



# Confidentiality of Substance Use Disorder Patient Records Final Rule (42 CFR Part 2)

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# 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 individual, agency or organization legal counsel

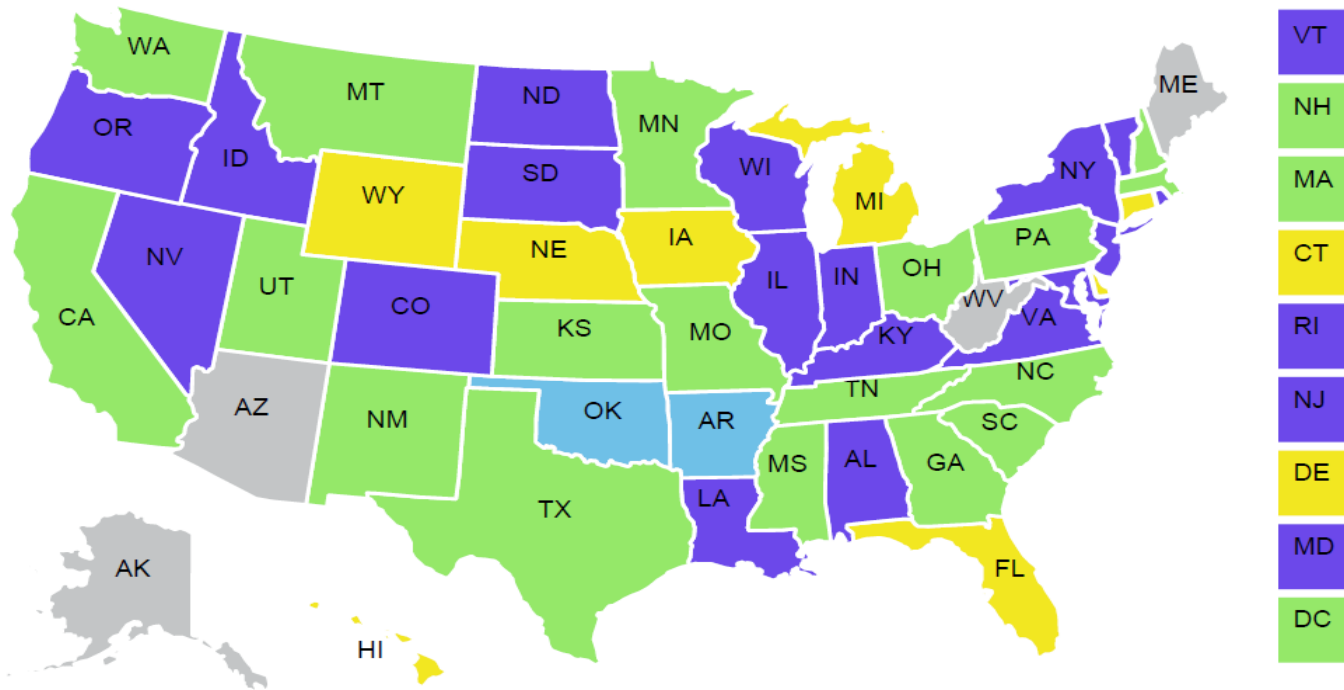
# Background: Health Privacy Legislation- Substance Use Disorders

- 1970s-Congress noted discrimination associated with substance use disorders (SUDs) and fear of prosecution deterred people from entering treatment
- Drug Abuse Office and Treatment Act of 1972 and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 authorized confidentiality for patient records. Now codified at 42 USC 290dd-2
- Persons with substance use disorders were (and continue to be) subject to discrimination in such areas as employment and housing
- At that time most treatment provided by specialty providers

# Background: Medical Privacy

- 42 CFR Part 2/42 USC § 290dd-2 is one of several state and federal statutes and regulations applying to medical information
- Examples: Health Insurance Portability and Accountability Act (HIPAA); Family Education Rights Privacy Act; VA Substance Use Disorder/HIV/Sickle Cell confidentiality provisions
- Courts have recognized privacy interest in medical records
- 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 statutes, licensing, facility policies, and accreditation requirements may reference Part 2
- If state law more protective than Part 2, should follow more stringent state law

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



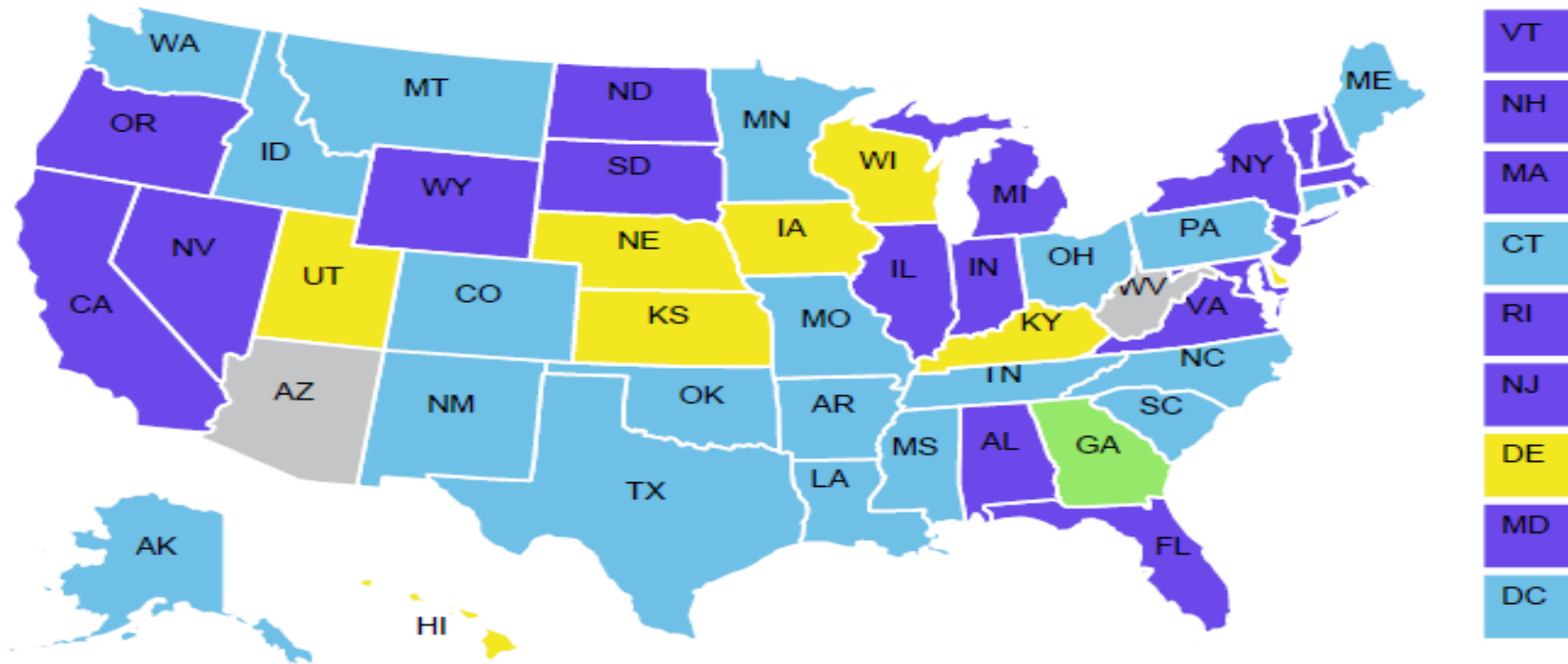
## State Consent Requirements for Disclosure of Records as Compared with Part 2

- 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  
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# Statute-42 USC § 290dd-2-Basis for Part 2 Regulation

- “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 except as authorized
- May be disclosed as permitted by written patient consent, to medical personnel to assist in bona fide medical emergency



# 42 USC § 290dd-2

- Records may be disclosed to “qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation” but individual patients cannot be identified in reports
- Can be disclosed pursuant to court order “showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm.” Court to consider physician-patient relationship, state interest, etc.
- 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 USC § 290dd-2

- Statute does not apply to exchange of records within or between Veterans Affairs or Uniformed Services. VA to issue own confidentiality regulations and coordinate with HHS
- Does not apply to reports under state law of child abuse or neglect to state/local authorities
- Applies to former patients and current patients
- Penalty: Violations to be fined under Title 18 of US Code (Crimes and Criminal Procedure)
- HHS Secretary shall issue regulations

# 42 CFR Part 2

- Regulation that implements federal substance use disorder (SUD) confidentiality statute (42 U.S.C. § 290dd-2)
- Regulations first promulgated in 1975 and before 2017 update were last substantively updated in 1987

# WHY REVISE 42 CFR PART 2?



- Significant changes have impacted health care delivery since 1987:
  - New models of integrated care that rely on information sharing to support coordination of patient care
  - Electronic infrastructure for information exchange
  - New focus on performance measurement
  - “Providers who in the past offered only general or specialized health care services (other than substance use disorder services) now, on occasion, provide substance use disorder treatment services, but only as incident to the provision of general health.”

# THE PROCESS: 42 CFR PART 2 NPRM



- 2014 Listening Session-1800 persons participated, 112 oral comments and 635 written comments
- SAMHSA collaborated with its federal partner experts in developing the Notice of Proposed Rulemaking (NPRM) and Final Rule (e.g., Center for Medicare and Medicaid Services, Office of the National Coordinator for Health Information Technology)
- NPRM published in the Federal Register on February 9, 2016 (81 FR 6988)
- Comment Period was 60 days and closed on April 11, 2016.
- 376 comments were received

# 42 CFR PART 2 FINAL RULE

- ➔ Final rule published in the Federal Register on January 18, 2017 (82 FR 6052)
- ➔ *Review by the administration resulted in a revised effective date of 3/21/2017*
- ➔ Supplemental NPRM concurrently published proposing additional changes (82 FR 5485)

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-4162-20)  
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  
a. Central Registry  
b. Disclose or Disclosure  
c. Maintenance Treatment  
d. Member Program  
e. Patient  
f. Patient Identifying Information  
g. Person  
h. Program  
i. Qualified Service Organization  
j. Records  
k. Treatment  
3. Terminology Changes  
4. Other Comments on Definitions  
E. Applicability (§ 2.12)  
F. Confidentiality Restrictions and Safeguards (§ 2.13)  
1. Delayed Implementation of List of Disclosures Provision  
2. Responsibilities Under the List of Disclosures Process  
3. Technological Challenges and Burden of the List of Disclosures Provision  
4. Recommendations to Further Protect Patient Privacy  
5. Other Comments and Recommendations on the List of Disclosures Provision  
G. Security for Records (§ 2.16)  
H. Disposition of Records by Discontinued Programs (§ 2.14)  
I. Notice to Patients of Federal Confidentiality Requirements (§ 2.22)

3. Documentation of Medical Emergency  
4. Other Comments on Medical Emergency N. Research (§ 2.52)  
1. General  
2. Suggestions for Improvement of the Research Provisions  
3. HIPAA and HHS Common Rule Requirements  
4. Data Linkages  
5. Multi-Payer Claims Database  
O. Audit and Evaluation (§ 2.53)  
P. Other Public Comments on the Proposed Rule  
1. Requests to Extend the Public Comment Period  
2. Rulemaking Process  
3. Implementation Timeliness and Other Barriers to Implementation  
4. Educational Opportunities  
5. Increased Enforcement  
6. Other Miscellaneous Comments on the Proposed Rule  
VI. Rulemaking Analyses  
A. Paperwork Reduction Act  
B. Regulatory Impact Analysis  
C. Regulatory Flexibility Act  
D. Unfunded Mandates Reform Act  
E. Federalism (Executive Order 13132)

**Acronyms**

ACD - 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>

# A Framework for Analyzing Part 2 issues

- 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 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)

# NEW DEFINITIONS (§2.11)

- *Substance Use Disorder*: replaced *Alcohol abuse* and *Drug abuse* in 1987 version of 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. 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

# DEFINITIONS (§2.11) (cont.)

- *Patient identifying information*: “Name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information”
- Diagnosis: means any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment

# DEFINITIONS (§2.11, (§2.12) (cont.)

- Diagnosis for Part 2 purposes does not include:
  - (i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement agencies or officials (Ex. Breathalyzer for DUI)
  - Or (ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved does not have a substance use disorder (*e.g.*, involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs)

# 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**?
  - New definition added to Final Rule in §2.11 (definitions) and further discussed in applicability section (§2.12(b))
  - A. Ex. 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 require 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)

- In addition to considering federal assistance, applicability is based on the definition of *Program*
- Applicability is fact-specific but key questions include:
- 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?
- Note that prong 3 does not use 'hold itself out'- have to be identified as specialized personnel by facility providing service

# Applicability

- General medical facilities: NPRM: “[H]ospitals, trauma centers, or federally qualified health centers would generally be considered ‘general medical facilities.’
- Therefore, primary care providers who work in such facilities would only be covered by the part 2 definition of a ‘Program’ if:  
(1) They work in an identified unit within such general medical facility that holds itself out as providing, *and* provides, substance use disorder diagnosis, treatment or referral for treatment, or (2) the primary function of the providers is substance use disorder diagnosis, treatment or referral for treatment *and* they are identified as providers of such services by the general medical facility.”

# \*\*\*\*\*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)
- Requires court order when informant or undercover agent used to investigate Part 2 program; information cannot be used to charge patients (§§2.11, 2.12, 2.17)

# 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)?

# 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
- Note that violation of Part 2 is a crime and may be reported

**KNOW  
YOUR  
RIGHTS**

# NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS (§2.22)

- Inform that crimes on premises and known/suspected child abuse and neglect are not protected from disclosure
- Notice must cite Federal law and regulations
- 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.

**KNOW  
YOUR  
RIGHTS**



# 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)

# 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))

## Part 2-Purpose and Effect (§2.2)

- Even when exceptions to Part 2 exist or a patient consents to disclosure, absent a court order or legal mandate 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.”**

# 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

# 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 known or suspected substance use disorder

# 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)
  - By statute, Part 2 does not apply to SUD information shared within Armed Forces and VA or between Armed Forces and VA. VA has own confidentiality requirements ((§ 2.12)
- 
- **Two other situations: Patient consents in writing to disclosure; consent includes required elements (§2.13, §2.31, §2.33)**
  - **Court orders authorizing disclosure and use (§§2.61-2.67)**

## Internal Communications- 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)

- Those with whom information is shared must have “have need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment.”
- FAQ guidance, 2010, umbrella organization: “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.” Would need qualified service organization agreement for this purpose



# 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 with medical personnel 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
- Involuntary commitment can be emergency



# Crimes on Premises; Part 2 and Duty to Warn

- Part 2 programs can report immediate threats to life/safety, such as crimes on premises or threats
- Can only disclose information related to the incident and individual name/address/last known location
- Final Rule: Part 2 does not impose a duty to warn—or a duty to disclose any information. It only governs when disclosures may be made, not when they must be made.
- 2011 SAMHSA FAQ Guidance: For **Immediate threats to health or safety that do not involve medical emergencies or crimes on programs premises or against program personnel**. Part 2 programs and health care providers ... who have received Part 2 patient information, can make reports to law enforcement about an immediate threat to the health or safety of an individual or the public *if patient-identifying information is not disclosed*.

# 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
- Does not currently include care coordination, which has a treatment component

# Qualified Service Organization Agreements (QSOAs)(§2.11)

- Communications between Part 2 programs and QSOAs of information needed by the QSOA to provide services to the Part 2 program are an exception to Part 2 consent requirements
- Must enter into written agreement with Part 2 program
- Must comply with record storage and security requirements
- Must agree to resist in judicial proceedings any use of Part 2 records for purposes that violate Part 2

# 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 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
- Permits the part 2 program to determine who is qualified to conduct an audit or evaluation

## Criminal Justice-**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 limited in duration taking into account type of proceeding, anticipated length of treatment and other circumstances

## Criminal Justice-**Disclosures to elements of the criminal justice system which have referred patients (§2.35)**

- 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))
- Re-disclosure only for official purposes and in connection with purpose for which consent was given
- Ex. Parole revocation following drug court ‘failure’



# Criminal Justice (§2.35)

- Law enforcement officials in police department, probation/parole staff and court staff probably would not meet definition of federally assisted Part 2 program
- This means a probation officer could re-disclose what they are told by clients about a substance use disorder (depending on state law and other applicable requirements). However, a Part 2 program could not disclose Part 2 information to a probation officer without written consent
- Corrections staff in some cases could be covered by part 2 (e.g., SUD unit or programs)

# Criminal Justice (§2.35)

- There are no provisions in Part 2 specifically focused on correctional settings
- Consent would generally be needed to disclose SUD diagnosis or treatment provided in a corrections setting to outside health providers
- For Part 2 to apply, must be federally assisted program. Final Rule: “For example, if a federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by the regulations in this part unless the program itself received federal assistance” (§2.12)

# 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 (Final Rule, p. 6997)
- Examples: May include patient's treating provider, a hospital emergency room, an insurance company/third-party payer, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research.
- Must follow Part 2 re-disclosure and other requirements
- 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

# Lawful Holder

- Not formally defined in regulatory text. But important concept for Part 2
- The patient themselves is not a lawful holder and can be provided their own records without written consent (§ 2.23; Final Rule)
- The patient's legal representative similarly may be provided such records
- A patient who has obtained a copy of their records or a family member who has received such information from a patient would not be considered a "lawful holder of patient identifying information" in this context. (Final Rule, p. 6997)
- It is permissible for a *patient to disclose* information to a personal health record or similar consumer health application but if a part 2 program or lawful holder of patient identifying information discloses that information to the personal health record or other similar consumer application on behalf of the patient, consent would be required (Final rule, p. 6070)

# PROHIBITION ON RE-DISCLOSURE (§2.32) (cont.)

- Information disclosed under Part 2 should be accompanied by a 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

# PROHIBITION ON RE-DISCLOSURE (§2.32)

- The final rule clarifies that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both, and allows other health-related information shared by the part 2 program to be re-disclosed, if permissible under other applicable laws
- Ex. Records include high-blood pressure information and SUD. Part 2 applies to the SUD information being re-disclosed but not the high blood pressure provided this information does not identify the individual as having/having had an SUD
- But re-disclosure of cirrhosis could imply the patient had an SUD because it may be caused by alcohol or drug use.
- Similarly, a prescription for methadone without also noting it was for cancer pain could identify an SUD patient because methadone may be used in medication assisted treatment.

# 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': 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 (Ex. HIE and all my treating providers)
- The final 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

# What is the Treating Provider Relationship? (§2.11)

*Treating provider relationship*: final rule revises the consent requirements to permit, in certain circumstances, a general designation of individuals or entities to which a disclosure can be made, but only if they have a *treating provider relationship* with the patient whose information is being disclosed

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.
- 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.

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"> <li>1. The name(s) of an individual participant(s) (<i>e.g.</i>, Jane Doe, MD, or John Doe).</li> <li>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).</li> <li>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).</li> </ol>

# 2017 SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING (SNPRM)

- In addition to the final 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

## CLARIFICATIONS

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

# STAKEHOLDER CONCERNS: USE & DISCLOSURE



→ Comments to proposed rule (2016) highlighted varying interpretations of the rule's restrictions on lawful holders and their contractors' and subcontractors' use and disclosure of patient identifying information for purposes of carrying out payment, health care operations, and other health care related activities.

# PROPOSED PROVISIONS § 2.32 & § 2.33

→ SNPRM seeks comments on the following proposed provisions:

- § 2.32 (Prohibition on Re-disclosure) – to consider whether an abbreviated notice would be appropriate and in which circumstances
- § 2.33 (Disclosures Permitted with Written Consent) – to broaden the circumstances in which certain disclosures for the purposes of payment and health care operations can be made



# PROPOSED PROVISION: § 2.53

- § 2.53 (Audit and Evaluation)
  - to expressly address **further disclosures** to contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or CHIP audit or evaluation





# Disclosures Permitted With Written Consent (§2.33): PII & Required Consent

- SAMHSA proposed to explicitly list and limit under § 2.33(b), specific types of activities for which any lawful holder of patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities.
- List of activities is similar to HIPAA Privacy Rule's definitions of “payment” and “health care operations,” but excludes those related to diagnosis, treatment, or referral for treatment (e.g., care coordination or case management).
  - *Consent is required, and contractors, subcontractors, and legal representatives must perform a function that is consistent with the stated purpose of the consent and only use the information to perform that function.*

# FINAL RULE AND SNPRM NEXT STEPS

## → SAMHSA will:

- Review SNPRM comments received by the deadline and determine how to move forward
- Complete subregulatory guidance
- Provide additional webinars, other presentations, and outreach materials
- Consistent with the 21<sup>st</sup> Century Cures Act, “convene relevant stakeholders” at a meeting to discuss impact of Part 2 on “patient care, health outcomes, and patient privacy.”



# Court Orders



- 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)?

# 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, 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

# Part 2 Court Cases-Sample

- *Crooker v. Stewart*, US District Court, D. Maryland, 2014, Civil Action No. ELH-14-1539
- Situation: Federal prisoner in Cumberland, MD, states that while at prison medical center in Mass. he was subject to drug testing (urinalysis) after disclosing drug use to prison psychologist. and sanctioned by losing 41 days of good conduct time for using narcotic (morphine) not prescribed by medical staff. The prisoner cites Part 2 arguing that the statute prohibits use of SUD records to investigate or charge a patient
- The court noted that the psychologist advised the prisoner that what he said could be shared with other Bureau of Prisons staff
- Prisoner could not show he was participating in a treatment program covered by the statute

# Part 2 Court Cases-Sample

- *Crooker v. Stewart*, US District Court, D. Maryland, 2014, Civil Action No. ELH-14-1539
- Prisoner could not show prison psychologist was covered by Part 2 provisions regarding disclosure of records (2.13). Also, the hearing relied on prisoner's self-admission of substance use, not what the prison psychologist disclosed to others
- Even if the psychologist were covered, Part 2 regulations permit disclosure to law enforcement of crimes on the premises of the program and between a part 2 program and an entity that has direct administrative control over the program. (§ 2.12(c)(3), (5))
- Prisoner was not *criminally* charged. Prison disciplinary hearings are civil in nature.
- Court: The exclusionary rule that would limit use of evidence illicitly or improperly obtained by law enforcement has been held not to apply to parole revocation hearings given interest in protecting public; this would argue as well in prison discipline proceedings.



# Part 2 Court Cases-Sample

- *Doe v. Broderick*, 225 F.3d 440 (4th Cir. 2000)
- Following a jewelry store robbery, a Fairfax County (VA) police detective obtains search warrant for records from a nearby methadone clinic (including plaintiff's) based on suspicion that those in treatment may engage in "criminal activities to support [their] daily drug addictions."
- Plaintiff files civil (42 USC 1983) claim against county, detective and other officers alleging unreasonable search and seizure and violation of 42 USC 290dd-2
- Part 2 program employee initially refuses to permit access to file room but did so after being threatened by police with obstruction charges. Files returned after 2 weeks by police.

# Part 2 Court Cases-Sample

- *Doe v. Broderick*, 225 F.3d 440 (4th Cir. 2000),
- Files included plaintiff's "name, photograph, address, methadone dosage information, urine screen history, and confidences Doe shared with his counselors at the clinic"
- Court: "There is no question that the confidentiality and disclosure provisions contained in section 290dd-2 were not satisfied."
- But **THERE IS NO PRIVATE RIGHT OF ACTION UNDER PART 2.**

# Part 2 Court Cases-Sample

- *Doe v. Broderick*, 225 F.3d 440 (4th Cir. 2000),
- Court: “In our view, Congress did not enact section 290dd-2 for the principal benefit of Doe and others who receive treatment at drug rehabilitation facilities.” Generally, criminal statutes do not create private rights of action. “The language used in section 290dd-2 suggests that Congress was concerned primarily with fostering programs aimed at curtailing our nation's staggering substance abuse problems. The primary beneficiary is the public.”
- However, search of clinic records was without probable cause, violated 4<sup>th</sup> amendment.

# 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...

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# QUESTIONS OR COMMENTS?

## THANK YOU

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The screenshot shows the SAMHSA website interface. At the top, there is a navigation bar with links for Home, Newsroom, Site Map, and Contact Us. Below this is a search bar with the text 'Search SAMHSA.gov' and a 'Search' button. To the right of the search bar are social media icons for Facebook, Twitter, YouTube, and a Blog icon. A secondary navigation bar contains links for Find Help & Treatment, Topics, Programs & Campaigns, Grants, Data, About Us, and Publications. The main content area features 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, it says 'Frequently Asked Questions (FAQs) regarding the Substance Abuse Confidentiality Regulations.' A section titled 'Applying the Substance Abuse Confidentiality Regulations' follows, with the text: 'Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 42 CFR Part 2 (REVISED)'. A disclaimer at the bottom states: '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.'