Welcome to the HHS-Region VIII Webinar:

Confidentiality of Substance Use Disorder Patient Records: A Webinar for Health Centers in Region 8

July 17, 2018

This Webinar is supported by the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services in cooperation with the Community Health Association of Mountain/Plains States (CHAMPS) and the Health Resources and Services Administration, U.S. Department of Health and Human Services
Mission
The mission of CHAMPS is to provide opportunities for education and training, networking, and workforce development to Region VIII (CO, MT, ND, SD, UT, WY) community health centers so we can better serve our patients and communities.

Vision
All patients and communities benefit from the impact of the resources that CHAMPS provides to community health centers.

Values
Support
Excellence
Responsiveness
Vision
Integrity
Collaboration
Effectiveness
HRSA
Health Center/NHSC: Behavioral Health Funding
July 17, 2017

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Overview

• Health Centers – Behavioral Health Services
• Health Centers – Supplemental Funding
• National Health Service Corps – SUD/Opioid Expansion
• Nearly 90% of health centers provide mental health services.
• 69% of health centers provide substance use disorder (SUD) services.
• Approximately 9,200 mental health professional FTEs provided more than 8.5 million mental health visits (including psychiatrists, psychologists, and social workers)
• More than 1,100 substance use disorder service professional FTEs provided over 1.1 million visits for substance use disorder services.
Health Centers – Supplemental Funding

• Behavioral Health Integration (BHI)
  • Aims to improve and expand the delivery of behavioral health services through integrated primary care and behavioral health
  • $106 million was awarded to expand behavioral health capacity at over 430 health centers in FY 2014-15

• Substance Abuse Service Expansion (SASE)
  • Improve and expand the delivery of SUD services, with a focus on screening and referral to treatment, and medication-assisted treatment (MAT) for opioid use disorders.
  • Increase SUD provider FTEs and increase the number of patients receiving MAT
  • $94 million was awarded to over 270 health centers in 2016
Health Centers – Supplemental Funding

• Access Increases in Mental Health and Substance Abuse Services (AIMS)
  • Supports expanded access to mental health services, and substance abuse services with a focus on opioids and their integration into primary care
  • Increase personnel, leverage health information technology, provide training, and increase the number of patients receiving behavioral health services, with a focus on opioids
  • More than $200 million was awarded to nearly 1,200 health centers in 2017
Health Center – Upcoming Supplemental Funding

• Expanding Access to Quality Substance Use Disorder and Mental Health Services (SUD-MH)
  • The purpose of the funding is to support health centers in implementing and advancing evidence-based strategies to:
    • Expand access to quality integrated SUD prevention and treatment services, including those addressing opioid use disorder and other emerging SUD issues, to best meet the health needs of the population served by the health center; and/or
    • Expand access to quality integrated mental health services, with a focus on conditions that increase risk for, or co-occur with SUD, including opioid use disorder
National Health Service Corps – SUD/Opioid Expansion

• NHSC Substance Use Disorder/Opioid Expansion
  • The NHSC received $105 million to expand and improve access to quality opioid and substance use disorder (SUD) treatment in rural and underserved areas nationwide. New categories of outpatient services and sites will be eligible for NHSC.
  • SUD/Opioid funding:
    • General Substance Use Disorder (SUD) Treatment
    • Medication Assisted Treatment (MAT) Program
    • Opioid Treatment Program (OTP)
  • Sites are eligible to “opt-in” if they provide any of these services.
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SAMHSA: A Brief Overview

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Regional Administrator – Region VIII
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U.S. Department of Health and Human Services
Mission
Reduce the impact of substance abuse and mental illness on America’s communities
$23.4 Million Available for the Infant and Early Childhood Mental Health Grant Program (IECMH)
The purpose of this program is to improve outcomes for young children by developing, maintaining, or
enhancing infant and early childhood mental health promotion, intervention, and treatment services. SAMHSA
expects to fund up to 9 grantees with up to $500,000 per year for up to five years. Due date is June 29, 2018.

$196 Million Available for the Targeted Capacity Expansion: Medication Assisted Treatment –
Prescription Drug and Opioid Addiction Program (MAT-PDOA)
The new funding will expand access to medication-assisted treatment for people with opioid use disorder.
SAMHSA expects to fund up to 125 grantees up to $524,670 per year for up to 3 years. Due date is July 9, 2018.

$930 Million Available to Combat the Opioid Crisis (State Opioid Response Grant (SOR))
The program aims to address the opioid crisis by increasing access to medication-assisted treatment, reducing
unmet treatment need, and reducing opioid overdose related deaths. Due date is August 13, 2018.

$50 Million Available to Help Tribes Address Opioid Crisis (Tribal Opioid Response Grant (TOR))
The grants, which will go to tribes and tribal organizations, will fund prevention, treatment, and recovery
activities in response to the opioid crisis. Due date is August 20, 2018
An Overview of 42 CFR part 2 Applicability to Health Centers

Suzette Brann & Mitchell Berger
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
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: What it is and Why it Exists
Why 42 CFR 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 CFR Part 2 Statute and Regulation

✓ 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.
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.
Exceptions in 42 U.S.C. § 290dd-2

✓ 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.

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

✓ Last substantive update was 31 years ago.

✓ 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.

• Final 2017 rule: “SAMHSA has endeavored to strike an appropriate balance between the important privacy protections afforded patients with substance use disorders and the necessary exchange of information to improve treatment outcomes for these individuals.”
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.
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.
42 CFR part 2 Listening Session, Jan. 31, 2018

See [https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines](https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines) for further information
Part 2 Listening Session, Jan. 31, 2018

- 86 in-person participants at SAMHSA building in Rockville, MD, and roughly 1200 online (phone/Web conference). Comments accepted in-person, via phone and in writing to PrivacyRegulations@samhsa.hhs.gov through Feb. 28, 2018.

- Comments emphasized aligning part 2 and HIPAA, further steps to foster care coordination and integrated care, need to respect stigma of SUD and impact on patients of privacy and confidentiality violations, need for more subregulatory guidance/technical assistance, electronic health records and consent implementation challenges.

- Sample comment: “Anything that you can do to better align part 2 specifically with HIPAA is very much appreciated, and we urge administration to implement regulations that can bring us to that and really allow us to integrate care in the way that we would love to for the benefit of our patients.”-American Psychiatric Association

- Sample comment: “We specifically want to acknowledge the clarifications […] regarding the ability for lawful holders to disclose part 2 information with Medicaid agencies and other contracted managed care entities in the performance of Healthcare operations. We also wish to applaud the clarifications permitting part 2 data disclosures for Medicaid and shift audits and evaluations…. Those are positive changes to facilitate appropriate Medicaid oversight of the services that they provide. However, our members do remain concerned with the prohibition on disclosures for diagnosis, treatment, or referable treatment […] Medicaid agencies and their partners continue to pursue delivery system and payment reforms to promote coordinated and integrated care across all healthcare needs.”-National Association of Medicaid Directors.
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).
A Framework for Understanding the ‘New’ 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.
✓ **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**: 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).
A Framework for Understanding the ‘New’ Part 2 – Applicability

✓ 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 the ‘New’ 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.
Covered Programs

Covered programs are Part 2 programs. Part 2 Programs are defined as those programs that are federally assisted (federally assisted as defined in § 2.12(b) and programs as defined in § 2.11).

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.
✓ 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.
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.
- Ex. participating in Medicaid or Medicare.
- Ex. being authorized to conduct maintenance treatment or withdrawal management (42 CFR Part 8)
- Ex. 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

- 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)).
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 the ‘New’ 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)
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.
The research exception has been revised to:

1. permit part 2 data to be disclosed by any individual or entity that is a 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.
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.
A Framework for Understanding Part 2- Exceptions

(§ 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.

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.
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;”
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>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.</td>
</tr>
</tbody>
</table>

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.
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
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.
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.
A Framework for Understanding the New 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 case
• 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)
• 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)
How 42 CFR part 2 May Apply to Health Centers
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.

**Question:**

If your program is supported by the Internal Revenue Service because of tax deductions or because it has been granted of tax exempt status, is it a part 2 program?
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.

**Question:**

Would treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide SUD diagnosis, treatment, or referral for treatment be covered by part 2?
Part 2 Designation & Buprenorphine

- 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.

**Question**

What are some of the other considerations that will determine if a buprenorphine program is a part 2 program?
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.
Applicability to Audit & Evaluations

✓ For records that are not copied or downloaded from a part 2 program, patient-identifying information may be disclosed in the course of a records review on the premises with a few caveats.

✓ For records that are copied, removed, downloaded or forwarded, the auditor or evaluator must agree in writing to:

1. Maintain and destroy the patient identifying information;
2. Retain records in compliance with applicable federal, state, and local record retention laws; and
3. Comply with the limitations on disclosure
Diane just overdosed and emergency room personnel found a business card from Berger OTP in her pocket. Can the emergency room personnel call Berger OTP to get information on her SUD treatment?
Suzette is in Berger OTP, a part 2 program, in Des Moines, IA and is going to college in Denver, CO. She needs to continue her dosing while in school. Could the part 2 program in Denver check the IA central registry to verify that she was enrolled in Berger OTP?
In 2018, patient privacy remains a critical concern. However, equally important is the need for:

- Providers to be able to share information to improve SUD patient treatment
- SUD patients to benefit from integrated care
- Patients, providers, and the overall health system to benefit from use of new technologies and approaches (e.g., Health Information Exchanges, Electronic Health Records, and Multi-payer Claims Databases)
- Further consideration of the benefits of aligning Part 2 with HIPAA. See 2018 Final Rule: “SAMHSA plans to explore additional alignment with HIPAA and is considering additional rulemaking”
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