Part 2 Compliance – Where Nobody Knows Your Name

Vicki Bokar, RN  
Exec. Director, Corporate Compliance
Mary Legerski, JD, RN, CPC  
Director, Corporate Compliance

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
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

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
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

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)
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**

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 …”
Polling Question #1

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
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.

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).
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

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
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.

Polling Question #2
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

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.
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

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
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

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
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

- 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
• 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

• 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
Polling Question #3

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

A. Yes
B. No
• After discussions with the ED provider and his family, Mr. Smith agreed to be admitted to the Part 2 program and transportation was arranged.

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

- Mr. Smith tested at work site
- Mr. Smith taken to nearest ED for testing
- Mr. Smith agreed to be admitted to inpatient program

Work → ED → Part 2 Program

- H&P
- Nurses notes
- Consent form
- Consult
- Blood and ETOH tests
- + Urine test
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
• 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?

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
• 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?

• 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?
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

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
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

Key Takeaways

• Read and understand the regulations
  - SAMHSA is a great resource (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!
Questions?