

## Changes to Part 2 Regulations: An Implementation Checklist for HIPAA Covered Entities Not Considered Part 2 Programs

Healthcare providers who are HIPAA-covered entities but not Part 2 programs must still comply with the new Part 2 rules to the extent they receive substance use disorder records subject to Part 2 (referred to in this Checklist as “Part 2 records”).

- Work with your EHR vendor to determine how you will identify Part 2 records in your system, including whether Part 2 records should be segregated and how you can ensure disclosures from your EHR of Part 2 records comply with the notice and consent requirements to accompany redisclosures.
- Revise your current policy relating to the use and disclosure of Part 2 records to:
  - Allow for use/disclosure of Part 2 records as allowed by HIPAA and any applicable state law, with the exception of uses/disclosures for civil, criminal, administrative and legislative proceedings against the patient;
  - Include in your policy a statement that the redisclosure of part 2 records must be accompanied by the required statement and a copy of the patient’s consent or summary of the scope of the consent;
  - Require any use/disclosure of part 2 records in civil, criminal, administrative or legislative investigations and proceedings against the patient to require a court order or specific, stand-alone patient consent meeting HIPAA’s authorization requirements.
- Develop a process to ensure any disclosure by your organization of Part 2 records (including as allowed by HIPAA) contains one of the following Statements and a copy of the patient’s written consent or a summary of the scope of the consent. One of the following Statements must accompany the Part 2 record anytime you disclose it:
  - 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.”

- Revise your policy to provide that how you use and disclose Part 2 records pursuant to a patient's general consent for treatment, payment and health care operations will be modified if you are notified the patient has revoked or restricted such uses/disclosures.
- 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.
- Update your Notice of Privacy Practices to address Part 2 protections.
  - Revise your description of how PHI may be used/disclosed for treatment, payment and healthcare operations or without a patient authorization to include a statement that such use or disclosure must also comply with applicable law, including Part 2 and consider adding examples related to Part 2 covered records;
  - Include a statement that substance use disorder treatment records received from Part 2 programs or testimony relaying the content of such records shall not be used or disclosed in civil, criminal, administrative or legislative proceedings against the individual unless based on written consent or a court order after notice and an opportunity to be heard is provided to the individual or holder of the record as provided in 42 CFR Part 2. A court order authorization use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed;
  - If you intend to use or disclose Part 2 covered records for your fundraising purposes, include a statement that the individual has the opportunity to elect not to receive any fundraising communications.