Overview of 42 CFR part 2: Confidentiality of Substance Use Disorder Patient Records

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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.
SAMHSA’s Primary Care Initiatives & Collaborations

• SAMHSA supports the Primary Care and Behavioral Health Integration project
• SAMHSA and the Health Resources and Services Administration support integrated care (https://www.integration.samhsa.gov)
• SAMHSA consults with CMS and states on health homes covering behavioral health populations.
• SAMHSA and HRSA collaborate on health workforce initiatives, including training and education (see June 2018 Supplement, American Journal of Preventive Medicine)
• SAMHSA is working with CMS and others on Certified Community Behavioral Health Clinics.
• SAMHSA provides information on reimbursement for behavioral health providers and national and state spending and programs
Background on 42 CFR part 2: What it is and Why it Exists
Why 42 CFR part 2 Exists?

• Congress noted in 1970s that discrimination associated with substance use disorders (SUDs) and fear of prosecution deterred people from entering treatment.

• Authorizing statute for confidentiality of SUD patient records regulations was 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, education, housing, child care and in the health care system.
42 USC § 290dd-2 on the Confidentiality of records is the basis for 42 CFR part 2 regulations and can only be changed by Congress.

42 USC § 290dd-2 required the HHS Secretary promulgate regulations codified as “42 CFR part 2” or “part 2.”

Part 2 regulations were first promulgated on July 1, 1975.

Substantive revisions were made in 1987, 2017, 2018.

✓ “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.

✓ However, SUD records may be disclosed, as permitted, with the prior written consent of the patient.
A consumer/patient’s SUD information may be disclosed without consent:

- 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 evaluations (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.
Exclusions in 42 U.S.C. § 290dd-2

✓ Statute does NOT apply to:

• Exchange of records within the Department of Veterans Affairs (VA) or between the VA and the Uniformed Services.

• Reports under state law of suspected child abuse or neglect.

✓ Statute states that violations would be fined under Title 18 of the US Code (Federal Crimes and Criminal Procedures). This is why regulations state violations should be reported to US Attorney in the district where a violation allegedly occurred.

✓ SAMSHA may be able to address administratively if allegation against an opioid treatment program because SAMSHA oversees accreditation/certification.
How would a patient become aware of part 2?

- 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.
Regulations-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.

**Lawful Holder:**

A lawful holder of patient identifying information is an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as a result of one of the exceptions to the consent requirements in the statute or implementing regulations and, therefore, is bound by part 2.
Background: part 2 and State Law

- 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.
2017 & 2018 Revisions to 42 CFR part 2
Why Revise 42 CFR part 2 in 2017?

✓ Previous substantive update had been in 1987.

✓ Significant changes in health care delivery:
  o New models of integrated care that rely on information sharing to improve safety and outcomes.
  o New focus on performance measurement and value-based reimbursement.
  o Evolving electronic infrastructure for managing and exchanging information.
The 2017 Revisions

Among the numerous changes made to the rule:

- Entire rule updated to apply to electronic as well as paper exchange of patient identifying information

- Definitions (§ 2.11) – revised/added several definitions. E.g., substance

- Applicability (§ 2.12) – Restrictions apply to information received from “Other lawful holders”

- Confidentiality restrictions and safeguards (§ 2.13)
The 2017 Revisions Continued

- Consent requirements (§ 2.31)
- Medical emergencies (§ 2.51)
- Research (§ 2.52)
- Audit and evaluation (§ 2.53)
Disclosures for Payment and Healthcare Operations (§2.33)

Revised to permit:

1. Additional disclosures of patient identifying information, with patient consent, to facilitate payment and healthcare operations such as claims management, quality assessment, and patient safety activities.

2. 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.
2018 Revisions

✓ Prohibition on Re-Disclosure (§2.32)

Clarified that the prohibition against 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. Revised to permit an abbreviated version of this mandatory notice that “42 CFR part 2 prohibits unauthorized disclosure of these records” to accommodate the character limitations in many electronic health records (EHRs).

✓ Audits and Evaluations (§2.53)

Revised to address further disclosures to contractors and legal representatives to carry out audits and evaluations.
Understanding the ‘New’ part 2
A Framework for Understanding part 2

Applicability: Is information covered/protected by part 2 (§§2.11-2.23)?
Exceptions: If so covered, does it fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?
Consent: 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)?

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).
✓ **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.

✓ **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.
Substance Use Disorder

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 (§2.11). For this regulation, does not include tobacco or caffeine use.

Diagnosis

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.
A Framework for Understanding part 2 – Applicability

✓ **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.
A Framework for Understanding part 2 – Applicability

✔ Treating Provider Relationship

• 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.

• 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.
A Framework for Understanding Part 2 – Applicability

✔ What is a Program? (§ 2.11)

1. An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

2. An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

3. Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.
A Framework for Understanding part 2 – Applicability

✓ What is a ‘part 2 program’?

Part 2 programs provide SUD diagnosis, treatment, or referral for treatment AND are federally assisted. Programs are considered to be federally assisted (§ 2.12(b)) if:

✓ Program carried out under license, certification, registration or other authorization by federal department or agency.
  • 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 controlled substance (e.g. DEA number) to extent it is used in SUD treatment. (e.g., medication-assisted treatment).
What is a part 2 program?

Part 2 programs provide SUD diagnosis, treatment, or referral for treatment AND are "federally assisted." Programs are considered to be federally assisted (§ 2.12(b)) if activity:

- Conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the US (excepting VA/uniformed services).

- Supported by funds provided by any department or agency of the United States by being:
  - A recipient of federal financial assistance in any form, including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment.
  - Conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, which could be used for SUD treatment.
  - Having tax-exempt status or receiving tax-exempt donations.
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)).
- Even when disclosures are permitted, what is shared should be limited to that information which is necessary to carry out the purpose of the disclosure (§2.13).
- Consider data segmentation to ensure that records that originate from part 2 programs are appropriately protected.
A Framework for Understanding Part 2 – Exceptions

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.”
A Framework for Understanding part 2- Exceptions

Some exceptions to consent, each of which has various caveats, qualifications and limitations, include:

- 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)*
- Bona-fide medical emergencies (§2.51)
- Audit and Evaluations (§2.53)
- Research (§2.52)-final rule aligns with HIPAA and Common Rule
- Disclosures to prevent multiple enrollments in maintenance or withdrawal programs within 200-mile radius (§2.34)*
- Disclosure to patient themselves (§2.23)
Medical Emergencies (§ 2.51)

✓ Providers now have more discretion to determine when a medical emergency exists. The revised language states that patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained.

✓ Following disclosure, the part 2 program shall document, in writing, the disclosure in the patient's records, including:

1. The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
2. The name of the individual making the disclosure;
3. The date and time of the disclosure; and
4. The nature of the emergency.
A Framework for Understanding part 2- Exceptions

✓ Research (§ 2.52)

The research exception has been revised to:

1. permit part 2 data to be disclosed by any individual or entity that is a part 2 program or lawful holder of part 2 data (previously only part 2 program directors could disclose part 2 data for research purposes).

2. permit disclosure of part 2 data to qualified personnel if the researcher provides documentation of meeting certain requirements related to other existing protections for human research (i.e., HIPAA Privacy Rule or Common Rule).

3. enable researchers holding part 2 data to link to data sets from federal and non-federal data repositories provided certain conditions are met.
A Framework for Understanding part 2- Exceptions

Audits & Evaluations (§ 2.53)

1. Revised to permit the part 2 program, not just the part 2 program director, to determine who is qualified to conduct an audit or evaluation of the part 2 program.

2. Clarifies that the Medicare and Medicaid audit or evaluation section includes the Children’s Health Insurance Program (CHIP).

3. Permits an audit or evaluation necessary to meet the requirements of a Centers for Medicare & Medicaid Services (CMS)-regulated Accountable Care Organization (ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity), under certain conditions.
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.”
A Framework for Understanding part 2- Exceptions

Central Registry: (§ 2.34): A part 2 program may disclose patient records to a central registry or to any withdrawal management or maintenance treatment program for the purpose of preventing the multiple enrollment of a patient if there is written consent except that:

(i) The consent must list the name and address of each central registry and each known withdrawal management or maintenance treatment program to which a disclosure will be made; and
(ii) The consent may authorize a disclosure to any withdrawal management or maintenance treatment program established within 200 miles of the program, but does not need to individually name all programs.

Limited information sharing to verify and prevent multiple enrollments

A central registry and any withdrawal management or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order.
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.
- Limited to those who need information (ex. probation/parole officers, prosecuting attorney(s)).
- Need signed, written consent.
- 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 must be in writing (paper or electronic) and requires 9 elements (§§ 2.13; 2.31-2.35):

1. Name of patient;
2. “From whom”: Name or general designation of the part 2 program, entity, or 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.

3. Amount and kind: A description of the amount and kind of information, including an explicit description of the substance use disorder information, to be disclosed. Should not just say “all my substance use disorder information” or “all of my records;”
The patient now has the option to specify exactly what he/she wants to be disclosed.

Examples of Part 2 Categories
- Diagnostic Information
- Medications and Dosages
- Lab Tests
- Allergies
- Substance Use History
- Trauma History Summary
- Clinical Notes
- Discharge Summary
- Employment Information
- Living Situation and Social Supports
- Claims/encounter Data
A Framework for Understanding the part 2 – Consent

✓ Consent must be in writing (paper or electronic) and requires 9 elements (§§ 2.13; 2.31-2.35):

4. “To Whom”: Name of individual(s) to whom disclosure is to be made or name of entity (if treating provider relationship exists).

5. Purpose of disclosure (e.g., “treatment”)

6. Revocation: notice that consent can be revoked (except to extent part 2 program or lawful holder has already relied on it)

7. Duration: 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

8.-9. Signature and date: Patient signature and date when signed. If consent on behalf of minor or incompetent person, should be signed by individual authorized to consent ((§§ 2.14, 2.15).
### Revisions to the “To Whom” Section of the Consent Form

<table>
<thead>
<tr>
<th>Individual or Entity To Whom</th>
<th>Treating Relationship</th>
<th>Primary designation</th>
<th>Required Additional Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>Yes</td>
<td>Name of individual(s) (e.g., Jane Doe, MD)</td>
<td>None</td>
</tr>
<tr>
<td>Individual</td>
<td>No</td>
<td>Name of individual(s) (e.g., John Doe)</td>
<td>None</td>
</tr>
<tr>
<td>Entity</td>
<td>Yes</td>
<td>Name of entity (e.g., Lakeview County Hospital)</td>
<td>None</td>
</tr>
<tr>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is a third-party payer as specified under § 2.31(a)(4)(iii)(A) (e.g., Medicare)</td>
<td>None</td>
</tr>
</tbody>
</table>
| Entity                       | No                    | Name of entity that is not covered by § 2.31(a)(4)(iii)(A) (e.g., HIE, or research institution) | At least one of the following:  
1. The name(s) of an individual participant(s) (e.g., 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 (e.g., 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  
Notes: Patient may choose all providers with a relationship; patient may designate further to include “past”, “current,” or “future” treating providers; patient may specify one or more individuals on health care team whom they do not have a treating provider relationship. |
Confidentiality restrictions and safeguards: General Designation List of Disclosures (§ 2.13)

Upon request, patients who have included a general designation in the “To Whom” section of their consent form must be provided a list of entities to which their information has been disclosed pursuant to the general designation. The list must be provided by the entity that serves as an intermediary in the exchange of patient identifying information (such as a health information exchange or accountable care organization). Part 2 programs are not responsible for providing this list.
eSignatures

The Rules now addresses both paper and electronic documentation.

- Electronic signatures (eSignatures) are permitted to the extent that they are not prohibited by any other applicable laws.
A Framework for Understanding part 2 – 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 (§§§2.12, 2.23, 2.61-2.67)?

- Procedures/process for criminal and civil cases
- 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 (§2.63; §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)
Health Centers and part 2
Applicability of the part 2 Designation

Understanding whether a program is federally assisted is critical. Federal assistance to program is required for part 2 to apply. If a patient’s SUD diagnosis, treatment, or referral for treatment is not provided by a part 2 program, that patient's record is not covered by these regulations.
Understanding what information is covered is critical. These regulations cover any information (including information on referral and intake) about patients receiving diagnosis, treatment, or referral for treatment for a SUD created by a part 2 program.
Buprenorphine: SAMHSA clarifies that the program definition does not categorically exclude buprenorphine providers.

However, holding a waiver to prescribe buprenorphine or holding a waiver and prescribing buprenorphine as part of primary care practice also does not lead to categorical inclusion of providers in the definition of a part 2 program; such determinations are fact-specific.
Screening, Brief Intervention, and Referrals for Treatment (SBIRT) is “an evidence-based practice used to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and illicit drugs” that may be reimbursed by private and public insurers;

A healthcare provider that does not otherwise meet the definition of a part 2 program would not become a part 2 program simply because they provide SBIRT within the context of general health care.
Applying Data Security Requirements

✓ Data Security (§2.16): All part 2 programs or other lawful holders of patient-identifying information must have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information.

✓ Disposition of records (§2.19): Both paper and electronic records should be sanitized and disposed of properly when a program discontinues operations
Conclusion: Resources-SAMHSA part 2 Information Website

QUESTIONS OR COMMENTS?

THANK YOU!!!
Please contact us for assistance:
PrivacyRegulations@samhsa.hhs.gov

For Further Information: https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines