



Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2) Colorado Bar Association, January 2018

Mitchell Berger

Substance Abuse and Mental Health Services Administration
U.S. Department of Health & Human Services



Disclaimer



→ This presentation is not intended to constitute legal advice. Any examples discussed are for illustrative purposes only. All questions about compliance with 42 CFR Part 2, HIPAA and other applicable state and federal laws and requirements should be directed to an individual's, agency's or organization's legal counsel.

Background: Health Privacy Legislation



- Congress noted discrimination associated with substance use disorders (SUDs) and fear of prosecution deterred people from entering treatment
- At that time most treatment provided by specialty providers
- Statute authorizing 42 CFR part 2 intended to ensure an individual's right to privacy and confidentiality.
- Persons with substance use disorders continue to be subject to discrimination in such areas as employment and housing

Background - 42 CFR Part 2

- Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. §1175) and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. §4582) authorized confidentiality for patient records
- Statute now at 42 USC § 290dd-2
- Initial part 2 regulations promulgated on July 1, 1975
- Substantive revisions: 1987, 2017, 2018

42 U.S.C. § 290dd-2

- **This statute is the basis for 42 CFR part 2 and cannot be changed except by Congress**
- “Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States” shall be confidential
- May be disclosed as permitted by prior written consent of the patient
- Subject to certain exceptions/exclusions

42 U.S.C. § 290dd-2

→ Exceptions to consent requirement:

- To medical personnel to the extent necessary to meet a bona fide medical emergency
- To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation but individual patients cannot be identified by those personnel in any report or otherwise disclosed
- If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm)
- Except as authorized by court order, no record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient

42 U.S.C. § 290dd-2

- Statute does not apply to:
 - Exchange of records within the Department of Veterans Affairs or between the VA and the Uniformed Services. VA to issue regulations and coordinate with HHS
 - Reports under state law of suspected child abuse or neglect
- Penalty: Violations fined under Title 18 of US Code
- Instructs HHS Secretary to promulgate regulations
- These regulations known as “42 CFR part 2” or “part 2”

Regulations-Penalty (§2.3)

- Penalty: Violations to be fined under Title 18 of US Code (Crimes and Criminal Procedure).
- Purpose and Effect (§2.2): Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute
- Penalty is enforced by DOJ, not SAMHSA
- Reports of violations to US Attorney in district where violation occurs
- For opioid treatment program, report to SAMHSA and DOJ
- No enforcement cases to date but due to criminal penalty regulation and statute likely to be “strictly construed” by courts
- While there is no federal private right of action, may be other penalties- accreditation issues, bad public relations, licensing issues for health professionals, perhaps state law claims (e.g., negligence)

Regulations-NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS (§2.22)

- At time of admission to Part 2 program or, if patient incapacitated, at time when patient is capable of rational communication, the program must provide written summary of part 2
- Paper or electronic
- Include description of limited situations when Part 2 program can disclose information
- Notice may include information on state law and program policies that are not inconsistent with Part 2
- Requires statement regarding the reporting of violations and providing contact information for the appropriate authorities.

Why Did SAMHSA Recently Revise 42 CFR Part 2?

- The last substantive update was 30 years ago.
- Significant changes have impacted health care delivery since 1987:
 - New models of integrated care that rely on information sharing to improve patient safety
 - Electronic infrastructure for managing and exchanging information
 - New focus on performance measurement
- SAMHSA wanted to ensure that patients with substance use disorders have the ability to participate in, and benefit from new integrated health care models without fear of putting themselves at risk of adverse consequences

42 CFR PART 2 FINAL RULE

- ➔ Final rule published in the Federal Register on January 18, 2017 (82 FR 6052)
- ➔ *Effective date of 3/21/2017*
- ➔ SNPRM concurrently published proposing additional changes (82 FR 5485)
- ➔ Final Rule based on SNPRM (...) January 3, 2018

6052 Federal Register / Vol. 82, No. 11 / Wednesday, January 18, 2017 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2
(SAMHSA-4162-0)
RIN 0930-AA21

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. These modifications also help clarify the regulations and reduce unnecessary burden.

e. Withdrawal Management
2. Existing Definitions
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b. Disclose or Disclosure
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d. Member Program
e. Patient
f. Patient Identifying Information
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F. Confidentiality Restrictions and Safeguards (§ 2.13)
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VI. Rulemaking Analyses
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C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Federalism (Executive Order 13132)

Acronyms
ACC Accountable Care Organization
ABAM American Board of Addiction Medicine

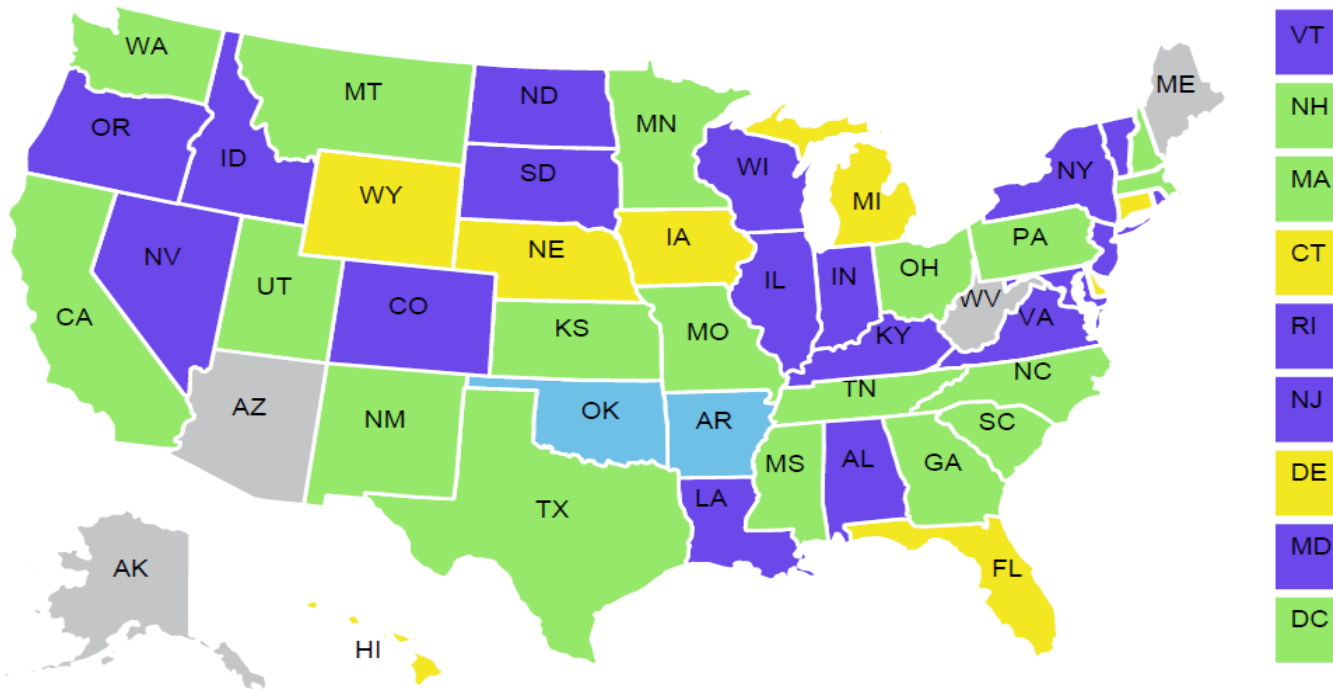
<https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records>

Background: Medical Privacy



- Part 2 aligns with HIPAA to extent feasible under its governing statute
- SUD records and information may be subject to both HIPAA and Part 2 and state laws
- If both HIPAA and Part 2 apply, follow the law that is more stringent
- Part 2 (§ 2.20) does not preempt more stringent state laws

State laws and Substance Use Disorder Records-Disclosure **with** Patient Consent



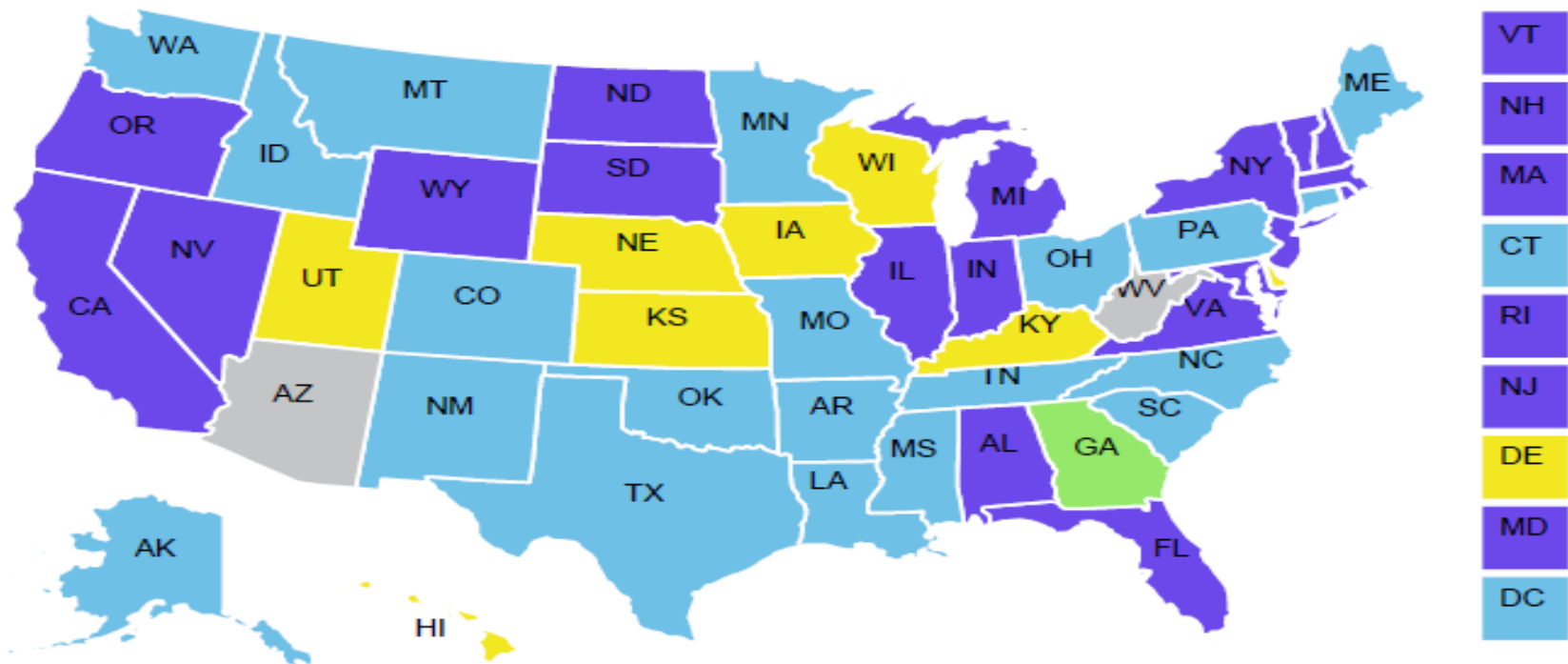
State Consent Requirements for Disclosure of Records as Compared with Part 2

- Stricter than Part 2
- Same as Part 2
- Less strict than Part 2/Part 2 Controls
- No law specifying consent requirements; Part 2 controls
- State has separate requirements for entities not governed by Part 2

Source:
Healthinfolaw.org

State laws and Substance Use Disorder Records- Disclosure **without** Patient Consent

[Last Updated 10/24/2013]



State Disclosure Without Consent Requirements Compared with Part 2

- Stricter than Part 2
- Same as Part 2
- Less strict than Part 2/Part 2 Controls
- No law specifying disclosure requirements; Part 2 applies
- State has separate requirements for entities not governed by Part 2

Healthlaw
info.org

A Framework for Understanding Part 2

- Applicability: Is information protected by Part 2 (§§2.11-2.23)?
- Exceptions: If protected, does it fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?
- Consent: If not, will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?
- Court orders: If no exception/exclusion to Part 2 applies and patient does not consent to disclosure, can a court order be obtained (§§2.61-2.67)?

→ Approach adapted from: Dennis Helms, A Guide to the New Federal Rules Governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 4 Contemp. Drug Probs. 259 (1975)

Applicability



→ Applicability: Is a patient's information protected by Part 2 (§§2.11-2.23)?

Applicability

- These regulations impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of **any part 2 program (§2.2)**
- Regulations apply to any information, whether or not recorded, which “[w]ould identify a patient as having or having had a **substance use disorder** either directly, by reference to publicly available information, or through verification of such identification by another person” (§2.12)

DEFINITIONS (§2.11)

- *Substance Use Disorder*: replaced *Alcohol abuse* and *Drug abuse* (2017 rule)
- A cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For this regulation, does not include tobacco or caffeine use

DEFINITIONS (§2.11) (cont.)

- *Patient*: individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a part 2 program. 2017 rule updated terminology and added that the definition includes both current and former patients
- *Records*: any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). Explicitly includes electronic records
- *Treatment*: care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient
- *Part 2 program*: federally assisted and meets definition of 'program' discussed below

APPLICABILITY(§2.12)

- Applicability to given information is based on whether the entity is *federally assisted* and *holds itself out as providing SUD diagnosis, treatment and referral*
- Applicability is fact-specific so is hard to generically state whether a given program is or is not a Part 2 program but key questions include:
 - A. Is the program *federally assisted*?
 - A. Program carried out under license, certification or registration by federal department or agency

APPLICABILITY(§2.12)

- Program carried out under federal license/certification may include:
- participating in Medicaid or Medicare;
- being authorized to conduct maintenance treatment or withdrawal management (42 CFR Part 8);
- registration under Controlled Substances Act to dispense medication-assisted treatment (e.g. DEA number);
- Federal assistance also means supported by federal funding to states or local governments or directly:
- Being tax-exempt or receiving tax-deductible donations
- Conducted in whole or part, directly or via contract, by federal entity (**BUT** Veterans Affairs and Armed Forces are exempt from Part 2 by statute and covered by VA and DOD confidentiality provisions)
- Note: In some cases, states may reference compliance with Part 2 even if facility is self-pay or private and otherwise would not be considered to be federally assisted

APPLICABILITY(§2.12)

- B. Is a unit/entity/individual other than a general medical facility a Part 2 Program
- 1. Do they “hold themselves out” as providing diagnosis/treatment/referral for SUD?
- Ex. Licensed/certified/registered to provide these activities
- Ex. Advertisements, notices or statements about such services
- Ex. Consultation activities about such services

APPLICABILITY(§2.12)

For services provided by specialized staff in general medical facilities:

- 2. If a general medical facility, are services provided by an identified unit within the general medical facility that **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment?
- 3. For medical personnel or other staff in a general medical facility or practice, is their **primary function** to provide SUD diagnosis/treatment/referral and **are they identified** as providers of such services by the facility/practice?

Lawful Holder

- Not formally defined in regulatory text. However, important concept for Part 2
- “An individual or entity who has received such information as the result of a part 2-compliant patient consent (with a re-disclosure notice) or as a result of one of the limited exceptions to the consent requirements specified in the regulations” and is therefore bound by Part 2 (2017 Final Rule, p. 6997)
- Examples: May include patient's treating provider, a hospital emergency room, an insurance company, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research.
- Providers and entities that are not covered by Part 2 that possess SUD data that **did not originate** in Part 2 program are not subject to part 2 requirements

Disclosure of Part 2 information



→ Exceptions: If information is covered by Part 2, does it fall under one of the exceptions or exclusions (§2.12, §§2.51-2.53)?

Disclosure (§§2.12(a); 2.11)

- Part 2 restrictions on disclosure apply to
- A. Information that “[w]ould identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person” AND
- B. Is from a federally-assisted Part 2 program

What does it mean to disclose Part 2 info?

- Disclose (§2.11): Many ways to 'disclose' such as providing testimony, sharing written records, sharing patient identifying information in a way that the patient to be re-identified, verbal discussions with staff or others outside the SUD treatment program, submitting claims information to a payer (e.g., Medicare)
- Applies whether or not information has been recorded (§2.12(a))

Disclosures-§2.13(a)



- Even when disclosures are permitted, should only share information needed:
- Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure.
- Consider data segmentation and use of Consent2Share or programs with similar functionality

Part 2-Purpose and Effect (§2.2)

- Even when exceptions to Part 2 exist or a patient consents to disclosure, absent a court order disclosures by program are not compulsory:
- **“The regulations in this part prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.”**

Disclosure (§§2.2; 2.12(a); 2.31, 2.51-2.53)

- In most cases, disclosures are permissive not mandatory (e.g., a program 'may' disclose. Need court order/subpoena for mandatory)
- Some exceptions to consent, each of which has various caveats, qualifications and limitations, include:
 - Bona-fide medical emergencies (§2.51)
 - Audit and Evaluations (§2.53)
 - Research (§2.52)
 - Disclosures to prevent multiple enrollments in maintenance or withdrawal programs within 200-mile radius (§2.34)
 - Disclosure to patient themselves (§2.23)
 - Disclosure does not identify patient(s) as having or having had an SUD (e.g., anonymous disclosure or no Part 2 information mentioned)
 - The individual themselves voluntarily discloses his or her substance use disorder patient information

Disclosure (§§2.2; 2.12(a); 2.31, 2.51-2.53)

- Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program (§2.12)
- Qualified Service Organization Agreements (§§2.11; 2.12(c)(4))
- Crime on program premises or against program personnel or threat of such activity (§ 2.12)
- Disclosures to elements of the criminal justice system which have referred patients (§2.35)

Per statute, Part 2 does not apply to SUD information shared within Uniformed Services and VA or between Uniformed Services and VA. VA has own confidentiality requirements ((§ 2.12).

MEDICAL EMERGENCIES (§2.51)

- The final rule revises the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a “bona fide medical emergency” exists.
- Information can be shared by Part 2 program in these circumstances when consent cannot be obtained.
- Treating provider makes determination
- Part 2 program must document following disclosure date/time, medical personnel information shared with, nature of emergency



Qualified Service Organization Agreements (QSOAs)(§2.11; § 2.12(c)(4))

- A QSOA is a “two-way agreement between a part 2 program and the entity providing the part 2 program and an individual or entity providing a service to a part 2 program”
- QSOs provide services to a part 2 program under a written agreement (QSOA). Such services include data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy
- Final Rule: “agreements between more than those two parties (*e.g.* multi-party agreements) are prohibited. A QSOA cannot be used to avoid obtaining patient consent in the treatment context.”

RESEARCH (§2.52)



- The final rule allows a part 2 program or other lawful holder of patient identifying information to disclose part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule).
- Data in reports must be aggregated/de-identified
- Researchers must agree to resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part.

AUDIT AND EVALUATION (§2.53)

- Permits an audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (including CMS-regulated Qualified Entities)
- Audit and evaluation not defined but can include financial and quality purposes
- If records not copied or removed from premises can be disclosed to individual/entity who agrees to comply with re-disclosure and other requirements and is acting on behalf of government agency/third-party payer
- If forwarded/removed, must comply with record retention requirements
- Information can only be disclosed for audit and evaluation purposes back to program from which it was obtained and not used to prosecute/investigate patients
- Includes provisions for both paper and electronic patient records
- Part 2 program may determine who is qualified to conduct an audit or evaluation

Special Situation-**Disclosures to elements of the criminal justice system which have referred patients (§2.35)**

- Part 2 program may disclose information about a patient to those individuals within the criminal justice system who have made participation in the part 2 program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody
- Ex. Drug courts, parole, other programs as a condition of release or participation may require waiver of confidentiality
- Need signed, written consent
- Limited to those who need information (ex. probation/parole officers, prosecuting attorney(s))
- Consent can be revoked based on specific event occurring (e.g., probation ends) or certain amount of time elapsing- this way program can monitor. By contrast, other consents can be revoked at any time (except to degree program already has relied on the consent)(§ 2.31(a)(6))
- Redisclosure only for official purposes and in connection with purpose for which consent was given
- Ex. Parole revocation following drug court 'failure'

Consent



→ Consent: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Disclosure (§§2.12(a); 2.31, 2.33)

- If no exceptions/exclusions apply, Part 2 information can only be disclosed with written consent or through court process
- Consent must be **in writing** and requires certain elements:
 - 1. Must include name of patient
 - 2. Amount and Kind: How much and what kind of information to be disclosed- should not just say “all my substance use disorder information” or “all of my records”
 - Also should be granular options or categories such as diagnostic information, medications, employment information, trauma history, allergies. Can use checkboxes next to categories.
 - 3. Purpose of disclosure (e.g., “treatment”)

Disclosure (§§2.12(a); 2.31, 2.33)

- 4. 'From whom': Name of specific entity/individual permitted to make the disclosure
- The final "From Whom" provision of the consent requirements specifies that a written consent to a disclosure of patient identifying information must include the specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.
- 5. 'To Whom' Name of individual(s) to whom disclosure is to be made or name of entity (if treating provider relationship exists)
- If no treating provider relationship, name of third-party payer or name of entity or individual participants with treating provider relationship or general designation
- The final 2017 rule requires that, upon request, patients who have included a general designation in the "To Whom" section of the consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures)

Disclosure (§§2.12(a); 2.31)

- 6. Date, event or condition upon which consent will expire. Must ensure consent will last no longer than necessary to serve purpose for which it is provided
- 7. Other elements- notice that consent can be revoked (except to extent person/entity making disclosure has already relied on it)
- 8.-9. Patient signature and date when signed

- Consent can be paper or electronic. The final rule permits electronic signatures (to the extent that they are not prohibited by any applicable law).
- Part 2 consent can be separate form from any consent required by HIPAA or other laws or combined as long as it has required elements

Disclosure and consent

TABLE 1—DESIGNATING INDIVIDUALS AND ORGANIZATIONS IN THE “TO WHOM” SECTION OF THE CONSENT FORM

42 CFR 2.31	Individual or entity to whom disclosure is to be made	Treating provider relationship with patient whose information is being disclosed	Primary designation	Required additional designation
(a)(4)(i)	Individual	Yes	Name of individual(s) (<i>e.g.</i> , Jane Doe, MD).	None.
(a)(4)(i)	Individual	No	Name of individual(s) (<i>e.g.</i> , John Doe)	None.
(a)(4)(ii)	Entity	Yes	Name of entity (<i>e.g.</i> , Lakeview County Hospital).	None.
(a)(4)(iii)(A)	Entity	No	Name of entity that is a third-party payer as specified under § 2.31(a)(4)(iii)(A) (<i>e.g.</i> , Medicare).	None.
(a)(4)(iii)(B)	Entity	No	Name of entity that is not covered by § 2.31(a)(4)(iii)(A) (<i>e.g.</i> , HIE, or research institution).	At least one of the following: <ol style="list-style-type: none"> 1. The name(s) of an individual participant(s) (<i>e.g.</i>, Jane Doe, MD, or John Doe). 2. The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (<i>e.g.</i>, Lakeview County Hospital). 3. A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed (<i>e.g.</i>, my current and future treating providers).

CONSENT REQUIREMENTS (§§2.13; 2.31)- To whom

→ The final (2017) rule:

- Allows, in certain circumstances, a patient to include a *general designation* in the “To Whom” section of the consent form.
 - Distinction between those with and without a treating provider relationship with the patient.
- When using a general designation in the “To Whom” section, their right to obtain, upon request, a list of entities to whom their information has been disclosed, pursuant to the general designation (list of disclosures)(see §2.13)
- Patient’s decision whether to use or not use general designation



Read the Fine print

What is the Treating Provider Relationship? (new concept in Final 2017 Rule)

Treating-provider relationship when:

- A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and;
- The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.
- May not need formal written agreement. Making appointment or telephone consultation may be sufficient. Can exist even if no in-person encounter
- SAMHSA considers an entity to have a treating provider relationship with a patient if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.

NOTICE OF PROHIBITION ON RE-DISCLOSURE

(§2.32)

- Required to accompany the disclosure of patient identifying information
- Notice that information should not be further re-disclosed without written consent
- Such information should not be used for criminal investigation or prosecution
- General authorization for the release of medical or other information is *NOT* sufficient to permit re-disclosure of part 2 information

2017 SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING (SNPRM)

- In addition to the final (2017) rule, SAMHSA issued a SNPRM on January 18, 2017 (82 FR 5485)
 - Sought to obtain additional comments and information on some additional proposed clarifications to 42 CFR part 2

<https://www.regulations.gov/document?D=HHS-OS-2016-0005-0378>

Supplemental Notice of Proposed Rulemaking (SNPRM)

- SNPRM published in the *Federal Register* on January 18, 2017
- Comments on proposed rule in 2016 highlighted varying interpretations of the rule's restrictions on use and disclosure of patient identifying information by lawful holders and their contractors and subcontractors for purposes of carrying out payment, health care operations, and other health care-related activities
- Commenters noted that third-party payers, other lawful holders of patient identifying information, and their contractors and subcontractors and legal representatives play a critical role in the provision of health care services

SNPRM

- The SNPRM provided SAMHSA the opportunity to obtain additional public comment about changes that would recognize the important role of contractors, subcontractors and legal representatives
- The SNPRM proposed that, consistent with part 2 consent provisions, lawful holders of patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities such as claims processing, business management, training, and customer service. This list is similar to the activities described in the HIPAA Privacy Rule's definition of the terms “payment” and “health care operations,” although SAMHSA did not adopt these definitions in their entirety

Disclosures Permitted With Written Consent (§2.33): PII and Contractors & Subcontractors

→ SAMHSA proposed new regulatory text under § 2.33(c) *requiring that lawful holders that engage contractors and subcontractors to carry out payment and health care operations that will entail using or disclosing patient identifying information include specific contract and subcontract provisions requiring contractors and subcontractors to comply with the provisions of part 2.*

- Appropriate comparable instrument will suffice in cases involving a legal representative.



SNPRM

- Proposed changes to Audit and Evaluation provisions to expressly address further disclosures to contractors, subcontractors, and legal representatives, and to permit audits and evaluations of “other lawful holders of patient identifying information”
- Sought comment on whether to add an abbreviated notice to accompany re-disclosure for use in certain circumstances where a shorter notice may be warranted (e.g., for electronic health record systems)

Final [SNPRM] Rule

- Permits lawful holders to disclose or re-disclose patient identifying information to their contractors, subcontractors and legal representatives for purposes of carrying out the lawful holder's payment and health care operations activities, when patient consents to disclosure for those activities
- Must have contract/legal instrument in place re Part 2
- Includes an optional abbreviated notice on prohibition on re-disclosure (required to accompany the disclosure of patient identifying information): *"42 CFR part 2 prohibits unauthorized disclosure of these records."*
- Finalizes audit and evaluation provisions
- Made some minor technical amendments to other part 2 provisions

Court Orders

- Court orders: If no exception/exclusion to Part 2 applies and patient does not consent to disclosure or seeking consent impractical, can a court order be obtained (§§2.61-2.67)?

*****Criminal investigations*****

- Restriction on the use of any information subject to the regulations in this part to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (§2.12)
- Applies to any person who obtains that information from a part 2 program, regardless of the status of the person obtaining the information or whether the information was obtained in accordance with the regulations (§2.12)
- Cannot use such info as evidence in criminal proceeding or to investigate or prosecute a crime (§2.12)
- Information obtained by patient access to his or her patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation (§2.23)

Court Orders

- Unless exceptions apply would need court order in corrections setting to disclose Part 2 information for non-criminal purposes or to criminally investigate or prosecute patients or to investigate/prosecute a Part 2 program
- Court order authorizes disclosure by Part 2 program but does not compel it. Also need subpoena or legal mandate concurrent with order (§2.61)
- Confidential communications in treatment can only be disclosed if serious threat (e.g., to third parties, child abuse), in connection with civil/administrative proceeding where patient offers testimony on these matters or to investigate “extremely serious crime” such as homicide, rape, armed robbery (§2.61; §2.12)

Court Orders

- To authorize disclosure of Part 2 information to **criminally prosecute or investigate** patient, person holding records (including state or local agency) must be provided notice, opportunity to appear and be **legally represented** (§2.65)
- Court must consider if other ways to obtain information, is crime 'extremely serious', likelihood records will disclose information of substantial value and whether potential injury to patient, physician-patient relationship and Part 2 program is outweighed by public interest and need for disclosure
- The person holding the records or any law enforcement or prosecutorial officials who are responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws can apply for such orders

Court Orders

- To authorize disclosure for **non-criminal purposes**, both patient and holder of Part 2 records must be provided notice, opportunity to appear or respond, court must find alternatives not available or likely to be effective and public interest and need for disclosure would outweigh harm to patient, physician-patient relationship and treatment services
- Any person having a legally recognized interest in the disclosure which is sought can apply for such orders for non-criminal purposes (§2.64)
- For both criminal/non-criminal orders- even with order limit disclosure to persons and portions of records necessary (§§2.64-2.66)
- Court may seal record of civil proceedings
- Application to court must use fictitious name (§§2.64-2.66)
- Procedures such as notice, hearing spelled out

CLOSING THOUGHTS: PRIVACY & BEST CARE

- 42 CFR Part 2 and other regulations provide ground rules, but how these rules are applied to ensure privacy *and* the best care requires careful analysis and monitoring.
- Who needs what information when?
 - Who determines who needs what information when?
 - What are the consequences & outcomes?
 - And more...

QUESTIONS OR COMMENTS?

THANK YOU

Questions:

PrivacyRegulations@samhsa.hhs.gov

The screenshot displays the SAMHSA website interface. At the top, the SAMHSA logo is on the left, and navigation links for Home, Newsroom, Site Map, and Contact Us are on the right. A search bar is located in the top right corner. Below the logo, a horizontal menu contains links for Find Help & Treatment, Topics, Programs & Campaigns, Grants, Data, About Us, and Publications. The main content area shows a breadcrumb trail: About Us » Who We Are » Laws and Regulations » Confidentiality Regulations FAQs. The page title is "Substance Abuse Confidentiality Regulations". Below the title, there is a sub-header "Frequently Asked Questions (FAQs) regarding the Substance Abuse Confidentiality Regulations." and a section titled "Applying the Substance Abuse Confidentiality Regulations". This section includes the text: "Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 42 CFR Part 2 (REVISED)". A disclaimer follows: "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." On the left side of the page, there is a sidebar menu with links for About Us, Who We Are, Leadership, Regional Administrators, Offices and Centers, Laws and Regulations, Confidentiality Regulations FAQs, and Listenina Session.