
Confidentiality of Substance Use Disorder Patient Records Rule

Tom Bixby

THOMAS D. BIXBY LAW OFFICE LLC

TBIXBY@TBIXBYLAW.COM

(608) 661-4310

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With Apologies to Judith Viorst

Part 2:

The Terrible, Horrible, No Good, Very Bad Rule

Part 2 Rule General Overview

Part 2 Terminology

Patient Identifying Information

- Relates to Patient of a Part 2 Program
- Individually identifiable (per HIPAA)
- Patient received diagnosis, treatment or referral for SUD

Part 2 Program

- Holds itself out as providing SUD treatment
- Receives Federal assistance
- May be a unit of larger facility (“Mixed-Use” facility)

Lawful Holder

- Any entity in lawful possession of Patient Identifying Information

General Rule—Consent Required

Consent to receive and use PII

- Consent must name recipient
- Consent must specify purpose for permitted disclosure
- Recipient must limit use to specified purpose

Consent to re-disclose PII

- Re-disclosure prohibited without consent*
- Consent must be **very** specific

Exceptions to Consent Requirement

Audit & Evaluation

- Audit or “Evaluation” of Lawful Holder
- For regulators and entities providing financial assistance
- Written agreement required

Research

- In accordance with HIPAA
- **Not** Limited Data Sets

Medical Emergencies

- Bona fide medical emergency

Part 2 Rule Consent

Consent: Nine Elements

1. Patient name
2. Who can make disclosure
3. Type and kind of information to be disclosed
4. Right to revoke
5. Date or condition for expiration of consent
6. Signature
7. Date
8. Purpose of the disclosure—recipient's permitted uses
9. The recipient

Consent: 4 types of Permitted Recipients

1. Named “Intermediary”

2. Named Third-Party Payer

- Acme Health Plan (**not** “my health plan”)

3. Named entity with Treating Provider Relationship

- Betty Ford Clinic;
- Anytown General Hospital

4. A named individual

- Ms. Jane Doe
- Dr. Jerome Adams

Notice with Disclosures by Consent

- Notice that Part 2 applies (“Part 2 Disclaimer”)
 - Must accompany each disclosure of PII permitted by consent
 - Two options, but **must be verbatim**
 - Long form (paragraph: 143 words, 900+ characters—see next slide)
 - Short form (sentence: 10 words, 55 characters):

42 CFR part 2 prohibits unauthorized disclosure of these records

- General warning not sufficient for Disclaimer

Part 2 Disclaimer (long 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.

Payment & Health Care Operations Consent

Permitted Purpose of Consent

- Purpose is recipient's "payment & health care operations activities"

Permits re-disclosure (subject to contract terms)

- To contactors & subcontractors (*i.e.*, business associates)
- Names or other designation of contractors are **not** required

Part 2 Disclaimer required

Permits disclosure directly to contractor/subcontractor

Payment & Health Care Operations Consent

(Limited) Alignment with HIPAA

- Allows contractors to **use**, but not **re-disclose** PII
- Allows some (not all) Payment & Health Care Operations Activities

Activities **not** permitted by consent:

- Case management & care coordination
- Utilization review and others not listed, but not prohibited

Contractor/Subcontractor terms

- Comply with Part 2 Rule
- Implement appropriate safeguards
- Report unauthorized use, disclosure or breach of PII
- No re-disclosure (except to Third-Party Payer or subcontractor)

Intermediary Consent

Intermediary consent

- Must specify name of **Intermediary**
- Must describe how Intermediary may re-disclose Patient Identifying Information
- Must provide notice of right to accounting of re-disclosures

Intermediary

- Is **not** a health care provider or Third-Party Payer
- Is entity “such as” Health Information Exchange or research institution

Permits re-disclosure to

- Named **individual** “participant”
- Named entity “participant” w/ Treating Provider Relationship
- General designation of “participants” w/ Treating Provider Relationship

Disclosure Without Consent

Audit & evaluation of Lawful Holder by

- Gov't agency that provides financial assistance to Lawful Holder
- Gov't agency that regulates Lawful Holder
- Third-Party Payers covering patients at Part 2 Program
- Other entities that provide financial assistance to Lawful Holder

“Evaluation”

- Not defined

Disclosure Without Consent

Audit & evaluation

- May be conducted by contractor or subcontractor

Subject to written agreement to:

- Maintain and destroy PII per Part 2 requirements
- Retain records in accordance with applicable law
- Re-disclose PII only to Lawful Holder
- Use only for audit/evaluation or Part 2 Court Order

Compliance with Part 2 Rule

Getting Consent

To submit a claim,
Part 2 Program
must:

- Get patient's written consent
- Include Part 2 Disclaimer with any disclosure

To Pay a claim,
Health Plan must:

- Recognize claim as having Patient Identifying Information
- Have patient's written consent
- Include Part 2 Disclaimer with any re-disclosure

Part 2 Program is:

- Face-to face with patient
- Wants Health Plan to pay the claim

Getting Consent

Part 2 Program: Expand scope of consent to include

- Enable Health Plan's Payment & Health Care Operations
- Enable Health Plan to send payment information to Part 2 Program

Plan: provide template consent to include:

- Part 2 Program's treatment, payment & health care operations activities
- Health Plan's payment & health care operations activities
- Health Plan's re-disclosure of PII to Part 2 Program

Case Management/Care Coordination

Use an Intermediary Consent

- Name Intermediary
- Permits re-disclosure to provider "participants"
- Re-disclosure accounting right

Tailor for Case Management/Care Coordination

- Name case manager/care coordinator as Intermediary
- General designation of Providers w/ Treating Provider Relationship
- Purpose: Case Management/Care Coordination

Audit and Evaluation

Health Plan's Utilization Review

- Plan request for PII to conduct Utilization Review
- Plan agrees to required terms

DOI Inquiry

- DOI request for PII for complaint, Market Conduct Exam, etc.
- DOI must agree to required terms

Required terms: written agreement to:

- Maintain and destroy PII per Part 2 requirements
- Retain records in accordance with applicable law
- Re-disclose PII only to Lawful Holder
- Use only for audit/evaluation or pursuant to Part 2 Court Order

Enforcement

Violators subject to US Criminal Code

- Penalties limited to fines (no prison!)
- Report violations to local US Attorney

No Regulatory Enforcement

- No enforcement rule
- No mechanism to report Third-Party Payers to SAMHSA

Rule “to be construed strictly in favor of . . . violator”

Questions?

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