUD info in criminal, civil and administrative proceedings.
- Replaces criminal penalties with HIPAA penalties.
- Prohibits discrimination against persons based on SUD info.
- Requires breach notification for improper disclosure of SUD info.
- Requires HHS to promulgate regulations applicable to uses or disclosures of SUD info after 3/27/21.
- Requires HHS to update HIPAA notice of privacy practices rules.

(CARES Act 3221, amending 42 USC 290dd)

➤ *In limbo until final rules issue...*

42 CFR PART 2 REGULATIONS (EFFECTIVE 8/14/20)

- Finalizes rules proposed in 2019, primarily to facilitate coordinated care.
 - Limits application to non-part 2 providers who record oral info or segregate part 2 records.
 - Consent requirements relaxed.
 - Easier to disclose to central registries and prescription drug monitoring programs.
 - Exception for medical emergencies expanded.
 - Modifies rules for research disclosures.
 - Modifies rules for audit disclosures.
- Does not address CARES Act § 3221.
(85 FR 42986 (7/15/20))

ANTICIPATED REGULATIONS



- Watch for new regs implementing CARES Act § 3221 by (or maybe after?) **March 27, 2021.**

PENALTIES

42 CFR part 2

- Enforced by Dept. of Justice (“DOJ”)
- Criminal penalty
 - \$500 for first offense
 - \$5000 for subsequent offenses

(42 CFR 2.3)

- Might be subject to private lawsuit, e.g.,
 - Common law privacy tort.
 - Negligence *per se*
 - Other?

CARES Act § 3221

- Eliminates criminal penalties.
- Incorporates HIPAA penalties for part 2 violation.
 - Penalties of \$199* to \$59,522* per violation.
 - Mandatory penalties of \$11,904* to \$59,522* per violation for “willful neglect.”
- Must report breaches of unsecured PHI per HIPAA.



HIPAA CIVIL PENALTIES

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none">• \$119* to \$59,522* per violation• Up to \$25,630* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none">• \$1,191* to \$59,522* per violation• Up to \$102,522* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none">• \$11,904* to \$59,522* per violation• Up to \$256,305* per type per year• Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none">• At least \$59,522* per violation• Up to \$1,754,698* per type per year• Penalty is mandatory

(45 CFR 102.3, 160.404; 85 FR 2879)

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APPLICABILITY



APPLICABILITY: 42 CFR PART 2

- Generally prohibits use or disclosure of records without patient consent if:
 - Record identifies a patient as having, having had, or referred for a substance use disorder (“SUD”); and
 - SUD record is created, obtained, or maintained by a federally assisted drug or alcohol abuse program.

(42 CFR 2.12(a))

- “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)

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, Medicaid, 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.
 - *But HIPAA may still apply.*

(42 CFR 2.12(b))

APPLICABILITY: FEDERALLY ASSISTED “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; <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

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>)

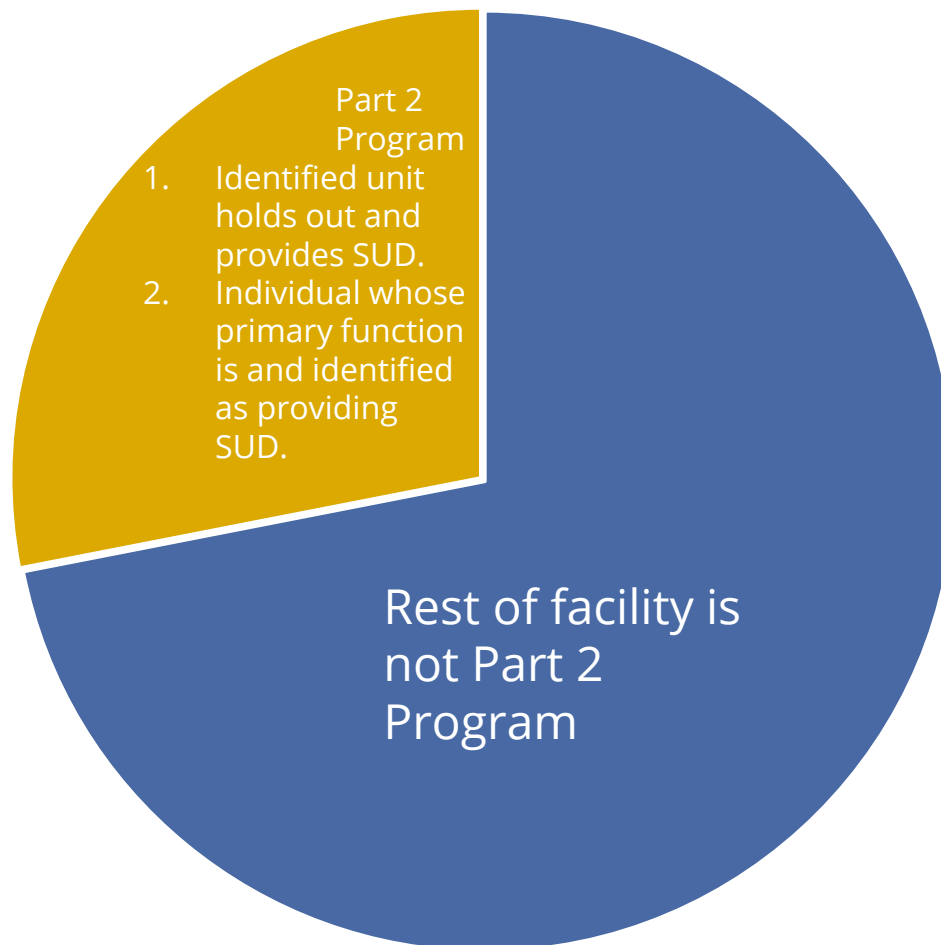
APPLICABILITY: FEDERALLY ASSISTED “PROGRAM”

- Part 2 program is not:
 - Emergency room personnel who treat overdose.
 - Providers who prescribe controlled substances to treat SUD but who do not hold themselves out as providing SUD treatment.

(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



- 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 control
 - To QSO
 - Other exception
- Program must have administrative controls in place to share SUD info.

CONFIDENTIALITY



SUD RECORD

- Generally prohibits use or disclosure of records without patient consent if:
 - Record identifies a patient as having, having had, or referred for a substance use disorder (“SUD”); and
 - Is SUD record is 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))

“RECORDS”

- Any info, whether recorded or not, created, received or acquired by a part 2 program relating to a SUD patient.
 - E.g., diagnosis, treatment, referral for treatment, billing, e-mails, voicemails, texts, etc.
 - Paper, electronic, oral, images, etc.
- Includes written info conveyed by part 2 provider to non-part 2 provider.
 - Non-part 2 provider may segregate records.
- Not oral info conveyed by part 2 provider to non-part 2 provider for treatment with consent of patient even though non-part 2 provider reduces to writing.

(42 CFR 2.11, as amended)

“PATIENT IDENTIFYING INFO”

- Applies to any info initially prepared by a part 2 program that would identify the patient as having or having had a SUD, including records indicating patient was diagnosed with, received, or was referred for SUD treatment.
 - E.g., name, address, SSN, 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.
 - Diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual does not have a SUD (e.g., involuntary ingestion of drugs or reaction to prescribed dosage).
 - De-identified info.

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

ENTITIES THAT MUST MAINTAIN CONFIDENTIALITY

- Prohibition against disclosure applies to:
 - Part 2 program.
 - Entities having direct administrative control over the part 2 program.
 - “Lawful holders”, e.g., persons who:
 - Receive SUD info from a part 2 program, and
 - Receive required notice prohibiting redisclosure.

(42 CFR 2.12(d)(2), as amended)

DISCLOSURE TO NON-PART 2 PROVIDERS

- Part 2 provider may disclose part 2 info to non-part 2 provider with patient consent.
- Part 2 does not apply to non-part 2 provider's own records so long as they do not incorporate the part 2 record.
 - Oral part 2 info does not cause the non-part 2 provider's records to become subject to part 2 even though the non-part 2 provider records it.
 - Written part 2 info does not cause the non-part 2 provider's own records to become subject to part 2 so long as the part 2 info is segregated.

(42 CFR 2.12(d)(2), as amended; 85 FR 42991)

➤ *Segregate part 2 records to avoid having non-part 2 program records become subject to part 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 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 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))

DISCLOSURE OF SUD INFO

With patient's written consent

- For treatment, payment or healthcare operations.
- For other purposes specified in consent.
- Consent must contain required elements.
- Must include notice prohibiting redisclosure.

(CARES Act 3221; 42 CFR 2.31-2.33)

➤ *Compare HIPAA.*

Without patient's written consent

- Within part 2 program if need to know.
- To those with administrative control over program.
- Qualified Service Organization ("QSO") 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.

PERMITTED DISCLOSURES WITH PATIENT CONSENT

- General: consent must be specific to use or disclosure.
- For treatment, payment or healthcare operations:
 - Patient may consent once for all future SUD disclosures by covered entity, business associates, and part 2 programs to use or disclose info for treatment, payment or healthcare operations as permitted by HIPAA.
 - SUD info may be redisclosed as permitted by HIPAA.
 - Applies until consent revoked.
 - Must account for such disclosures if maintain electronic health medical record.

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

- *Obtain patient's consent re treatment, payment and healthcare operations.*
- *CARES Act does not confirm elements for consent.*

CONSENT FOR DISCLOSURE: REQUIRED ELEMENTS

Per regulations, consent may be written or electronic but must contain following elements:

- Patient's name.
- Specific names or general designation of part 2 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.

(42 CFR 2.31)

CONSENT FOR DISCLOSURE: REQUIRED ELEMENTS (cont.)

- Name(s) of individual or entity recipients of info.
 - *Do not need to identify specific person at entity.*
 - If recipient facilitates exchange health info or is research institution, written consent must include:
 - Name(s) of individual or entity participant(s); or
 - General designation of an individual or entity participant(s) or class of participants that must be limited to participant(s) who has a treating provider relationship with the patient whose info is being disclosed.
 - When using general designation, a statement must be included on consent form that the patient confirms understanding that, upon request, they must be provided a list of entities to which their info has been disclosed pursuant to the general designation (see 42 CFR 2.13(d)).
 - See “List of Disclosures” below.

(42 CFR 2.31(a)(4), as amended)

CONSENT FOR DISCLOSURE: REQUIRED ELEMENTS (cont.)

- Statement that consent may be revoked at anytime unless part 2 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 upon which consent will expire, which can be no longer than necessary to serve the purpose of consent.
- Signed by patient or person legally authorized to consent on behalf of patient.
- Date of signature.

(42 CFR 2.31)

- *May not rely on consent that has expired, is facially defective or false, or has been revoked.*
- *And must include Notice of Redisdisclosure...*



NOTICE OF REDISCLOSURE

- If disclose with written consent, must include one of these notices with the SUD records produced:
 - “This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is 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)

PERMITTED 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 qualified service org (“QSO”).
 - Must have agreement with QSO (“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))

PERMITTED 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)

PERMITTED DISCLOSURE WITHOUT PATIENT CONSENT (cont.)

- Research, subject to conditions.

(42 CFR 2.52, as amended)

- Audit of part 2 program or lawful holder on behalf of govt agency, third party payers, QIO, entity with administrative control, subject to conditions.

(42 CFR 2.53, as amended)

- Disclosures to public health authorities if info is de-identified per HIPAA, 45 CFR 164.514(b).

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

LIMITS ON DISCLOSURE

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

(42 CFR 2.13(a))

- *Similar to HIPAA “minimum necessary” standard.*

QUALIFIED SERVICE ORGANIZATIONS

- Program may disclose to qualified service organizations (“QSOs”) to extent info needed by QSO to perform services to part 2 program.
 - E.g., data processing, collections, dosage prep, lab analyses, legal, accounting, or other professional service, medical staffing, population health management, etc.
 - *Compare “lawful holders” who receive info with patient consent.*
- Must have written agreement between program and QSO (“QSOA”).
 - *Compare HIPAA business associate agreement (“BAA”)*

(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 not 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 patient gives written consent to disclosures for payment or healthcare operations, recipient (“lawful holder”) may further disclose to contractors, subs and legal representatives to carry out such purposes if:
 - Have written contract or other legal instrument by which contractor is bound by part 2.
 - Furnish notice of redisclosure.
 - Require recipient to implement appropriate safeguards to protect info.
 - Require recipient to report unauthorized uses, disclosures, or breaches.
 - Lawful holder discloses only minimum necessary.
 - Recipient may only further disclose to contracted entity help them fulfill purposes of disclosure by lawful holder.

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

LAWFUL HOLDERS: DISCLOSURE FOR PAYMENT OR OPERATIONS

- Billing, claims, collections, etc.
- Clinical professional support, e.g., QA, utilization review, etc.)
- Patient safety activities
- Peer review, training, assessments, etc.
- Accreditation, certification, licensing, credentialing, etc.
- Underwriting, enrollment, premium rating, etc.
- Third party liability coverage.
- Address fraud, waste, abuse.
- Medical review, legal, auditing.
- Business planning, development
- Business management and general administrative duties.
- Customer service.
- Resolution of internal grievances.
- Sale, transfer, merger, dissolution.
- Determine eligibility of coverage, claims adjudication, subrogation.
- Review of medical necessity, coverage.
- Care coordination and/or case management.
- Others.

(42 CFR 2.33(b), as amended)

DISCLOSURES TO 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 law, and
 - Part 2 program or lawful holder obtains patient's written consent prior to reporting the info.

(42 CFR 2.36, as amended)

➤ *Include in consent form.*

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.
- Central registry or withdrawal program may communicate limited info re prescriptions or to avoid multiple enrollments.

(42 CFR 2.34, as amended))

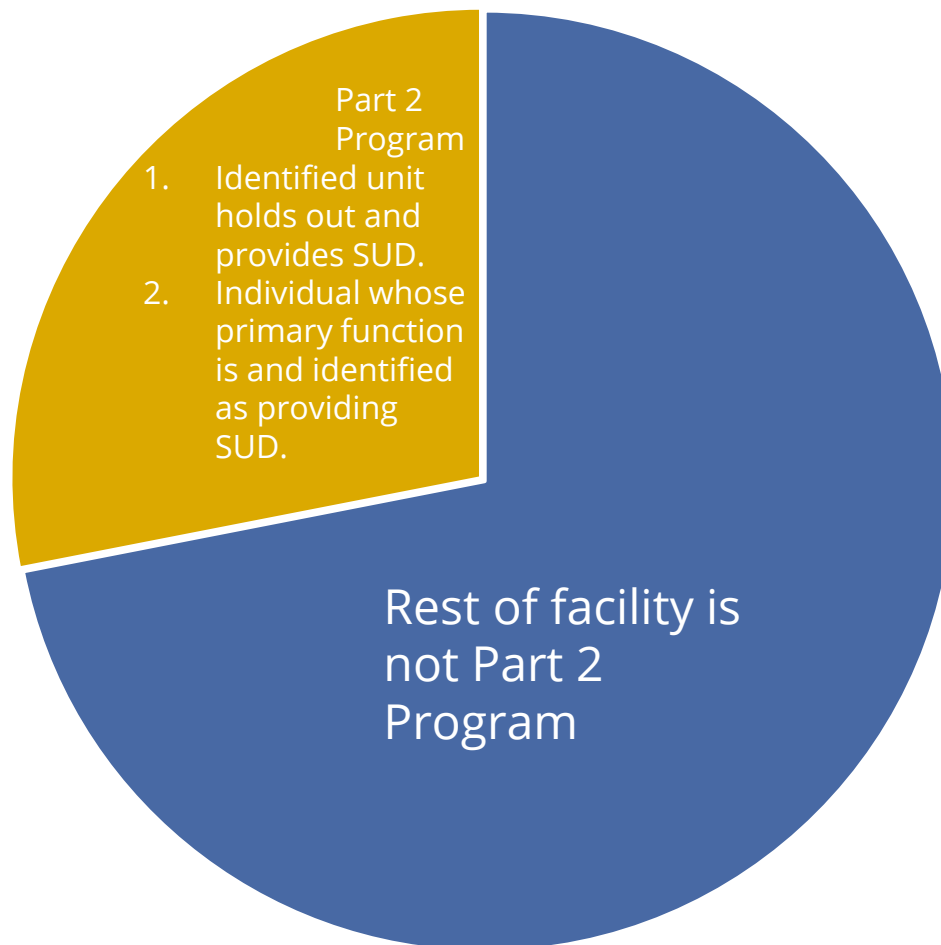
DISCLOSURES TO CRIMINAL JUSTICE SYSTEM THAT REFERRED PATIENT

- 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 additional 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)

SHARING SUD INFO WITHIN PART 2 PROGRAM

General Medical Facility



- 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 control
 - To QSO
 - Other exception
- Program must have administrative controls in place to share SUD info.

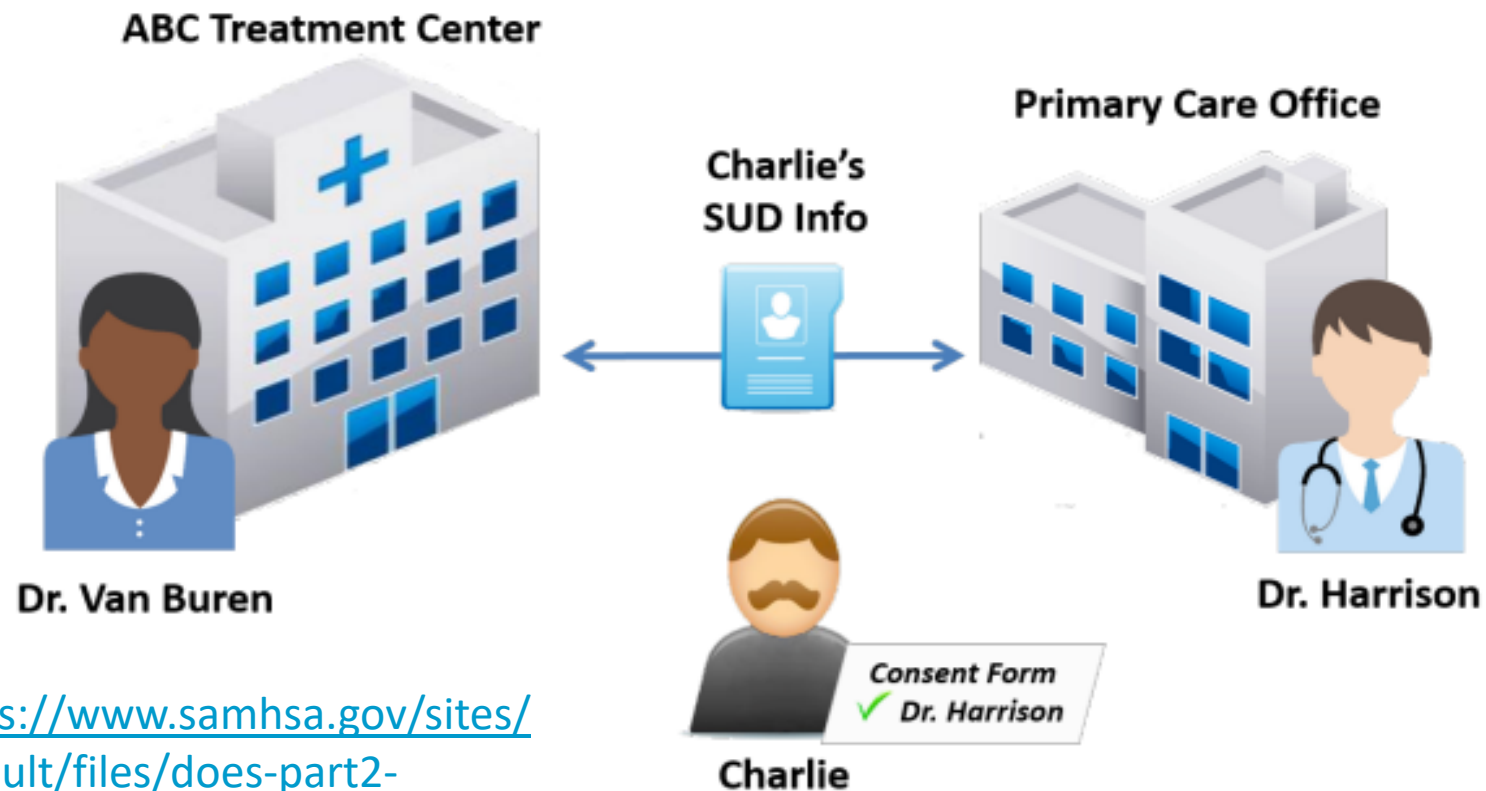
SHARING SUD INFO WITHIN PART 2 PROGRAM

- “[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>)

SCENARIO: TREATMENT PROGRAM

SCENARIO 1: OPIOID TREATMENT PROGRAM

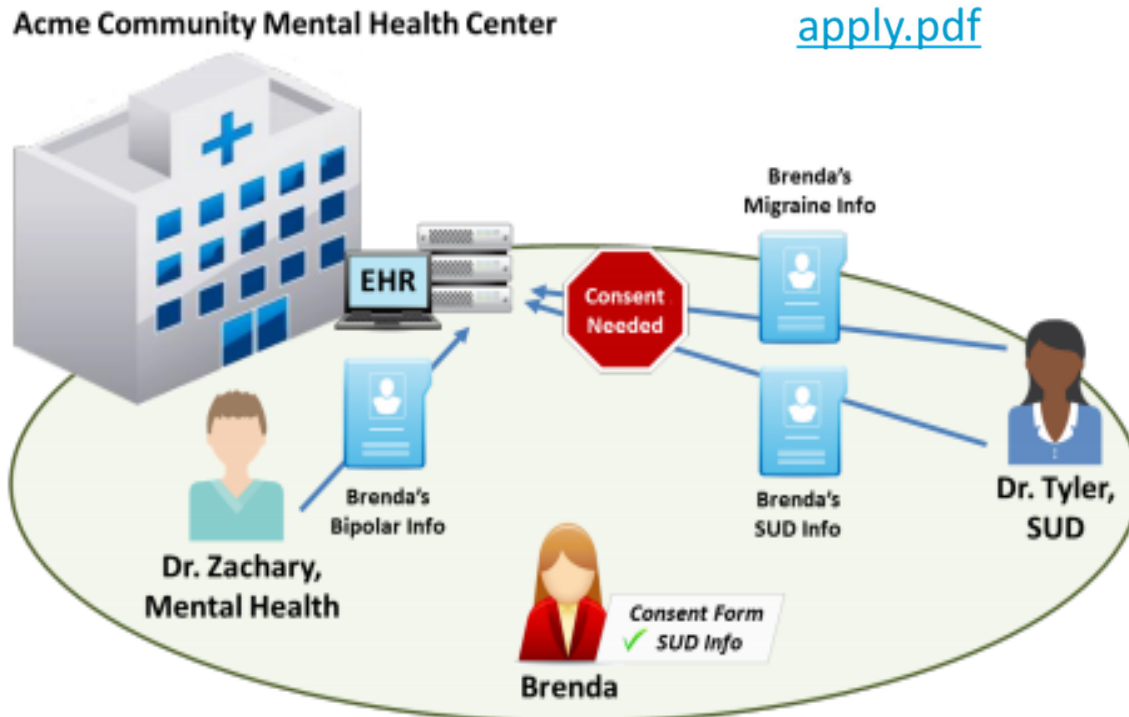


<https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>

SCENARIO: GENERAL MEDICAL FACILITY

SCENARIO 2: MIXED-USE FACILITY

<https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>



SCENARIO: INTEGRATED CARE SETTING

SCENARIO 4: INTEGRATED CARE SETTING

<https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>



Blue Mountain Physician Group

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



Dr. Pierce

- DEA registration
- SAMSHA waiver
- SUD not primary function

Brooke

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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 not consent to care under state law:
 - May not disclose minor's request for treatment to parent/guardian without minor's written consent unless minor lacks capacity.
 - 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.

(42 CFR 2.14)

INCOMPETENT PERSONS OTHER THAN MINORS

- If patient has been adjudicated as incompetent, consent for disclosure may be given by guardian or other individual authorized by state law to act on patient's behalf.
- If patient has not been adjudicated as incompetent but suffers from medical condition that prevents knowing or acting, part 2 program director may consent to disclosure of part 2 info 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.
- For other disclosures, written consent may be given by the following in decreasing order of priority:
 - Executor, administrator, or personal representative appointed under applicable state law.
 - Patient's spouse.
 - Any responsible family member.

(42 CFR 2.15(b))

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.
- Regulations have specific 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.*

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.

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

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

(42 CFR 2.17)

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)

ADDITIONAL REQUIREMENTS



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 laws and regulations, including:
 - Describe limited situations in which part 2 program may acknowledge that patient is present or disclose SUD.
 - ~~State that violation of law is a crime + contact info for 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 are not protected.
 - Cite federal laws and regulations.

(42 CFR 2.22)

HIPAA NOTICE OF PRIVACY PRACTICES

- By 3/27/21, HHS must update HIPAA notice of privacy practices rules, 45 CFR 164.520, to address SUD rules, including:
 - Statement of patient’s rights; and
 - Description of each purpose for which covered entity is permitted or required to use or disclose protected health info without the patient’s written authorization.

(CARES Act 3221(i))

➤ *See Proposed changes to HIPAA rules, 86 FR 6446 (1/21/21)*

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 exceptions satisfied. (45 CFR 164.524)
- Information Blocking Rule prohibits “actors” from blocking access to electronic health info unless exceptions satisfied. (45 CFR part 171)

LIST OF DISCLOSURES

- If (i) patient who has consented to disclosure to entity that facilitates exchange of health info (e.g., HIE) or research institution, and (ii) participants re identified through general designation per 2.31(a)(4)(ii)(B), patient 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))
- *Compare HIPAA right to accounting of disclosures.*

SECURITY

- Part 2 programs and lawful holders must have formal policies and procedures to reasonably protect against unauthorized use or disclosure of 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 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 concerning how paper or electronic records are maintained.
 - Must destroy records upon expiration of retention period.

(42 CFR 2.19)

DISPOSITION OF RECORDS: PERSONAL DEVICES, ACCOUNTS

- If patient contacts part 2 program employee's personal e-mail or cell phone account, employee should immediately:
 - Immediately:
 - Forward info through authorized channel,
 - Delete the info from personal account;
and
 - Respond through authorized channel.

(85 FR 42988-89)

- *Allows part 2 program to comply with disposition requirements without having to "sanitize" the personal device.*
- *Beware more restrictive state record retention laws.*

BREACH NOTIFICATION

- Part 2 program must notify individual (and HHS?) if there is a breach of SUD records to same extent covered entity must provide notification of breach of protected health info.

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

➤ *Unresolved questions—*

- *Do Breach Notification Rule standards and exceptions apply?*
- *Does entity report to OCR?*
- *But breach of part 2 info likely triggers HIPAA breach reporting, anyway.*

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)

ADDITIONAL RESOURCES



WWW.SAMHSA.GOV/ABOUT-US/WHO-WE-ARE/LAWS-REGULATIONS/CONFIDENTIALITY-REGULATIONS-FAQS

Substance Abuse Confidentiality x +

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

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Substance Abuse Confidentiality Regulations

Frequently Asked Questions (FAQs) and Fact Sheets regarding the Substance Abuse Confidentiality Regulations.

Fact Sheets regarding the Substance Abuse Confidentiality Regulations

- [Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me? \(PDF | 1.5 MB\)](#)
 - This fact sheet explains a 42 CFR Part 2 Program and how healthcare providers can determine how Part 2 applies to them.
- [Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data? \(PDF | 1.7 MB\)](#)
 - This fact sheet describes how 42 CFR Part 2 applies to the electronic exchange of healthcare records with a Part 2 Program.

Applying the Substance Abuse Confidentiality Regulations

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

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

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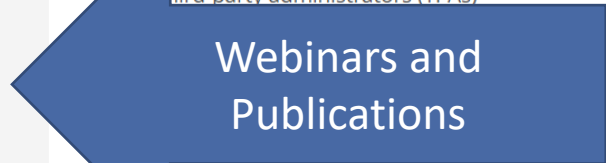
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3/11/2021	EMTALA
3/18/2021	Creating, Managing and Terminating Patient Relationships
3/25/2021	Antitrust
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QUESTIONS?



Kim C. Stanger
Office: (208) 383-3913
Cell: (208) 409-7907

kcstanger@hollandhart.com