

# Privacy and Confidentiality of 42 CFR Part 2

Federal regulation that governs the uses and disclosures of substance use disorder (SUD) records and treatment facilities.

Presented by  
Karolina Austin, CHPE  
Operation PAR  
HIM Director and Privacy Officer

1

The information presented in this course is designed to help grasp an understanding of the federal requirements of confidentiality as it pertains to substance use disorder records and treatment facilities.

The information is not intended to replace any legal advice or counsel you or your organization may have received from an attorney.



2

## Operation PAR Inc. (PAR)

- ▶ Operation PAR, Inc. began after a mother discovered her teenage daughter experimenting with drugs. This mother, Shirley Coletti, sat up all night and worried with her friend and neighbor, James T. Russell, who was then Pinellas County's State Attorney. Mrs. Coletti discovered that there was no place for parents like herself to turn for help. So, with the assistance of several parent advocates, Pinellas County Sheriff Don Genung, State Attorney Russell and former Pinellas County Commissioner Charles Rainey, Operation Parental Awareness and Responsibility was founded, an organization that would provide parents the necessary resources to battle drug addiction.
- ▶ Operation PAR, Inc. has been putting Florida's families first since incorporating as a nonprofit organization in 1970. Prior to receiving federal funding, Operation PAR provided treatment services with a volunteer staff of paraprofessionals and professionals. Today, staffed with more than 400 employees, Operation PAR provides integrated addiction and mental health services at its various sites in Pinellas, Pasco, Hernando, Manatee, Sarasota and Lee counties.
- ▶ Operation PAR is nationally and internationally known for its unique and award winning scientific research initiatives. We are a member of the NIDA Clinical Trials Network as a participating member of the Florida Node Alliance managed by the University of Miami. We have collaborated with:
  - ▶ Substance Abuse and Mental Health Services Administration (SAMHSA),
  - ▶ Center for Substance Abuse Treatment (CSAT),
  - ▶ National Institute on Drug Abuse (NIDA),
  - ▶ Florida Office of Drug Control
  - ▶ Governor's Drug Free Communities
  - ▶ Florida State University/Florida Department of Children and Families



3

## Course Objectives

- ▶ Give guidance to agencies of the regulation pertaining to substance use disorder records and facilities.
- ▶ Understand the foundation of substance abuse facility regulations.
- ▶ Understand the difference between federal, and state laws that govern the confidentiality of substance use disorder records and facilities.
- ▶ Understand the importance of treatment facilities and how they operate.



4

# Course Topics

- ▶ 42 CFR Part 2 regulations
  - ▶ Who must comply
  - ▶ New Definitions
  - ▶ What information is protected
  - ▶ Consent requirements
  - ▶ Relationship between state laws and HIPAA
  - ▶ Audits and Evaluations/ Research
  - ▶ List of Disclosures
  - ▶ Medical Emergency
  - ▶ Qualified Service Organization
  - ▶ Security for records requirements
  - ▶ Child abuse and neglect reporting
  - ▶ Notice to patients of federal confidentiality requirements

\*\*Items in RED are areas that changes were made.\*\*



5

## 42 CFR Part 2 Regulations

Module 1  
The Basics

6

6

## Who Must Comply

- ▶ Organizations that provide alcohol or drug abuse diagnosis, treatment or referral for treatment **and Receives Federal Assistance**
  - ▶ An individual or entity who holds itself out as providing and providers, SUD diagnosis, Treatment, or Referral for treatment; or,
  - ▶ An individual unit within a general medical facility that holds itself as providing, and provides, SUD diagnosis, treatment or referral treatment' or,
  - ▶ Medical personnel or other staff in a general medical facility whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment and who are identified as such providers



7

## Revised and New Definitions

- ▶ Terminology changes
  - ▶ **Alcohol or drug abuse**- replaced with Substance Use Disorder
  - ▶ A **“lawful holder”**- individual or entity who has received SUD information as a result of a patient’s written consent or pursuant to an applicable exception and are therefore required to comply with 42 CFR Part 2
  - ▶ **“Holds itself out”**- means any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment



8

## What Information Is Protected?

- ▶ Information that would identify a patient as an alcohol or drug patient, either directly or indirectly.
- ▶ Includes any information whether oral or written, that would directly or indirectly reveal a person's status as a current or former patient.
- ▶ Protects information in any format whether written, verbal, or is recorded in some other form
  - ▶ This means that the memories and impressions of program staff are considered "records" protected by the regulation even if they are never recorded in any form  
42 CFR Part 2 § 2.11



9

## Non-Client/ Patient

- ▶ The final rule removes the permission granted under the existing regulations to disclose that an identified individual is not and never has been a patient
- ▶ Final rule guidance states that confirming the identity of an individual who is not and has never been a patient while remaining silent on the identity of an actual patient, could by inference, compromise patient privacy if the individual are of a small group of individuals.



10

# Consent Requirements



11

## What is a consent vs. authorization under 42 CFR Part 2

- ▶ 42 CFR Part 2 does not have a difference between an authorization or consent.
- ▶ The term “consent” is used more often than “authorization”
- ▶ Both are one and the same under 42 CFR Part 2.
- ▶ 42 CFR Part 2 does not allow for verbal consent of any kind.
- ▶ No information may be released without prior written authorization/consent.



12

## Authorization/ Consent Requirements

- ▶ Name or general designation of the program(s) making the disclosure
- ▶ The name of the individual or organization that will receive the disclosure (to whom) (non-treatment providers require names of individual)
- ▶ The name of the patient who is the subject of the disclosure
- ▶ The purpose or need for the disclosure
- ▶ Description of how much and what kind of information will be disclosed. (specific records)
- ▶ The patient's right to revoke, and the exceptions to the right to revoke
- ▶ Re-disclosure statement
- ▶ Condition of treatment
- ▶ Date/event or condition upon which the authorization will expire
- ▶ Signature of the patient
- ▶ Date on which the authorization was signed



13

## Requirements continued

- ▶ **To Whom-** If the organization has a **treatment provider** relationship with the client/patient, only the name of the organization needs to be listed in the “to whom” section of the consent.
- ▶ If the organization or agency does not fall under the treatment provider definition then the name of the individual at the organization who will be receiving the information must be listed.



14

## Requirements continued

**Treatment Provider Relationship-** means regardless of whether there's been an in-person encounter:

- ▶ 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.



15

Recipient is...	Form must include...
An individual	The name of the individual
An entity with a treating provider relationship	The name of the entity
Third party payer	The name of the entity
An entity without a treating provider relationship	The name of the entity, <i>Plus:</i> • name of the individual participant(s) • Name of entity participant(s) who has a treating provider relationship; and/or • General designation of individual or entity participant(s) or class of participant(s) who has a treating provider relationship

16



Category	Examples	How to write
Individual	Names of anyone, including lawyers, court personnel, public health agency staff, social workers, case managers,	Joe Avatar Jane Avatar
Treating Provider Entity	Hospitals, Primary Care, Medical Practices, SUD treatment programs, behavioral health organizations, jail nursing stations	ABC Treatment Facility, Jail Nursing Station, ABC Hospital,
Non-treating Provider Entity	Health information exchanges (HIE), courts, schools, law office, employers, DCF, CPI	Joe Avatar at Department of Children and Families Jane Avatar at Child Protection Investigation
General Designation	All of the patient's treating providers, all of the patient's mental health care providers, patient's treatment team at a specific hospital	All my treating providers, all my mental health care providers my Neurosurgery team at ABC Hospital <small>17</small>

17

## Amount of information and what kind (specific records)

Description of the amount and kind of information to be disclosed

- ▶ The amount & what kind of information disclosed must be limited to that which is necessary to fulfill the purpose of the consent
- ▶ Cannot state "Any and All"
- ▶ Must include explicit description of the SUD information that may be disclosed



18

## Consent- Amount & Kind

- ▶ The amount & what kind of information disclosed must be limited to that which is necessary to fulfill the purpose of the consent. Cannot state “Any and All”

### Unacceptable descriptions

- ▶ All of my health information
- ▶ All of my medications
- ▶ Entire record

### Acceptable descriptions

- ▶ All of my substance use disorder information (as long as more granular options are included)
- ▶ All of my Methadone Dosing information



19

## To Whom Additional Changes

- ▶ To whom- can specify past present and future treating providers
- ▶ According to SAMHSA if patient does not specify past, present, and/or future treating providers, you should presume patient intends disclosure only to current treating providers.



20

## List of Disclosures



21

## General Designation (to whom)

- ▶ If a general designation (e.g., “all my treatment providers”) is used on the consent form, the entity must have a mechanism in place to determine whether a treating provider relationship exists with the patient whose information is being disclosed.
- ▶ According to SAMHSA, if the patient does not specify past, present, and/or future treating providers, should presume patient intends to disclose only to current treating providers



22

## General Designation Continued

- ▶ HIE or ACO requires participating providers to attest to having a treating provider relationship before accessing a patients Part 2 info
- ▶ HIE or ACO provides a patient portal where patients can designate their treating providers



23

## List of disclosures continued

- ▶ Patients request must be in writing
- ▶ Patient only has the right to list of disclosures made in past 2 years
- ▶ The intermediary entity (e.g., HIE, ACO), not the Part 2 program is responsible for providing the list of disclosures to the patient
- ▶ For each disclosure, list must contain
  - ▶ Name of entity to which disclosure was made
  - ▶ Date of disclosure
  - ▶ Brief description of Patient identifying information disclosed



24

HIPAA vs. State Statute vs. 42 CFR break down		
HIPAA	FL. Statute 397	42 CFR Part 2
Allows disclosure to parents or guardians without consent	Must have written consent from minor to disclose to parents	Must have written consent from minor to disclose to parents
Allows disclosure for court order or subpoena	Good Cause must be conducted and issued in the court order or subpoena.	Good Cause must be conducted with notification to all parties. All parties must be allowed to make a written or verbal argument
Can release for TPO purposes without authorization	Must obtain written authorization to release for TPO	Must have written authorization
Consent age for minor is 18	Consent age for minor is 13 for out patient treatment	Follows State Statute
Allows for release without consent for Mandated reporting for child abuse and neglect	Allows for release without consent for Mandated reporting	Refers to State Statute

25

# Medical Emergencies



26

The definition of medical emergency changed under the Final Rule:

- ▶ Before, information could be disclosed to “medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention”.
- ▶ Now, information can 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*”



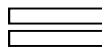
27

## Breakdown

Bona fide medical emergency



Patient’s informed consent cannot be obtained



Information may be disclosed to treating medical personnel without patient consent



28

# Qualified Service Organizations



29

# Qualified Service Organizations

- ▶ QSOAs are 2-way agreements -info can only flow between Part 2 program & QSO, not to third parties
- ▶ **“Population health management”** added to list of services a QSO may provide to a Part 2 program
- ▶ Refers to “increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group.”



30

## QSO continued

- ▶ Clarified that QSOAs may *not be used to provide treatment to patients, or to avoid obtaining patient consent:*
- ▶ Changed “medical services” to “medical staffing services” in list of services QSO may provide
- ▶ QSOAs may not be used for “care coordination” because it has a patient treatment component



31

## Audit and Evaluation



32



## Changes to 42 CFR Part 2 Research

- ▶ Info may be disclosed for scientific research by both Part 2 programs and lawful holders, under certain conditions
    - ▶ Who can decide whether a disclosure Part 2 protected information for research?
      - ▶ Part 2 program director, managing director, or “individual otherwise vested with authority to act as chief executive officer”, or their designee.
- Researchers are permitted to link both federal and non-federal data repositories (“data linkages”) if certain conditions are met.



33

## Security for Records



34

# Security for Records

- ▶ Changes to 42 CFR Part 2 provides that Part 2 programs and lawful holders must have in place formal policies and procedures to protect against unauthorized uses and disclosures of Part 2 information and protect against reasonably anticipated threats or hazards to the security of Part 2 information
- ▶ The Policies and procedures must address specific areas for paper and electronic records



35

For Paper Records:	For Electronic Records
Transferring and removing records	Creating, Receiving, Maintaining and Transmitting Records
Destroying records including sanitizing the hard copy media, to render patient ID non-retrievable	Destroying records including sanitizing electronic media on which records are stored to render the patient identifying information non-retrievable
Maintain records in a secure room, locked filing cabinet, safe, or other similar container, or storage facility when not in use	Using accessing electronic records or other electronic media contain patient identifying information
Using and accessing workstations secure rooms, locked file cabinets safes or other similar containers and storage facilities that use or store	Rendering the patient identifying information non-identifiable in a manner that creates a very low risk of re-identification
Rendering patient identifying information non-identifiable in a manner that creates a very low risk of re-identification	

36

# Child Abuse Neglect and Reporting

## Mandated Reporting



37

## HIPAA Mandated Reporting

- ▶ § 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual.
  - ▶ A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect
  - ▶ Allows for records to be disclosed to appropriate agencies for investigation purposes by subpoena or court order



38

## 42 CFR Part 2

- ▶ 42 CFR Part 2 § 2.12(c) (6)
- ▶ Allows programs to comply with mandatory child abuse reporting requirements under state law
- ▶ Must be some reason to suspect actual or imminent harm to the child.
- ▶ Applies only to initial report and to a written confirmation of that initial report (responses to follow-up investigation of initial reports and court inquires in child abuse or neglect case, must be authorized either by consent or another provision)
- ▶ Does not cover release of records even records sought by subpoena or court order
- ▶ **Does NOT cover reports of Adult Abuse or Neglect. Must Report Anonymously**



39

## 42 CFR Part 2 Continued

- ▶ The fact that a court may have mandated a parent into alcohol or drug treatment does not alter the need for authorization to disclose patient information
- ▶ Child welfare staff may condition parents' ability to remain or be reunited with their children on their participation in or successful completion of alcohol or drug treatment does not relieve the parents' treatment providers of their obligation to comply with the regulations



40

# 42 CFR Part 2 Regulations Involving Court Orders, Subpoenas, Arrest/Search Warrants

Module 2

41

41

## 42 CFR Part 2 § 2.61

- ▶ Neither a search warrant nor an arrest warrant constitutes the type of court order that authorizes a program to disclose patient-identifying information.
- ▶ A subpoena, search warrant or arrest warrant, even when signed by a judge and labeled a court order, is NOT sufficient when standing alone, to require or even permit a program to make a disclosure.
- ▶ A subpoena can compel a staff member's presence at court



42

42

## 5 requirements an investigative, law enforcement or prosecutorial agency must meet for issuing a compliant 42 CFR Part 2 order (good cause)

1. The crime involved is extremely serious such as threatening to cause death or serious injury The records sought are likely to contain information of significance to the investigation
2. There is no other practical way to obtain the information
3. The public interest in disclosure outweighs any actual potential harm to the patient, the doctor patient relationship, and the ability of the program to provide services to other patients
4. When law enforcement personnel seek the order, the program has the opportunity to be represented by independent counsel



43

## 2.65 Application

- ▶ An order authorizing the disclosure or use of patient records to investigate or prosecute a patient in connection with a criminal proceeding may be applied for by the person holding the records or by any law enforcement or prosecutorial officials who are responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws.
- ▶ The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny



44

## 2.65 Notice and Hearing

- ▶ Notice and hearing- adequate notice in a manner which will not disclose patient identifying information to other person of an application by a law enforcement agency or official
- ▶ An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order and
- ▶ Opportunity to be represented by counsel independent of counsel for an applicant who is a law enforcement agency or official.



45

## 2.65 Review of evidence

- ▶ Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application



46

In addition to the requirements to obtain the order, the following criteria must met

- Must limit disclosure to those parts of the patient's record that are essential to fulfill the purpose of the order
- Disclosure must be restricted to those law enforcement and prosecutorial officials responsible for conducting the investigation or prosecution
- The information may be used only to investigate the extremely serious crime or suspected crime specified in section 2.65e
- No disclosure of confidential communications may be made unless the requirements of 42 CFR part 2 § 2.63 are met
- **Under no circumstances may the court authorize a program to turn over the entire patient record to a law enforcement investigative or prosecutorial agency**



47

Contact Information

- ▶ Karolina Austin
  - ▶ Office: 727-545-7544 Ext 229
  - ▶ Cell: 727-200-1281
  - ▶ Fax: 727-545-7546
  - ▶ Email:  
[kaustin@sastampabay.org](mailto:kaustin@sastampabay.org)



48



## References

- ▶ Legal Action Center  
<https://lac.org/>
- ▶ SAMHSA- Substance Abuse and Mental Health Services Administration  
<https://www.samhsa.gov>
- ▶ CFBHN- Central FL Behavioral Health Network  
<https://www.cfbhn.org/>
- ▶ Electronic Code of Federal Regulations  
<https://www.ecfr.gov/>

