

# Part 2 Compliance – Where Nobody Knows Your Name

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## 42 CFR Part 2: Confidentiality of Substance Use Disorder (SUD) Records

- **What Programs Are Covered by Federal Confidentiality Laws?**
  - 42 CFR Part 2 applies to any program that:
    - provides substance abuse diagnosis, treatment, or referral for treatment and
    - is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States
    - apply to all current and former treatment information
- Relationship to State laws

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## What Information Is Protected?

- Records created, received or acquired by a Part 2 Program relating to an individual's SUD, including:
  - Patient Identity
  - Diagnosis
  - Prognosis
  - Treatment
  - Referral for treatment
- "Records" includes billing records, verbal information, voicemails and text messages

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## What is the Purpose of the Regulations?

- Established to provide comprehensive privacy protections to promote patient confidentiality in substance use disorder treatment
- Based on the assumption that people are more likely to seek such care if they are assured their need for treatment will not be unnecessarily disclosed to others

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## What Constitutes Disclosure of Patient Identifying Information?

- Communications that either directly or indirectly identifies an individual as having applied for, received, or been referred for SUD care
- Includes:
  - Acknowledgement or confirmation of participation in treatment
  - Disclosure of his or her Part 2 health records
  - Testimony about any care received
  - Anecdotal information that could lead to inference of patient's identity and SUD diagnosis

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## When Can Part 2 Protected Information Be Shared?

- Information can be shared if written consent is obtained
- Disclosure mandated by the state
  - Reporting incidents of child-abuse-and neglect (*but* Part 2 restrictions continue to apply to the SUD information)
  - Cause of death is being reported\* or
  - With a valid court order

\* (42 C.F.R. § 2.15(b))

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## When Can Part 2 Protected Information Be Shared? (cont'd).

- **Permitted Disclosures:**
    - Cases of a bona fide medical emergency
    - Reporting crimes that occur on program premises or against staff
    - To entities having administrative control of Part 2 program
    - To qualified service organizations
    - To outside auditors, evaluators, central registries, and researchers
- \*\*Specific conditions and limitations apply to all of the above

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## Release of Information (ROI) in Medical Emergencies

- Patient identifying information may be disclosed to:
  - Medical personnel in a bona fide medical emergency where patient's prior informed consent cannot be obtained
  - To medical personnel of the FDA “*who assert a reason to believe health of individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction ...*”

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## Polling Question #1

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What are Permitted Disclosures under Part 2 which do not require a patient's consent?

- A. In response to a subpoena
- B. Reporting crimes on the premises
- C. To a treating medical provider
- D. To a Health Information Exchange

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## COVID -19 & SAMHSA

- Substance Abuse and Mental Health Services Administration (SAMHSA) has provided additional guidance:
  - Identifying information may be disclosed by a part 2 program to medical personnel, without patient consent, when necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained
  - Information disclosed to the medical personnel who are treating the medical emergency may re-disclose for treatment purposes as needed

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## ROI of Information Medical Emergencies: Additional Requirements

- Immediately following the disclosure, the Part 2 Program shall document, in writing, the disclosure in the patient's records, including:
  - The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility
  - The name of the individual making the disclosure
  - The date and time of the disclosure and
  - The nature of the emergency (or error, if the report was to FDA)

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## Part 2 Consent Requirements

- Name(s) or general designation(s) of Part 2 programs making the disclosure
- Name of person/entity that will receive the disclosure
- Name of patient
- Purpose of disclosure
- How much & what kind of information to be disclosed (including explicit description of the SUD info)
- Statements:
  - Right to revoke consent and exceptions to this right
  - Program's ability to condition treatment, payment, enrollment, or eligibility
  - Others (e.g. when general designation is used)
- Expiration date/event/condition
- Signature of patient/personal representative
- Date signed

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## Part 2 Consent Requirements: Relationships Matter

- If the receiving entity has a treating provider relationship with the patient:
  - Name of the entity is required on the form
- If the receiving entity does not have a treating provider relationship with the patient:
  - You may be able to use general designation, but, the consent must include a statement re: patient's right to request and receive a list of entities to whom the disclosure was made

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## Part 2 Restrictions on Disclosure

- Apply to any information obtained by a federally assisted drug abuse or alcohol abuse program (Part 2 Program), whether or not recorded, which would identify a patient as having or having had a substance use disorder

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## Polling Question #2

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**Question: Does 42 CFR Part 2 permit the disclosure of information without a patient's consent for the purposes of treatment, payment, or health care operations?**

A. Yes

B. No

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## **Part 2 More Stringent Than HIPAA**

**Answer B:** Generally, no. With limited exceptions (e.g., bona fide medical emergencies and audits and evaluations), Part 2 requires written patient consent for such disclosures

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## Some More Exceptions

- Some types of exchange, however, may take place without patient consent between a Part 2 Program and a Qualified Service Organization when a QSO Agreement (QSOA) exists
- Within a Part 2 Program; or
- Between a Part 2 program and an entity with administrative control over that program

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## Qualified Service Organization Agreement (QSOA)

- A QSOA under Part 2, which is similar but not identical to a business associate agreement
  - allows for disclosure of information between a Part 2 Program and an organization that provides services to the program
  - Disclosure must be limited to what is needed for the QSO to provide services to the Program

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## COVID & Telehealth

- SAMHSA recommends use of telehealth and/or telephonic services to provide evaluation and treatment of patients
  - Initial evaluations
  - Evaluations for consideration of use of buprenorphine products to treat opioid use disorder
  - Individual or group therapies such as evidence-based interventions including cognitive behavioral therapy for mental and/or substance use disorders

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## Telehealth

- CMS released guidance March 17, 2020, that allows patients to be seen via live videoconferencing *in their homes*, without having to travel to a qualifying “originating site” for Medicare telehealth encounters, regardless of geographic location
- Telemedicine is the use of live videoconferencing to facilitate a patient encounter.
  - For Medicare, Medicaid, and most private insurers, this does not include telephone alone

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Let's look at a few cases to see what type of information is collected, where it may be collected, where it will be stored and how it will be shared....

### The Case of Mr. Smith\*

\*Not a real patient



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- Mr. Marshall Smith is a 31 year old engineer who was tested at the worksite based on concerns for impairment
- His test came back positive and he was sent to Nowhere Cares Facility for treatment
- When he arrived he was sent to NCF's ED where he was registered

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- At registration he signed the following:
  - Consent for treatment
  - Acknowledgement of Notice of Privacy Practices

Note: these were later scanned into his record

- During his evaluation in the ED, the ED provider ordered drug tests [labs], did a history and physical and documented his notes in the electronic record

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- Mr. Smith's blood tests came back positive for alcohol and a trace of cocaine
- Sunny Acres, an Alcohol and Drug Recovery Center (ADRC) was consulted and they stated they had an inpatient bed if the patient was agreeable to treatment
- The consult information was documented in the electronic record
- The drug test result was linked to his ED encounter

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## Polling Question #3

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Are the results of alcohol and drug levels obtained in the ED considered part 2 records?

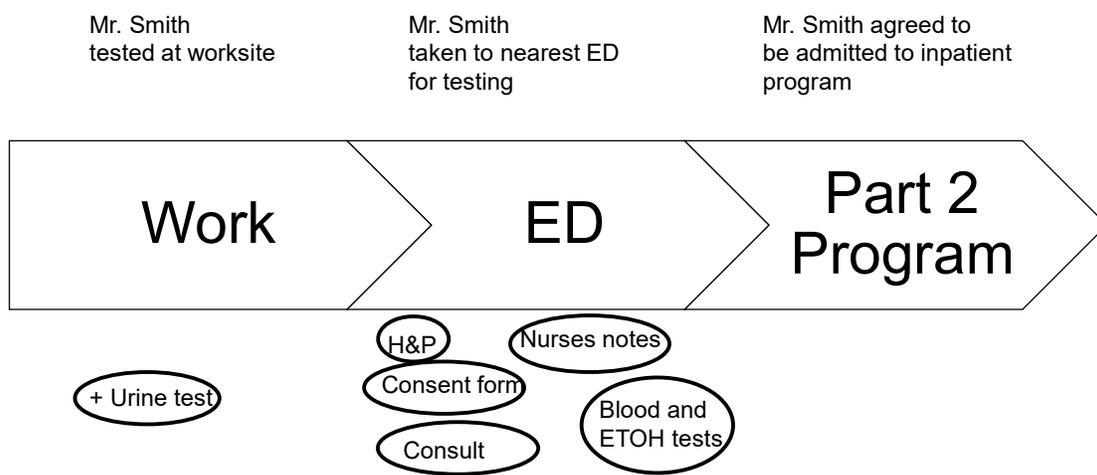
- A. Yes
- B. No

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- After discussions with the ED provider and his family, Mr. Smith agreed to be admitted to the Part 2 program and transportation was arranged

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## What type of records do we have so far and where are they being stored?



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Visit for **Smith, Marshall**

### Clinical Referrals

Referral Type	Suggested Provider	Reason	Refresh	Ins Referral Req'd
Part 2			<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No
Program			<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No
			<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No

### Assessment

Assessment Note:    Record Diagnosis to Face Sheet  Yes  No

Need to gather prior records and studies.

### Diagnosis

Reload ICD-9 Lists

Mod.	ICD-9 3:	Mod.
F19.10	Other Psychoactive substance dependence, uncomplicated	

### CPTs

Reload CPT Lists

Super CPT Set:

Visit CPT Set:

Number of Visit Codes to Display:

Visit CPT	Modifiers				Dx Nums	Units	Price	Charge
	1	2	3	4				
99213 - EP Office Visit 15					1,2	1	\$49.24	\$49.24

Operation/Procedure CPT:

Number of Ops to Display:

Op CPT Set:

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- Mr. Smith arrives at Sunny Acres
- The intake process included multiple documents including consent for Part 2 treatment, acknowledgement of receiving patient rights information, etc.
- Additional blood work is drawn to assess the current drug and alcohol level
- An intake assessment was completed by Dr. Jones, the Part 2 provider

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- On day 3 Mr. Smith is ready for discharge
- The discharge nurse asks him if he wants his information shared with his primary care doctor for on-going treatment
  - If he agrees – what does the nurse need to do?
  - If he signs a consent to release information for on-going treatment, can his Part 2 information become part of a HIE [Health Information Exchange]?
  - Is a notice regarding re-disclosure requirements required to go with the records which are released?

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## The Case of Sheri Jones

- The same day Mr. Smith was a patient at Nowhere Cares Facility ED, Sheri was brought to the same ED by ambulance
- Sheri had attempted suicide by overdosing with several narcotics
- In the ED she was intubated and taken to the ICU

\*Note this is not a real patient



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- On day 2 she had recovered medically, was extubated and a psychiatric consult was requested
- The Psychiatrist evaluated her and found she was depressed but also discerned that she had an underlying substance abuse disorder
  - Is the Psychiatrist's evaluation protected under Part 2?

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- On day 3 Sheri was transferred to a chemical dependency unit within Nowhere Cares Facility
- There she was ordered Suboxone along with her anti-depressant medications
- In NCF's electronic record, medications automatically populate the patient's medication list
  - Should the Saboxone order be protected under Part 2?
  - What about the anti-depressants?

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## The Complexities of Dealing with Part 2 Records Requires a Team Approach

- Recommendations:
  - Engage internal Information Technology staff to help determine how to manage the information
    - Can the lab work be linked to the part 2 record?
    - Where will the medical consult be?
    - Determine how to have the medications ordered during a Part 2 stay not populate the medication list which is visible to all providers

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## Recommendations (cont'd)

- Enlist the assistance of experts from the vendor providing your electronic medical record
- Ask if they are aware of any best practices in dealing with Part 2 records
- Investigate all options available to maintain the confidentiality of the Part 2 records
- Do your own due diligence to determine where all Part 2 records are
- Evaluate all QSO relationships for compliance (including any HIE provider)
- When new processes are put in place to manage the records – test the process before putting it into full production

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## Recommendations (cont'd)

- Determine if patients want to release their information for their on-going treatment needs
  - Have a Part 2-compliant consent form prepared and signed
  - Ensure the re-disclosure message is programmed into the system for any release to HIEs, etc.
  - Prepare staff to deal with a patient's revocation of the consent
- Ensure processes are documented in SOP's
- Educate staff on processes and ensure this education is part of orientation for new Part 2 providers and staff

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## Key Takeaways

- Read and understand the regulations
  - SAMHSA is a great resource ([www.SAMHSA.gov](http://www.SAMHSA.gov))
- Educate all stakeholders on Part 2 requirements
- Utilize experts at your facility to determine the best strategies
- Get input from Part 2 providers and staff
- Be proactive with electronic health record (EHR) system upgrades and Health Information Exchanges (HIEs) as processes that may have been in place today may not be there tomorrow!

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Questions?