

# Data Sharing and Confidentiality: Webinar Series – Part 2

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for People with Serious Mental Illness

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# AGENDA

## 42 CFR Part 2

1. Overview

2. Applicability

3. Exceptions to Applicability

4. Disclosures

5. Health Information Exchanges (“HIEs”) and Networks



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# 1. Overview



# “PART 2” BASICS

- **Statute:** 42 U.S.C. § 290dd-2
- **Regulations:** 42 CFR Part 2 (“Confidentiality of Alcohol and Drug Abuse Patient Records”)
- **Federal Agency:** Substance Abuse and Mental Health Services Administration (“SAMHSA”), of the U.S. Department of Health & Human Services (“HHS”)
- **Generally:** Imposes restrictions on the disclosure and use of substance use disorder (SUD) patient records which are maintained in connection with the performance of any Part 2 program, unless certain circumstances exist.
- **Purpose:** Ensure that patients receiving treatment for a SUD in a Part 2 program are not made more vulnerable than others. Enacted to encourage people to get treatment when needed without stigma.



# RELATIONSHIP TO STATE LAWS AND HIPAA

- **“Part 2” is a floor; not a ceiling**
- **State law may not authorize or compel any disclosure prohibited by Part 2**
- **State laws may, however, be more restrictive than those set forth in Part 2**
- **Some alignment between Part 2 and HIPAA, but in some instances, Part 2 provides more stringent federal protections than those of HIPAA**





# DEFINITIONS: 42 CFR § 2.11

**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. Excludes tobacco or caffeine use.

**Disclose:** To communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.

**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). Includes both paper and electronic records.

**Patient identifying information:** The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information.



# 2. Applicability



# APPLICABILITY

## General Rule:

Part 2 restricts disclosure and use of ***substance use disorder records*** which are maintained in connection with the performance of a ***federally assisted*** Part 2 ***program***.

**CONFIDENTIAL**

# APPLICABILITY: WHAT IS PROTECTED?

**Substance Use Disorder 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, voicemails, and texts.
- For Part 2, records include both paper and electronic records.



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# APPLICABILITY



# APPLICABILITY: FEDERALLY ASSISTED

- **Conducted (in whole or in part) by federal government**
- **Supported by federal funding**
  - Includes federal block grants or other funds channeled through state or local governments (e.g., Medicaid)
  - Funding does not need to be for SUD services
- **Carried out under federal license, certification, registration or authorization**
  - Certification of provider status under the Medicare program
  - Authorization to conduct methadone maintenance treatment
  - Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders
- **Receives tax exempt status from the IRS**



# APPLICABILITY: PART 2 PROGRAM (SUMMARY)

1. An **individual or entity** (other than a general medical care facility) who ***holds itself out*** as providing, and ***provides***, substance use disorder diagnosis, treatment or referral for treatment
2. An **identified unit within a general medical facility** which ***holds itself out*** as providing and ***provides***, substance use disorder diagnosis, treatment, or referral for treatment
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

See 42 CFR § 2.11



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# APPLICABILITY: PART 2 PROGRAM

**“Holds itself out”:** Any activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, potentially including:

- Authorization by state or federal government to provide these services
- Certifications in addiction medicine
- Advertisements, notices, or statements
- Consultation activities





# APPLICABILITY: PART 2 PROGRAM (DEEP DIVE)

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

**Translation:** If a provider is *not* a general medical care facility, then the provider meets the Part 2 definition of a “Program” if it is an individual or entity ***who holds itself out*** as ***providing, and provides*** substance use disorder diagnosis, treatment, or referral for treatment. (See 82 FR 6065).



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# APPLICABILITY: PART 2 PROGRAM (DEEP DIVE)

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

**Translation:** If the provider is an **identified unit** within a general medical facility, it is a “Program” if it *holds itself out* as providing, *and provides*, substance use disorder diagnosis, treatment, or referral for treatment. (See 82 FR 6065).

# APPLICABILITY: PART 2 PROGRAM (DEEP DIVE)

- 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

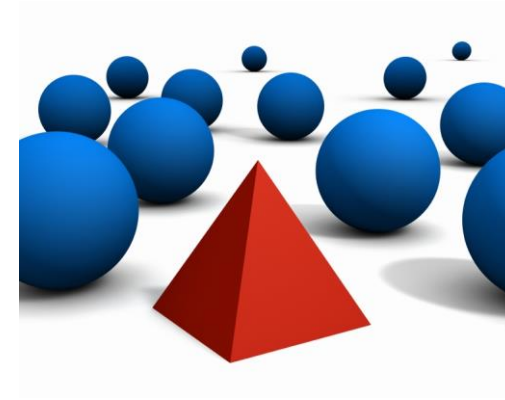
**Translation:** If the provider consists of medical personnel or other staff in a general medical facility, it is a “Program” if its *primary function* is the provision of substance use disorder diagnosis, treatment, or referral for treatment *and* is *identified as such specialized medical personnel or other staff* by the general medical facility. (See 82 FR 6065).



# APPLICABILITY: LAWFUL HOLDERS

- **Under the 2017 Final Rule, Part 2 regulations expanded applicability to lawful holders of patient identifying information.**
  - **Lawful holder:** An individual or entity who has received patient identifying information as the result of a patient consent or as a result of one of Part 2's limited exceptions to the consent requirements
  - **Patient identifying information:** Name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information

# 3. Exceptions to Applicability



# NOTABLE EXCEPTIONS

## Part 2 “Exceptions” to Applicability: 42 CFR § 2.12(c)

### Includes:

- Department of Veteran Affairs
- Armed Forces
- Communication within a Part 2 program or between a Part 2 program and an entity having direct administrative control over that Part 2 program.
- Qualified service organizations (QSOs)**
- Crimes on Part 2 program premises or against Part 2 program personnel
- Reports of suspected child abuse and neglect



# NOTABLE EXCEPTIONS (CONTINUED)

## ***Qualified service organizations (QSOs)***

- The restrictions on disclosure do not apply to communications between a Part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.

*See 42 CFR § 2.12(c)(4)*



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# NOTABLE EXCEPTIONS (CONTINUED)

## What is a QSO?

- **A QSO is an individual or entity who:**
  - (1) Provides services to a Part 2 program, such as 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, and ...

*See 42 CFR § 2.11*



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# NOTABLE EXCEPTIONS (CONTINUED)

## What is a QSO (continued)?

- **A QSO is an individual or entity who:**
  - ...(2) Has entered into a written agreement with a part 2 program under which that individual or entity:
    - (i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and
    - (ii) If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

See 42 CFR § 2.11



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# NOTABLE EXCEPTIONS (CONTINUED)

## What is a QSOA?

- QSOAs between more than two parties (e.g. multi-party agreements) are prohibited.
- A QSOA cannot be used to avoid obtaining patient consent in the treatment context.
- A QSOA can be used to share Part 2 information with a HIE when the HIE is a service provider to the Part 2 program, but the QSOA cannot be used to share information with the members of an HIE without patient consent.

# 4. Disclosures



# DISCLOSURE: GENERAL RULE

**General Rule:** Information that identifies an individual as a patient of a program is confidential and may not be disclosed without patient consent, unless an exception applies.

- Disclosure is permitted under exceptions, but is not required
- Unlike HIPAA, ***patient consent is required*** even for disclosures for the purposes of treatment, payment or health care operations

# DISCLOSURE: DEFINITION

**Disclosure:** Communicating any information identifying a patient as:

- Being or having been diagnosed with a SUD
- Having or having had a SUD
- Being or having been referred for treatment of a SUD:
  - Directly
  - By reference to publicly available information
  - Through verification of such identification by another person

# DISCLOSURE: MINIMUM NECESSARY

## Minimum Necessary Rule

Any disclosure made under Part 2 must be limited to that information which is necessary to carry out the purpose of the disclosure.

*See 42 CFR § 2.13(a)*



# DISCLOSURE: WRITTEN CONSENT

## Required Elements: 42 CFR § 2.31

- 1. Name of patient**
- 2. Amount and kind of information to be disclosed**
  - Explicit description - Can include “all my SUD information” as long as more granular options are included
- 3. “From Whom”**
  - Specific name or general designation of the Part 2 program permitted to make disclosure
- 4. “To Whom”**
  - To an individual or entity with a treating provider relationship: Name the individual/entity
  - To an entity without a treating provider relationship:
    - Name the third-party payor
    - Name the entity (HIE) and name either a participant or entity with a treating provider relationship or include a general designation
- **Purpose of disclosure**
- **Statement that the consent is subject to revocation at any time**
- **The date, event, or condition of expiration**
- **Signature of patient**
  - If the patient is a minor, incompetent, or deceased, signature of authorized individual when required.  
*See 42 CFR § 2.14 and 42 CFR § 2.15*
- **Date of signature**



# DISCLOSURE: WITHOUT CONSENT

1. Medical emergencies: 42 CFR § 2.51
2. Research: 42 CFR § 2.52
- 3. Audit and evaluation: 42 CFR § 2.53**
4. Court authorization: 42 CFR § 2.61



# DISCLOSURE: WITHOUT CONSENT

## **Audit and evaluation: 42 CFR § 2.53**

- Records not copied or removed
- Copying, removing downloading, or forwarding patient records
- Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation:
  - Includes audits and evaluations to meet requirements for a CMS regulated accountable care organization (ACO) or similar CMS-regulated organization (include a CMS-regulated Qualified Entity)
  - The Part 2 program, federal, state or local government agency or any other individual or entity may not disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation

# DISCLOSURE: RE-DISCLOSURE

- **Re-disclosure is prohibited.**
- **Each disclosure made with the patient's written consent must be accompanied by one of the following written statement:**
  - This information has been disclosed to you from records protected by federal confidentiality rules (*42 CFR Part 2*). The federal rules prohibit you from making any further disclosure of information in this record that identifies 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 unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is *NOT* sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; or
  - 42 CFR part 2 prohibits unauthorized disclosure of these records

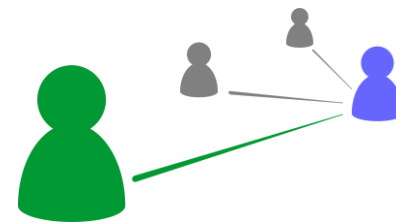


# 5. Health Information Exchanges (“HIEs”) and Networks



# DISCLOSURES TO HIES AND NETWORKS: TWO PRIMARY METHODS

- HIEs enable providers to access and securely share a patient's medical information – including SUD records covered by Part 2
- When used properly, HIEs can improve the speed, quality, and efficiency of health care
- Part 2 programs that wish to disclose SUD records to an HIE must either obtain patient consent to do so or execute a QSOA with the HIE



# DISCLOSURES TO HIES AND NETWORKS: TWO PRIMARY METHODS

## METHOD #1:

- Part 2 program and HIE sign QSOA acknowledging that HIE is providing information exchange services to Part 2 program and agrees to be bound by requirements of Part 2
- Part 2 program may then disclose patient information to HIE without patient consent, but...
- Providers participating in HIE need patient's consent to view patient's SUD records (*i.e.*, HIE could not lawfully re-disclose patient information to participating providers without patient consent as to particular provider(s))

See <https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf>



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# DISCLOSURES TO HIES AND NETWORKS: TWO PRIMARY METHODS

## METHOD #2:

- If Part 2 program and HIE do not sign a QSOA, then...
- Patient must complete consent form listing as recipients: (1) name of HIE, and (2) either the name of a specific individual and/or organization participating in the HIE, or a general designation of individuals/entities that have a treating provider relationship with the patient
  - Note: When using a general designation, the consent form must include a statement that the patient confirms his/her understanding that upon their request, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation
  - This list of entities is provided by the HIE, not the Part 2 program

See <https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf>



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# Additional Webinars in this Series

**All Webinars Scheduled for 1:00 - 2:00pm ET**

**Webinar 8:** [Employment & Professional Services Agreements](#); Wednesday, August 29

**Webinar 9:** [Forming Provider Networks to Participate in VBP Arrangements](#); Wednesday, September 12

**Webinar 10:** [Contracting for EHR Systems](#); Wednesday, September 26

To register for additional webinars, please use the links above or visit the Care Transitions Network website below for more information.

<https://www.thenationalcouncil.org/care-transitions-network-people-serious-mental-illness/technical-assistance/webinars/>



# QUESTIONS?

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