



ABHW

# ISSUE BRIEF

42 CFR Part 2 (Part 2) and Privacy and Confidentiality of Substance Use Disorder Records

*Updated July 2023*

## Background

42 CFR Part 2 (Part 2) is the federal regulation, initially developed in the 1970s, that governs the confidentiality of substance use disorder (SUD) treatment and prevention records and sets requirements limiting the use and disclosure of a patient's SUD records. The law aims to protect the privacy of individuals seeking SUD treatment while ensuring they receive the care they need. Part 2 imposes specific legal requirements different from the Health Insurance Portability and Accountability Act (HIPAA) and other privacy regulations. These regulatory differences make integrating SUD treatment services with primary care challenging since Part 2 data is currently retained in a separate database or isolated from a patient's overall health record. **The different management of Part 2 records perpetuates the stigma around SUDs since these records are the only health records treated in this manner. As a result, the law is a barrier to communication between healthcare providers serving persons with SUDs and has created silos of healthcare delivery.** The Part 2 regulation has undergone several revisions over the years, making it difficult for practitioners to keep up with the latest requirements. Additionally, some states have laws that further complicate the regulatory landscape. These complexities hinder practitioners from holding themselves out as SUD providers that diagnose and treat SUDs.<sup>1</sup>

**At a time when opioid overdoses and deaths are increasing, coupled with the impact of the recent coronavirus pandemic, care coordination must be as streamlined and straightforward as possible.** Our nation's overdose epidemic – now driven primarily by synthetic opioids – claimed the lives of nearly 109,000 Americans for the year ending October 2022.<sup>i</sup>

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<sup>1</sup> According to 42 CFR Part 2, to “hold self out” is to conduct activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder, diagnosis, treatment, or referral for treatment, e.g., through advertising or marketing. (42 CFR 2.11; 2.12(e))

In March 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act to respond to the coronavirus pandemic, which included revisions to Part 2 that more closely align it with HIPAA.<sup>ii</sup> Subsequently, in December 2022, the U.S. Department of Health and Human Services (HHS), through the Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA), released proposed draft regulations implementing most of the Part 2 provisions in the CARES Act.<sup>iii</sup>

The proposed regulation allows for improved care coordination and better aligns Part 2 with the regulatory requirements under HIPAA in the following ways:

- Permits patients to provide one written consent to use or disclose their Part 2 information by a covered entity, business associate, or a Part 2 program<sup>2</sup> for all future treatment, payment, or health care operations (TPO) as permitted by HIPAA, unless the patient revokes consent.
- Enforces the same civil and criminal penalties as those under HIPAA.
- Strengthens patient privacy by creating stronger protections prohibiting records from being used in civil, criminal, administrative, or legislative proceedings against a patient by any government authority unless authorized by a court order or patient consent.
- Mandates the ability to revoke consent for Part 2 data transmission effective only from the point of revocation going forward.
- Allows covered entities and business associates to disclose and redisclose data in accordance with HIPAA regulations.

The CARES Act prohibits discrimination against Part 2 Program patients related to housing, employment, and government benefits, but these discrimination provisions were not addressed in the proposed regulations.

The Association for Behavioral Health and Wellness (ABHW) is the founder and chair of the Partnership to Amend 42 CFR Part 2 (Partnership), a coalition of 50 organizations representing stakeholders from across the healthcare spectrum committed to aligning Part 2 with HIPAA to ensure appropriate access to patient information that is essential for providing whole-person care.

### Recommendations

As HHS, OCR, and SAMHSA move forward with finalizing the proposed regulation

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<sup>2</sup> According to 42 CFR Part 2, a Part 2 Program is an (1) individual or entity who holds itself out as providing substance use disorder diagnosis, treatment or referral; (2) an identified unit in a general medical facility that holds itself out as providing substance use disorder diagnosis, treatment or referral; or a (3) medical personnel in a general medical facility whose primary function is providing substance use disorder diagnosis, treatment or referral and who are identified as such providers. (42 CFR 2.11; 2.12(e))

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and implementing the new law, ABHW, and the Partnership recommend that the following provisions are appropriately addressed to ensure that the next Part 2 rule is aligned with HIPAA.

- Eliminate the Part 2 consent requirement to fully align the consent process with HIPAA for TPO purposes. If the Part 2 consent requirement remains, it will cause administrative burdens around data segmentation with HIPAA records and continue to hinder providers from holding themselves out as SUD providers.
- Ensure that the consent requirements are simple and straightforward so administrative processes are not imposed on patients, providers, or payers (including health plans and their subcontractors). The consent process should be easily folded into existing HIPAA compliance processes, ideally with the patient's acknowledgment of HIPAA practices and the patient's Part 2 consent incorporated into the same document at the intake process where feasible.
- Specify that once Part 2 data is transmitted or retransmitted, there is no requirement to isolate a patient's Part 2 data from the rest of a HIPAA database, with the regulatory requirement for data segmentation terminating upon transmission or retransmission.
- Extend safe harbor protections against civil and monetary penalties to Part 2 programs, providers, business associates, and covered entities acting in good faith when redisclosing Part 2 records. This protection is essential to encourage providers to hold themselves out as SUD providers and other entities to support Part 2 programs. Safe harbor protections will be critical as the healthcare system implements these new regulations.
- Develop robust technical assistance on the CARES Act and implementing regulations to be distributed to multiple stakeholders. This technical assistance should include numerous collaborations to create learning modalities, including webinars, written sub-regulatory guidance, sample wording, and public awareness campaigns.
- Similarly, HHS, OCR, and SAMHSA should explore, in conjunction with states and stakeholders, policy mechanisms for promoting care coordination for behavioral health data when state privacy laws impose restrictions beyond both Part 2 and HIPAA.
- Provide SUD-related claims data to providers practicing alternative payment models to help support their work in population health management.

To learn more about the Partnership, visit [www.helpendopioidcrisis.org](http://www.helpendopioidcrisis.org)

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<sup>i</sup> <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

<sup>ii</sup> <https://www.congress.gov/bill/116th-congress/house-bill/748>

<sup>iii</sup> <https://www.federalregister.gov/documents/2022/12/02/2022-25784/confidentiality-of-substance-use-disorder-sud-patient-records>