Background
42 CFR Part 2 (Part 2), the 1970s federal regulation that governs the confidentiality of substance use disorder (SUD) treatment and prevention records, sets requirements limiting the use and disclosure of a patient’s SUD records from certain substance use programs. This regulation is outdated and a barrier to communication between health care providers serving persons with SUDs and has created silos of health care delivery, which can compromise the quality of care and patient safety. Part 2 provisions are not compatible with the way health care is delivered currently; and failure to integrate services and supports can lead to risks and dangers to individual patients. Additionally, Part 2 perpetuates the stigma around addiction, as SUD records are the only health records treated in this manner.

The coronavirus pandemic has exacerbated the opioid crisis resulting in increased overdoses and deaths due to overdose, underscoring the need to ensure patients receive comprehensive, safe, effective, high-quality treatment, and care coordination. Additionally, the pandemic has once again brought to light the inequities within our health system; further highlighting the need to simplify coordination of care, prevent gaps in care, and expand access to SUD care.

In March 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the coronavirus pandemic. Included in the CARES Act were revisions to Part 2 that would more closely align Part 2 with the Health Insurance Portability and Accountability Act (HIPAA). The CARES Act permits a patient to provide one written consent to use or disclose their Part 2 information for all future treatment, payment, or health care operations (TPO), unless the patient revokes consent. If the Part 2 Program is breached, the patient is required to be notified. It also enforces the same civil and criminal penalties that are under HIPAA
and prohibits discrimination against Part 2 Program patients related to housing, employment, and government benefits.

Changes made to Part 2 will not only allow for improved care coordination, but will also strengthen patient privacy. Currently, Part 2 records are prohibited from being used in criminal or civil proceedings without patient consent or a court order. The new legislation creates stronger protections which expressly prohibit 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). Furthermore, SUD records specifically cannot:

- be entered into evidence in criminal prosecutions or civil actions;
- form part of the record for a decision or otherwise be taken into account in government agency proceedings;
- be used by a governmental agency for law enforcement purposes or investigations; or
- be used in a warrant application.

**Recommendations**

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

As the U.S. Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) move forward developing the new rule, ABHW and the Partnership recommend that the following provisions mandated by the CARES Act are appropriately addressed to ensure that the next Part 2 rule is aligned with HIPAA, as intended by Congress.

- Ensure that the consent requirements in the next rule are simple and straightforward so additional 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, preferably with the patient’s acknowledgement of HIPAA practices, and the patient’s Part 2 consent incorporated into the same document at intake where feasible.
Furthermore, the rule needs to include language to address the conflict with Part 2’s list of disclosures requirement. Specifically, section 2.31 of Part 2 mandates that “upon request, patients who have consented to disclose their patient identifying information using a general designation must be provided a list of entities to which their information has been disclosed pursuant to the general designation” (emphasis added). Due to the list of disclosures requirement, practitioners are often uncomfortable attempting to use the general designation in the consent.

- Include specific language directing covered entities and business associates to disclose and redisclose data in accordance with HIPAA regulations.

- Specify that once Part 2 data is transmitted or retransmitted, there is no requirement to segregate 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.

- Specifically state that the revocation of consent for Part 2 data transmission is effective only from the point of revocation going forward and the responsibility for seeing that the Part 2 data is not being transmitted either to another covered entity or business associate belongs to the Part 2 treatment entity that contributed the data and to the Part 2 program.

- HHS and SAMHSA should explore, in partnership with stakeholders, how to exclude behavioral health data from the Part 2 data and incorporate the findings into the rule and any subsequent frequently asked questions or guidance. Similarly, HHS and SAMHSA should explore, in conjunction with the States and stakeholders, policy mechanisms for promoting the use of behavioral health data for care coordination purposes when state privacy laws may impose restrictions beyond both Part 2 and HIPAA.

- Include a provision in the next rule, consistent with the last rule, to ensure that disclosures for the purposes of research from a HIPAA covered entity to a non-HIPAA covered entity are permissible.

- Include specific language to ensure that patient privacy rights are protected in accordance with the CARES Act and HIPAA.
• Provide SUD-related claims data to providers practicing in alternative payment models to help support their work in population health management.

To learn more about the Partnership: www.helpendopioidcrisis.org