



**BlueCross
BlueShield**

NATIONAL SUMMIT

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Confidentiality Of Substance Use Disorder Patient Records

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*INSPIRE
INNOVATE
ACT*

With Apologies to Judith Viorst

Part 2: the Terrible, Horrible, No Good, Very Bad Rule

General Overview

Part 2 Terminology

- Patient Identifying Information
 - Identifies a Patient
 - Of a Part 2 Program
 - Diagnosis, treatment or referral for Substance Use Disorder
- Part 2 Program
 - Holds itself out as providing SUD treatment
 - May be a unit of larger facility (“Mixed-Use” facility)
 - Receives Federal assistance
- Lawful Holder
 - Any entity in lawful possession of Patient Identifying Information

General Rule—Consent Required

- Lawful Holder Must Have Patient Consent
 - Disclose Patient Identifying Information
 - Use Patient Identifying Information
- Written Consent
 - Must specify:
 - Entity (type of entity) permitted to make disclosure
 - Permitted recipient(s)*
 - Type and kind of information to be disclosed
 - Purposes for permitted uses/disclosures
 - Right to revoke
 - Expiration date/signature/date of signature

Consent: Permitted Recipients

- A named individual
 - Ms. Jane Doe
 - Dr. Jerome Adams
- Named entity with Treating Provider Relationship
 - Betty Ford Clinic;
 - Anytown General Hospital
- Named Third-Party Payer
 - Blue Cross Blue Shield of Geography
- Named “Intermediary”

Disclosures pursuant to consent

- May condition coverage on signing consent
 - Payment, enrollment in health plan, eligibility for benefits
 - Provider may condition treatment
- Part 2 Disclaimer
 - Must accompany each disclosure of PII
 - Two options, but must be verbatim
 - Long form (paragraph: 143 words, 900+ characters)
 - 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

- Prior to February 2, 2018, Disclaimer was:
- 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.

Exceptions: Uses/Disclosures Without Consent

- Audit & Evaluation
 - Audits by regulator or entity providing financial assistance
 - “Evaluation”
 - Health oversight by DOI, CMS, etc.
 - Utilization management
- Research
 - In accordance with HIPAA
 - **Not** Limited Data Sets
- Medical Emergencies
 - Bona fide medical emergency

Data Partitioning

- Disclosure of Patient Identifying Information
 - Separate consent necessary for most disclosures
 - Special restrictions for audits, health oversight
- Use of Patient Identifying Information
 - Not permitted for all payment activities and health care operations
 - Case management/utilization review*
 - Population-based activities—improve health, reduce costs
- Part 2 Security Safeguards
 - Locked in file cabinet or safe
 - Limiting access to Patient Identifying Information

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

So it would appear a Blue Plan must . . .

- Locate Patient Identifying Information
 - In claims and other correspondence
- Partition Patient Identifying Information
 - Limit uses, avoid most disclosures
- Obtain Patient's written consent
 - Specify purposes for uses/disclosures
 - Specify recipients (at individual level)
- Refrain from any use or disclosure until get consent
- Procedure for Part 2 Disclaimer with disclosures



Part 2 Rule Survivor's Guide

Part 2 Rule Survivor's Guide: Principles

- We do not have to assume that others will violate the law
- We can rely on others to help us comply with the law



Part 2 Rule Survivor's Guide: Tool Box

- Payment & Health Care Operations Consent
 - Allows recipient to receive & use PII for certain activities
 - Allows re-disclosure to contractors for activities
- Intermediary consent
 - Case management & care coordination
- Evaluations
 - Utilization review and other “evaluations”

Survivor's Guide Tool Box

- Payment & Health Care Operations Consent
 - Purpose is recipient's payment & HCO activities
 - Named recipient: e.g., BCBS of Geography
- Permits re-disclosure (subject to contract terms)
 - To contactors & subcontractors
 - i.e., business associates
 - Stop-loss carriers (for ASO/ASC groups)
- Part 2 Disclaimer
- Permits direct disclosure

Survivor's Guide Tool Box

- 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)
- (Limited) alignment with HIPAA
 - Payment & Health Care Operations
- Activities **not** permitted by consent:
 - Case management & care coordination
 - Utilization review

Survivor's Guide Tool Box

- Intermediary consent
 - Must specify name of **Intermediary**
 - Must provide notice of re-disclosure accounting right
- Intermediary
 - Is **not** a 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

Survivor's Guide Tool Box

- Audit & evaluation of Lawful Holder by
 - Government agencies:
 - Providing financial assistance to Lawful Holder
 - Authorized by law to regulate Lawful Holder
 - Third-Party Payers covering patients at Part 2 Program
 - Other entities providing financial assistance to Lawful Holder
- “Evaluation”
 - Not defined
 - DOI complaints/market conduct exams
 - Third-Party Payer's Utilization Review

Survivor's Guide Tool Box

- 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 pursuant to Part 2 Court Order
- Written agreement with regulator
 - Part 2 Rule preempts State law
 - Agreement does not need to be a contract between parties



Blue Plan Compliance with Part 2 Rule

Applying Principles to Claims

- To submit a claim, Part 2 Program must:
 - Get patient's written consent
 - Include Part 2 Disclaimer with any disclosure
- To Pay a claim, Blue Plan must:
 - Recognize claim as having Patient Identifying Information
 - Get patient's written consent
 - Include Part 2 Disclaimer with any disclosure
- Part 2 Program is:
 - Face-to face with patient
 - Wants Blue Plan to pay the claim

Principle # 1: Do not assume others violate the law

- Two Problems:
 - Part 2 Programs do **not** include Part 2 Disclaimer with claims
 - Blue Plan does not know a claim has PII
- We **know** they are in violation!
- Cannot stick head in the sand!
 - Make good-faith effort to comply



Applying Principles to Claims

- Provide guide for Part 2 Disclaimer
 - In electronic claims (Loop 2300, NTE02)
 - In paper claims (field 19 (professional) 80 (institutional))
- Require all providers to furnish Disclaimer
 - Participation agreements (network providers)
 - Billing guidelines (all providers)
- Make furnishing Disclaimer condition of payment
 - Part 2 Program violates the law by failing to include
 - We need to flag PII to properly process
 - Reject claims known to contain PII without Disclaimer

Applying Principles to Claims

- Identify Part 2 Programs
 - Flag claims without disclaimer
 - Deny claims when appropriate (Mixed use facilities)
 - Push back on uncooperative Part 2 Programs
- May assume others do not violate the law
 - After implementing reasonable measures
 - Assume that no disclaimer means no PII

Principle # 2: Rely on others to help comply with the law

- Blue Plan's consent to use Patient Identifying Information
 - Part 2 Program is already required to obtain consent
 - Expand scope of consent to:
 - Enable Blue Plan's Payment & Health Care Operations
 - Enable Blue Plan to send payment information to Part 2 Program
- Provide template consent for:
 - Part 2 Program's TPO
 - Blue Plan's payment & health care operations activities
 - Blue Plan's re-disclosure of PII to Part 2 Program for its TPO

Applying Principles to Claims

- Require all Part 2 Programs to obtain consent
 - Participation agreements (network providers)
 - Billing guidelines (all providers)
- Make obtaining consent condition of payment
 - Blue Plan cannot use or disclose PII to:
 - Process claim without consent
 - Pay provider without consent
 - Blue Plan is permitted to condition eligibility for benefits on consent

Using other tools in the Tool Box: Intermediary Consent

- Intermediary Consent:
Case Management/Care Coordination
 - Vendor (or Blue Plan?) as Intermediary
 - Obtain consent directly from patient
 - Obtain consent through provider
- Case Management/Care Coordination Consent
 - Name case manager/care coordinator as Intermediary
 - General designation of Providers w/ Treating Provider Relationship
 - Purpose: Case Management/Care Coordination

Using other tools in the Tool Box: Intermediary Consent

- Consent permits Recipient to:
 - Use PII for case management/care coordination services
 - Re-disclose PII to treating providers
- Disclosure accounting requirement
 - Patient must request in writing
 - Provide list of re-disclosures for past two years
 - Include recipient, date, and description of information disclosed
 - 30 days to respond

Using other tools in the Tool Box

Audit and Evaluation

- Evaluation:
 - Utilization Review
 - Request PII for Utilization Review
 - 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

Terrible, horrible, no good, very bad stuff . . .

- Part 2 Rule does not fully align with HIPAA
- But, Survivor's Guide helps:
 - Require Part 2 Disclaimer—assume no PII without Disclaimer*
 - Require provider to obtain consent
 - Payment and Health Care Operations Consent
 - Care Management/Care Coordination Consent
 - Evaluations—Utilization Review
- Blue Plans will still will need to
 - Partition Patient Identifying Information from other PHI
 - Establish a procedure for including the Part 2 Disclaimer



Questions?

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Thank You



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