



TO: Laura Brown

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RE: Part 2 Rule

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Part 2 Summary

On February 8, 2024, the U.S. Department of Health and Human Services' Office for Civil Rights ("HHS-OCR") and the Substance Abuse and Mental Health Services Administration ("SAMHSA") finalized modifications to the Confidentiality of Substance Use Disorder regulations at 42 CFR Part 2 (the "Final Rule"). The Final Rule has been issued to implement Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act and to align Part 2 regulations with those promulgated under HIPAA. Notably, the Final Rule is effective April 16, 2024, and the compliance date for Part 2 programs is February 16, 2026.

Highlights of the Final Rule that will have a practical impact on Part 2 programs and require updates to policies, procedures, and patient forms are as follows:

1. **Patient Complaints**: Part 2 facilities will need to establish a procedure for patients to make complaints about privacy concerns. Patients will also have the ability to file complaints with the Secretary of HHS. Providers cannot take adverse action against a patient that files a complaint, nor can they require a patient to waive the right to file a complaint. Although this is new for Part 2 providers, it is in line with the rights that patients have under HIPAA, so Part 2 providers should be able to modify their current HIPAA policies and procedures to account for this requirement.
2. **Breach Notification**: The HIPAA breach notification rules are now applicable to a breach of Part 2 records, meaning that breach notification policies of Part 2 facilities will need to be updated.
3. **Business Associates**: If Part 2 facilities are not already utilizing business associate agreements with specific language related to qualified service organizations, this will need

to be updated in business associate templates due to the new definition of qualified service organizations.

4. Consents: The new rules permit the use and disclosure of Part 2 records for all future uses and disclosures for treatment, payment, and health care operations based on a single prior consent. Part 2 providers will need to update their policies to reflect this new flexibility.
5. Civil Enforcement: Violations of the new Part 2 Rules may now result in civil penalties, as Part 2 enforcement now aligns with the HIPAA Enforcement Rule. Prior to these new rules, all Part 2 violations were subject only to criminal penalties.
6. New Patient Rights: Two individual rights under the HIPAA Privacy Rule are now applicable to Part 2 records: (i) the right to an accounting of disclosures of records; and (ii) the right to request restrictions on disclosures.
7. SUD Counseling Notes: Similar to the requirement under HIPAA for psychotherapy notes, a separate patient consent is required prior to the use and disclosure of SUD counseling notes.
8. Public Health: Similar to HIPAA, disclosure of Part 2 records without patient consent is now permitted for public health purposes. However, this disclosure is limited to information that has been de-identified in accordance with the HIPAA Privacy Rule de-identification standard.
9. Notice Requirements: Part 2 programs will need to provide a patient notice, similar to the Notice of Privacy Practices under HIPAA, that details the program's privacy practices and patient's rights with respect to their information.
10. Investigative Agencies: For investigative agencies that act with reasonable diligence when they unknowingly receive Part 2 records, the new rules provide a civil and criminal safe harbor.

If you have any questions on the Part 2 Rule, please contact Meghan McNab at mmcnab@kdlegal.com, Chris Kulik at ckulik@kdlegal.com, or Stephanie Eckerle at seckerle@kdlegal.com.