

ATTORNEYS
AT LAW

PRIMMER PIPER
EGGLESTON &
CRAMER PC

Part 2 Substance Use Disorder Confidentiality 2024 Final Rule Impacts on Operations

John H. Wallace

jwallace@primmer.com

<https://www.primmer.com/all-professionals/john-h.-wallace>

OBJECTIVES

1. Review changes from the current Part 2 Rule (2020 Rule) to the 2024 Final Rule that will affect operations for
 - Part 2 Programs (P2P)
 - HIPAA covered entities that receive Part 2 records
 - Health Information Exchanges
2. Review impacts on operations and challenges to implementation
3. Identify questions for further discussion.

OUTLINE

1. Effective date and Compliance date (2 year implementation)
2. What is a Part 2 Program (P2P)? (unchanged)
3. What is a Part 2 Record? (unchanged)
4. What are the Consent Requirements? (revised)
 - Single (1 time) consent for future disclosures for TPO
5. P2Ps must provide Notice and Consent

CARES Act 2020 § 3221, align Part 2 with HIPAA

Requires HHS to revise Part 2 regulations and HIPAA to include:

- General consent - future uses for TPO
- Patient consent - P2P, CE, BA may use, disclose, and redisclose for TPO in the same manner as HIPAA
- Authorize disclosure of de-identified records for public health purposes.

Effective Date & Compliance Date

2 year implementation

- Feb. 16, 2024 HHS published Final Rule, Confidentiality of Substance Use Disorder (SUD) Patient Records
- April 16, 2024, Final Rule Effective Date
- Feb. 16, 2026, Compliance Date
 - Organizations have up to 2 years to develop policies, consent processes, and provide training to staff to comply with the Final Rule.
 - EHR system development to comply with the rule

Two issues will affect implementation

1. **NPP Rule:** HHS will release changes to HIPAA Notice of Privacy Practices (2024) for CEs to provide notice regarding use of Part 2 records
2. **Technology:** EHR systems will need to develop functionality for P2Ps to send downstream record recipients required Part 2 notice and summary of patient consent
 - HHS to provide technical guidance to P2Ps to help with implementation

What Hasn't Changed

- What is a P2P
- What is a Part 2 Record
- P2Ps cannot disclose patient records without consent unless an exception applies
- P2Ps and recipients of records are obligated to prevent unauthorized disclosure for use in legal proceedings against the patient

(Note: segmentation/segregation is no longer required but Notice and Consent is required)

P2P

1. Federally assisted, nonprofit providers
 - Receive federal grants;
 - Participate in state or federal health programs; or
 - Receive tax deductions or are tax-exempt; and are
2. SUD Provider or P2P: How entity or individual **holds itself out**
 - a. Entity that holds itself out as providing SUD diagnosis, treatment or referral
 - b. **Identified unit** within a general medical facility that holds itself out as providing SUD dx, tx, referral; or
 - c. Staff in a general medical facility whose **primary function** is identified as providing SUD dx, tx, or referral

Part 2 Record

- Information (recorded or not)
 - **Created, received, or acquired by a P2P**
 - **Relates to a patient**
 - **Patient identifying information**
 - Name, address, SSN, photo, or similar info where identity can be determined with reasonable accuracy and speed, or by reference to other publicly available information
 - Not internal numbers (MRN) assigned by a P2P
- PII + P2P = Part 2 record

Records, other than verbal communications for treatment

- Transmitted from a P2P to a non-part 2 provider
- Retain their characteristics as a part 2 record (protections flow with the data)

SUD Diagnosis Information is a Part 2 Record:

- Any record reflecting a diagnosis identifying a patient as having a SUD; **and**
- Initially prepared by a P2P in connection with treatment or referral.
 - Connection between diagnosis and P2P
 - Part 2 records must include notice identifying Part 2 information
 - Rule does not apply to SUD diagnosis or treatment not connected to a P2P (eg ED or primary care)

2024 Final Rule

Significant changes that will affect operations

1. Consent process to capture single consent
2. Requirement for disclosing Part 2 records
 - Record must include
 - notice of the prohibition on unauthorized use in legal proceedings; (currently required) and
 - Summary of individual's consent (new)

Consent forms – 9 elements

1. Patient name
2. Name(s) of entities or individuals permitted to disclose records
3. **Amount & kind** of information to be disclosed
4. **To whom** information can be disclosed
5. **Purpose** of the disclosure
6. Statement that consent subject to revocation at any time
7. **Expiration** of the consent
8. Patient signature
9. Date signed

3. Amount & Kind of information to disclose

2020 Amount & Kind:

- an explicit description of information to be disclosed

2024 Amount & Kind:

- specific description of the information to be used and disclosed.

“all records and information related to my treatment and payment for services.”

4. To Whom

2020 To Whom requirement:

- *Name or title of the individual or entity* to whom Part 2 information can be disclosed
- Health Information Exchange (HIE)
 - Names of participating individuals or entities, or
 - General designation of participants that is limited to treating providers

2024 To Whom requirement:

- Single Consent - class of recipients

“all providers involved in my health care, entities involved in payment for my care, and entities that support the sharing of my health information with all providers and payers involved in my health care”

5. Purpose of Disclosure

2020 Purpose of disclosure:

- disclosure limited to the information necessary to carry out the stated purpose

2024 Purpose of disclosure:

- TPO consent - single consent for treatment, payment, and health care operations
- CE and BAs may use and disclose for TPO (HIPAA)
- Consent form must include a statement about the potential for records to be redisclosed by recipients when they are disclosed under a TPO consent.
- P2P may condition treatment on patient signing TPO consent
 - P2Ps that condition treatment on a TPO consent should take reasonable steps to address patients' request for restrictions on uses and disclosures for TPO. 89 FR 12546

7. Consent to Disclosure: Expiration

2020 Expiration:

- Date, event, or condition that would cause consent to expire that lasts not longer than reasonably necessary to serve the purpose of the disclosure

2024 Expiration:

- “none”

Notice and copy of consent

For disclosures with patient consent, P2Ps must provide downstream record recipients with:

1. Notice of the prohibition on unauthorized use in legal proceedings.
2. Each disclosure must include patient's consent or a clear explanation of the scope of the consent

Notice of Prohibition on Re-Disclosure

To prevent unauthorized re-disclosure, all SUD records must be accompanied with one of the following notices

Long Version

This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is 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.

Short version 80 characters

42 CFR Part 2 prohibits unauthorized disclosure of these records

Notice and Copy or Summary of Consent

- Notice to inform downstream recipients of restrictions on redisclosure for use in a legal proceeding
- Each disclosure made with consent must be accompanied with a notice and a copy of the consent or a clear explanation of the scope of consent provided. 89 FR 12555
- Notice is required only for disclosures made with consent, notice not required for re-disclosures as permitted by HIPAA for TPO 89 FR 12555

Cares Act: Once a Part 2 record has been disclosed for TPO pursuant to patient's consent, any information may then be redisclosed in accordance with HIPAA.

Recipient still has obligation to protect records from unauthorized use.

Accounting for Disclosures

- P2Ps are required to provide an accounting of all disclosures made with consent in the 3 years prior to the request.
- P2Ps are required to provide an accounting of all disclosures for TPO that are made through an EMR.

Public Health Disclosures

The final rule permits disclosure to public health authorities without patient consent provided that the records are first de-identified in accordance with HIPAA.

SUD Counseling Notes

- The rule creates a special protections for SUD counseling notes that is similar to HIPAA's protection of psychotherapy notes.
- SUD counseling notes involve contents of conversations
- are separated from the rest of the patient's SUD and medical record.
- excludes medication prescription and monitoring, counseling session start and stop time, modalities and frequency of treatment, clinical test results, diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date.
- may only be disclosed with the patient's specific consent, and treatment cannot be conditioned on the requirement to consent to the disclosure of counseling notes.

This presentation is for general informational purposes only and not for the purpose of providing legal or professional advice on a specific issue or problem.

Due to the rapidly changing nature of the law, information contained in these slides may become outdated and is subject to change without notice.

Questions?