

Changes to Part 2 Regulations: An Implementation Checklist for Part 2 Programs

Policy Revisions Regarding Use & Disclosure. Part 2 programs will need to update their policies and procedures governing the use and disclosure of Substance Use Disorder (“SUD”) records.

- Incorporate new terms and revise current definitions to be consistent with revised 42 CFR 2.11.
- Adopt a new policy for “substance use disorder (“SUD”) counseling notes” which:
 - Requires the patient consent for use/disclosure unless one of the following limited exceptions applies: (i) use by the originator of the SUD counseling notes for treatment; (ii) use or disclosure for the part 2 program’s own training program; (iii) use or disclosure by the part 2 program to defend itself in legal action or other proceeding brought by the patient; (iv) use or disclosure to the Secretary of HHS to investigate compliance with part 2; (v) disclosure for purposes of identifying the cause of death of the patient; (vi) as allowed by 42 CFR 2.53 with respect to oversight activities of the originator of the SUD counseling notes; (vi) a court order in accordance with 42 CFR 2.63(a) or 42 CFR 2.64.
 - Requires the patient’s written consent to be in its own document, not combined with other consents except for another written consent for use/disclosure of SUD counseling notes.
 - Prohibits conditioning treatment, payment, enrollment or eligibility for benefits on the provision of a written consent for the use/disclosure of SUD counseling notes.
- Revise your current policy to allow for patients to consent to future uses and disclosure of SUD records (not including SUD counseling notes) for “treatment, payment and healthcare operations” pursuant to a general consent.
- Update your policies to require the patient’s written consent or a summary of the scope of the consent accompany SUD records when disclosing SUD records pursuant to a patient consent.
- Adopt a policy allowing patients to request restrictions of how their SUD records are used/disclosed for treatment, payment and healthcare operations and implement a process for reviewing and responding to such requested restrictions which seeks to use reasonable efforts to agree to the restriction if feasible.
- Adopt a policy prohibiting disclosure of SUD records to a health plan if the patient has requested the SUD records not be disclosed and has paid for the service.
- Align your policies regarding patient consent for disclosure of SUD records in legal proceedings (including testimony that discusses SUD records or communications between the program and an SUD patient) to include civil, criminal, administrative or legislative investigation or proceeding and require a court order or specific, stand alone patient consent for disclosure in such proceedings.
- Update policy on how SUD records may be de-identified to adopt HIPAA de-identification standard.

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- Adopt a process to receive complaints concerning the part 2 programs compliance with 42 CFR part 2.
- Include language prohibiting staff from intimidating, threatening, coercing, discriminating against or taking other retaliatory action against any patient for exercising their rights or filing a complaint or requiring a patient to waive their right to file a complaint as a condition of treatment, payment, enrollment or eligibility for a Part 2 program.

Revise Forms & Processes Relating to Patient Consent. To incorporate the relaxed consent requirements, Part 2 programs will need to:

- Update patient consent to align with HIPAA authorization requirements (as stated in 42 CFR 2.31).
 - If the part 2 program intends to use or disclosure SUD records to fundraise on its own behalf, include in the consent a statement about the patient’s right to elect not to receive any fundraising communications.
- Update notice language accompanying SUD records when disclosing pursuant to a patient’s written consent to use either:
 - Statement 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 this 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 a written consent to further use or redisclose the record (see 42 CFR 2.31).”
 - Statement 2: “42 CFR part 2 prohibits unauthorized disclosure of these records.”
- Implement a process to ensure disclosures pursuant a patient’s consent (including treatment, payment or health care operations disclosures) are accompanied by the Notice as well as a copy of the patient’s consent or summary of the consent’s scope.
- Work with your EHR vendor to address how SUD records subject to Part 2 are identified within the EHR and how disclosures comply with the notice and consent required to accompany disclosures.

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Incorporate Patient Rights Provisions. Part 2 programs who are already subject to HIPAA should already have policies in place for most of the patient rights which have now been incorporated into Part 2; however, if the provider maintains separate policies governing use/disclosure of SUD records or its Part 2 program, the provider will need to ensure these rights are extended to patients receiving services from the Part 2 program.

- Adopt a process to track disclosures pursuant to a patient's consent for purposes of providing the accounting if requested. Work with your EHR vendor on ensuring disclosures made for treatment, payment, healthcare operations can be accounted for.
- For Part 2 programs who are not HIPAA covered entities, create a new Notice of Privacy Practices meeting the requirements of 42 CFR 2.22 to distribute to patients prior to their first service, post it on the provider's website, and at physical locations where patients arrive for services.
- For Part 2 programs who are HIPAA covered entities, ensure your Notice of Privacy Practices includes the following:
 - Statement that SUD records that are disclosed to a part 2 program, covered entity or business associate pursuant to the patient's written consent for treatment, payment, and health care operations may be further disclosed by that part 2 program, covered entity or business associate without the patient's written consent to the extent the HIPAA regulations permit such disclosure except for in civil, administrative, criminal, legislative proceeding.
 - If the part 2 program intends to use/disclose records to fundraise, include a statement that the patient has the right to elect not to receive any fundraising communications.
 - Statement that a part 2 program may use or disclose records to fundraise for the benefit of the part 2 program only if the patient is first provided with a clear and conspicuous opportunity to elect not to receive fundraising communications.
 - Ensure your description of how to file a complaint includes the process for providing a complaint concerning the program's compliance with 42 CFR part 2.
- For Part 2 programs who are not HIPAA covered entities, adopt a new policy requiring notification of patients & OCR when identifiable health information has been breached.
- Monitor the status of final HIPAA regulations updating the accounting of disclosure requirement and once those rules are updated and the compliance date for such rules is known, adopt a policy requiring the Part 2 program to provide to patients, upon request, an accounting of all disclosures made with the patient's consent in the three years prior to date of the request (or shorter period if requested by patient) but requiring only disclosures of records for treatment, payment or healthcare operations if the disclosure was made through an electronic health record.

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