



Part 2 Final Rule

How the 2024 Part 2 Rule will affect Part 2 programs, health care providers, and the VHIE.

A. **Patient Notice:** alignment of new Part 2 program Notice of Privacy Practices (NPP) and HIPAA NPP

- HHS will be releasing guidance on NPPs Spring 2024, which will include directions for covered entities that are recipients of Part 2 records.
- Wait until new HIPAA NPP is published before implementing new notice and consent process

B. **Consent:** modify Consent process to capture single consent

2.31 Consent requirements

- (4)(i) single consent for all future uses and disclosures for treatment, payment, or health care operations (TPO)
- 2020 Rule – Consent forms have 9 elements including (1) To whom; (2) amount and kind; (3) purpose; and (4) expiration.

1. **To Whom**

- **2020 To whom:** Identify each individual or entity to whom Part 2 information may be disclosed (and redisclosed)
 - HIE: The names of participating entities to whom information may be disclosed, or a general designation authorizing HIE participants who have a treating provider relationship with the patient. The patient may obtain a list of entities to whom their information may have been disclosed.
- **2024 To whom:** Single Consent – name a 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”

2. **Amount and Kind**

- **2020 Amount and Kind** an explicit description of information to be disclosed.
- **2024 Amount and Kind:** Specific and meaningful description of the information to be used and disclosed.
“all records and information related to my treatment and payment for services.”

3. **Purpose**

- **2020 Purpose:** disclosure limited to the information necessary to carry out the stated purpose
- **2024 Purpose:** TPO consent - single consent for treatment, payment, and health care operations where patient consents for all such future uses or disclosures.
- Allows CE and BAs to use, disclose, and redisclose records for TPO as permitted by HIPAA. Patient consent will need to include a statement about the potential for



records to be redisclosed by the recipient when they are disclosed under a TPO consent.

- HHS states that Part 2 programs should not condition treatment on a TPO consent unless it has taken reasonable steps to address patients' request for restrictions on uses and disclosures for TPO. 89 FR 12546

4. 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"

Single Consent: I consent to the disclosure of all necessary records and information related to my treatment for the purposes of treatment, payment, and health care operations and all such future uses and disclosures to 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."

C. Notice and Consent Summary

1. Develop process for providing recipient with
 - (1) notice of prohibition on use in legal proceedings, and
 - (2) summary of consent
- Require new EMR functionality to add notice and consent summary
- All part 2 information must be accompanied with a notice on the prohibition on redisclosure and at least a clear explanation of the scope of any consent provided.

§ 2.32 Notice and copy of consent to accompany disclosure.

- (a) Each disclosure made with the patient's written consent must be accompanied by one of the following written statements (*i.e.*, paragraph (a)(1) or (2) of this section):
 - (1) This record which has been disclosed to you is protected by Federal confidentiality rules (42 CFR part 2). These rules prohibit you from using or disclosing this record, or testimony that describes the information contained in this record, in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient, unless authorized by the consent of the patient, except as provided at 42 CFR 2.12(c)(5) or as authorized by a court in accordance with 42 CFR 2.64 or 2.65. In addition, the Federal rules prohibit you from making any other use or disclosure of this record unless at least one of the following applies: (i) Further use or disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or as otherwise permitted by 42 CFR part 2. (ii) You are a covered entity or business associate and have received the record for treatment, payment, or health care operations, or (iii) You have received the record from a covered entity or business associate as permitted by 45 CFR part 164, subparts A and E. A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31).



(2) *Statement 2.* “[42 CFR part 2](#) prohibits unauthorized use or disclosure of these records.”

(b) Each disclosure made with the patient's written consent must be accompanied by a copy of the consent or a clear explanation of the scope of the consent provided.

- Notice is intended to inform downstream recipients of restrictions on redisclosure for use in a legal proceeding
- Notice is necessary to retain the “core patient protection against use of records in legal proceedings against the patient.”
- Each disclosure 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, and thus the notice would not be required for redisclosures as permitted by HIPAA for TPO or other permitted purposes. 89 FR 12555¹

D. Accounting for Disclosures (NEW)

- a. Part 2 programs are required to provide an accounting of all disclosures made with consent in the 3 years prior to the request.
- b. Part 2 programs are required to provide an accounting of all disclosures for TPO that are made through an EMR.

E. Public health disclosure (NEW)

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

F. 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 during SUD counseling sessions that are separated from the rest of the patient’s SUD and medical record. Counseling notes 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.

¹ The statement in the preamble that notice is not required for redisclosures as permitted by HIPAA may seem inconsistent with the statement that notice is necessary to retain the “core patient protection against use of records in legal proceedings against the patient.” However, the CARES Act states that once a Part 2 record has been disclosed for TPO pursuant to a patient’s consent, any information may then be redisclosed in accordance with the HIPAA regulations. Public Law 116-136 § 3221(b)(1) Mar. 27, 2020). Presumably, HHS does not have authority to impose a notice requirement for redisclosures that are subject to HIPAA as opposed to Part 2. While there may be no notice requirement for disclosures for TPO, HHS notes that any entity seeking to redisclose Part 2 records is obligated to protect the records from unauthorized use. 89 Fed. Reg. at 12572.



- Counseling notes 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.

G. Qualified Service Organization (QSO)

- QSOs support Part 2 programs
- A QSO that supports a Part 2 program that is also a covered entity is both a QSO and a business associate.
- A business associate that supports a covered entity that is only a recipient of Part 2 records and not a Part 2 program is only a business associate, and not a QSO.