42 CFR Part 2 Compliance: Patient Notice and Consent Requirements

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AGENDA

42 CFR Part 2: Webinar #2

1. Patient Notice Requirements
2. Consent Requirements
3. Patient Access

UPCOMING WEBINARS

42 CFR Part 2 Compliance Webinar Series:

Webinar #1: Does 42 CFR Part 2 Apply to You?

(Recorded August 7, 2018)

Webinar #3: Disclosures Without Patient Consent

(August 16, 2018)

QUESTIONS

Today's webinar will address the following questions:

- **What notice must be provided to patients?**
- **What are the required elements of a consent form for the disclosure of information protected by Part 2?**
- **How can patients access their information protected by Part 2?**

The next webinar will address the following questions:

- **What are the requirements for disclosing information protected by Part 2 without a patient's consent, including disclosures to auditors, contractors or vendors and law enforcement and/or courts?**

1. Notice to Patients

NOTICE: GENERAL RULE

42 CFR § 2.22 – Notice to patients of federal confidentiality requirements

- Part 2 Programs shall:
    1. Communicate to the patient that federal law and regulations protect the confidentiality of SUD patient records; and
    2. Give the patient a summary in writing of the federal law and regulations
        - Five required elements covered in the next slides

NOTICE: REQUIRED ELEMENTS

Written Summary: Element One

General description of the **limited circumstances** under which a Part 2 program may **acknowledge that an individual is present or disclose outside the Part 2 program** information identifying a patient as having or having had a SUD

- Acknowledging the presence of patients – 42 CFR §2.13(c)
    1. Presence:
        - Patient consent is required if the Part 2 program is publicly identified as a place where only SUD diagnosis, treatment or referral for treatment is provided
        - Patient consent is not required if the Part 2 program is not publicly identified as a place where only SUD diagnosis, treatment or referral for treatment is provided, and if the acknowledgement does not reveal that the patient has a SUD
    2. Responding to records requests:
        - Part 2 program may not affirmatively reveal that an individual has been, or is being, diagnosed or treated for SUD
        - Part 2 program may provide a copy of Part 2; however, it may not tell the requesting party that Part 2 restricts the disclosure of records of an identified patient

NOTICE: REQUIRED ELEMENTS

Case Study

ABC Health Center has six sites, including Fairview Clinic which is a Part 2 program specializing in MAT services. Because of the needs of the community, the Fairview Clinic now exclusively provides MAT services.

Debi receives primary care at another ABC Health Center site and receives MAT services at Fairview Clinic. Debi is being referred to the local hospital for an MRI. The hospital calls to request Debi's records.

- Can the Fairview Clinic confirm Debi is a patient without her consent?
- Can ABC Health Center confirm Debi is a patient without her consent?

NOTICE: REQUIRED ELEMENTS

Case Study

ABC Health Center's Fairview Clinic receives an Authorization to Release Patient Records form that Debi completed at the local hospital. The medical records clerk notices that the hospital's form does not meet the requirements under 42 CFR § 2.53. How should the medical record clerk respond?

A. Tell the hospital Debi's records are protected by 42 CFR Part 2

B. Send the hospital a copy of 42 CFR Part 2

C. Tell the hospital that Fairview Clinic's policy requires patients like Debi to complete a disclosure form which meets the requirements under 42 CFR Part 2

D. Tell the hospital that Fairview Clinic's policy requires patients to complete its disclosure form in order to release patient records

NOTICE: REQUIRED ELEMENTS

Written Summary: Element Two

Statement that violation of the federal law and regulations by a Part 2 program is a crime and that suspected violations may be **reported to appropriate authorities consistent with § 2.4, along with contact information**

- Reports of violations – 42 CFR § 2.4
    - May report any violation of the regulations to the US Attorney for the judicial district in which the violation occurred
    - May report any violation by an opioid treatment program to the US Attorney *as well as to* the SAMHSA office responsible for opioid treatment program oversight

NOTICE: REQUIRED ELEMENTS

Written Summary: Element Three

A statement that information related to **a patient's commission of a crime** on the premises of the Part 2 program or against personnel of the Part 2 program **is not protected**

- Crimes on Part 2 program premises or against Part 2 program personnel – 42 CFR § 2.12(c)(5)
    - Communications must be:
        - Directly related to a patient's commission of a crime on the premises of the Part 2 program or against Part 2 program personnel or to a threat to commit such a crime
        - Limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts

NOTICE: REQUIRED ELEMENTS

Written Summary: Element Four

A statement that reports of **suspected child abuse and neglect** made under state law to appropriate state or local authorities **are not protected**

- Reports of suspected child abuse and neglect – 42 CFR § 2.12(c)(6)
    - Note: Restrictions continue to apply to the original SUD patient records maintained by the Part 2 program including their disclosure and use for civil or criminal proceedings which may arise out of the suspected child abuse and neglect

NOTICE: REQUIRED ELEMENTS

Written Summary: Element Five

A **citation to the federal law and regulations**

NOTICE: REQUIRED ELEMENTS

Case Study:

Fairview Clinic includes the following statement on its Authorization to Release Patient Records form:

> 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

Does this meet the requirements for patient notice for a Part 2 program?

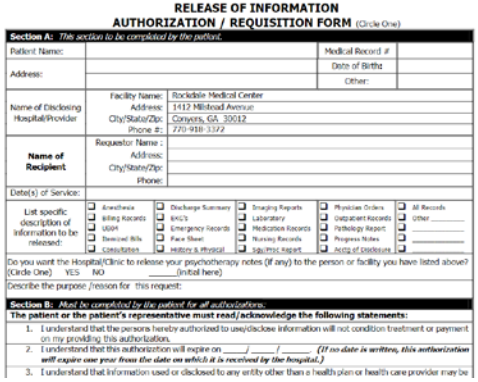
NOTICE: BEST PRACTICES

- Notice of Privacy Practices:
  - https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html

> *Instruction C: The Privacy Rule requires you to describe any state or other laws that require greater limits on disclosures. For example, "We will never share any substance abuse treatment records without your written permission." Insert this type of information here. If no laws with greater limits apply to your entity, no information needs to be added.*

- Other notice options:
  - New patient packet (including notice and consent forms together)

2. Disclosures with Patient Consent



RELEASE OF INFORMATION
AUTHORIZATION / REQUISITION FORM (Circle One)

Section A: *This section to be completed by the patient.*

Patient Name:		Medical Record #	
Address:		Date of Birth#	
		Other:	
Name of Disclosing Hospital/Provider	Facility Name:	Rockdale Medical Center	
	Address:	1412 Milstead Avenue	
	City/State/Zip:	Conyers, GA 30012	
	Phone #:	770-918-3372	
Name of Recipient	Requestor Name :		
	Address:		
	City/State/Zip:		
	Phone:		
Date(s) of Service:			

List specific description of information to be released:

☐ Anesthesia	☐ Discharge Summary	☐ Imaging Reports	☐ Physician Orders	☐ All Records
☐ Billing Records	☐ EKG'S	☐ Laboratory	☐ Outpatient Records	☐ Other _____
☐ UB04	☐ Emergency Records	☐ Medication Records	☐ Pathology Report	
☐ Itemized Bills	☐ Face Sheet	☐ Nursing Records	☐ Progress Notes	☐ _____
☐ Consultation	☐ History & Physical	☐ Op/Proc Report	☐ Accg of Disclosure	☐ _____

Do you want the Hospital/Clinic to release your psychotherapy notes (if any) to the person or facility you have listed above? (Circle One) YES NO _____(Initial here)

Describe the purpose /reason for this request:

Section B: *Must be completed by the patient for all authorizations.*

The patient or the patient's representative must read/acknowledge the following statements:

1. I understand that the persons hereby authorized to use/disclose information will not condition treatment or payment on my providing this authorization.
2. I understand that this authorization will expire on ____/____/____ ***(If no date is written, this authorization will expire one year from the date on which it is received by the hospital.)***
3. I understand that information used or disclosed to any entity other than a health plan or health care provider may be

DISCLOSURE: GENERAL RULE

- **General Rule:** Information that identifies an individual as a patient of a Part 2 program is confidential and may not be disclosed without patient consent, unless an exception applies
    - Unlike HIPAA, ***patient consent is required*** even for disclosures for the purposes of treatment, payment or health care operations

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

Required Elements - 42 CFR § 2.31

1. Name of patient
2. Amount and kind of information to be disclosed
3. "From Whom"
4. "To Whom"
5. Purpose of disclosure
6. Statement that the consent is subject to revocation at any time
7. The date, event, or condition of expiration
8. Signature of patient
9. Date of signature

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

Amount and kind of information to be disclosed - 42 CFR § 2.31(a)(3)

How much and what kind of information is to be disclosed, including an **explicit description** of the SUD information that may be disclosed

- May include free text space or options based on a "generally accepted architecture" or document
- Can include "all my SUD information" as long as more granular options are included, such as:
    - Diagnostic information
    - Medications and dosages
    - Laboratory test results
    - Substance use history summaries
    - Trauma history summary
    - Elements of a medical record such as clinical notes and discharge summary, claims/encounter data, current problem listetc.

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

"From Whom" - 42 CFR § 2.31(a)(2)

The specific name(s) or general designation(s) of the Part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure

- Include name of identified unit (clinic site or program) if health center meets second prong of "program" definition
- Include designation of "SUD providers" if health center meets third prong of "program" definition

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

"To Whom" - 42 CFR § 2.31(a)(4)

- To an individual – Name of individual
- To an entity –
    1. If entity has a treating provider relationship with the patient (such as a hospital, health care clinic or private practice) – Name of entity

DISCLOSURE: WRITTEN CONSENT

Treating Provider Relationship – 42 CFR § 2.11

(1) 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;

(2) 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.

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

"To Whom" - 42 CFR § 2.31(a)(4)

2. If the entity does not have a treating provider relationship with the patient:

- Third-party payer: Name of the entity (i.e. MassHealth)
- Other entities (such as a health information or a research institution):
    - Name of the entity(-ies) **AND**
    - One of the following:
        - The name(s) of an individual participant(s); **or**
        - The name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; **or**
        - General designation of an individual or entity participant(s) or class of participants limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed
            - Statement on the consent form confirming the patient understands that they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (*See* § 2.13(d)).

DISCLOSURE: WRITTEN CONSENT

Individual or Entity?	Treating provider relationship?	Primary "To Whom"	Secondary "To Whom" (if applicable)
Individual	Yes	Name of Individual	
Individual	No	Name of Individual	
Entity [Hospital, health care clinic, private practice etc.]	Yes	Name of entity	
Entity [Third party payer]	No	Name of entity	
Entity [HIE or research facility]	No	Name of entity	At least one of the following: (1) Name of individual participant (e.g., Dr. John Doe) (2) Name of participating entity with treating provider relationship (e.g., Lakeview County Hospital) (3) General designation of an individual or entity participant, or a class of participants with a treating provider relationship (e.g., my current and future treating providers)

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

Purpose of Disclosure - 42 CFR § 2.31(a)(5)

The disclosure must be limited to the information necessary to carry out the stated purpose

- Confidentiality restrictions and safeguards – 42 CFR § 2.13(a)
  - Patient records subject to Part 2 may be disclosed or used only as permitted by Part 2 and may not otherwise be disclosed or used in any civil, criminal, administrative or legislative proceedings conducted by any federal, state or local authority.
  - Any disclosure made under Part 2 must be limited to that information which is necessary to carry out the purpose of the disclosure.

DISCLOSURES WITH PATIENT CONSENT: REQUIREMENTS

Signature of Patient - 42 CFR § 2.31(a)(8)

Electronic signatures are permitted to the extent that they are not prohibited by state law.

Special attention to:

- Minor patients - 42 CFR § 2.14
- Incompetent or deceased patients - 42 CFR § 2.15

DISCLOSURES WITH PATIENT CONSENT: PROHIBITION ON RE-DISCLOSURE

Prohibition on re-disclosure - 42 CFR § 2.32

Each disclosure made with the patient's written consent must be accompanied by one of the following written statements:

- 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.

3. Patient Access

PATIENT ACCESS

Patient access and restrictions on use – 42 CFR § 2.23

- A Part 2 program may provide a patient with access to their own records, including the opportunity to inspect and copy any records that the Part 2 program maintains about the patient.
- A Part 2 program is not required to obtain a patient's written consent or other authorization under the regulations in this part in order to provide such access to the patient.

Final Thoughts

FINAL THOUGHTS

- **Remember, Part 2 restricts disclosure and use of SUD records which are maintained in connection with the performance of a federally-assisted Part 2 program or records received as a lawful holder**
- **Determine how to provide patients with the required notice about Part 2**
- **Review your health center's current procedures and forms related to disclosing records with a patient's consent/authorization and revise for compliance with the Part 2 requirements**

QUESTIONS?

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OTHER UPCOMING TRAINING EVENTS

Webinars		
August 16th @ 1 PM	A-133/ Subpart F Audits	
August 16th @ 3 PM	42 CFR Part 2 Compliance: Disclosure Exceptions	
September 6th, 13th, 20th and 27th @ 1 PM	CMS Emergency Preparedness Rule Webinar Series (Live Series)	
September 26th @ 1 PM	HRSA Program Compliance: Latest Developments and "Hot" Issues	
October 11th @ 1PM	FTCA: Key Elements	
Live Trainings		
September 12th – 14th	Federal Funding Academy	Louisville, KY
September 17th – 18th	340B Drug Discount Program Compliance	Washington, DC
September 19th – 20th	Ryan White Program Income - How Do I Account For It, What Can I Spend It On?	Washington, DC
September 25th – 26th	HIPAA: Fundamentals	Washington, DC
October 1st – 2nd	Health Center Compliance Intensive: Fundamentals	Washington, DC
October 3rd – 4th	Health Center Compliance Intensive: Advanced Concepts	Washington, DC

For more information and to register:
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