January 31, 2023

U.S. Department of Health and Human Services (HHS)
Office of the Secretary
Office for Civil Rights (OCR)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Attention: SUD Patient Records
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Notice of Proposed Rulemaking regarding Confidentiality of Substance Use Disorder (SUD) Patient Records (Docket No. HHS-OCR-0945-AA16)

On behalf of the American Society of Addiction Medicine ("ASAM"), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction and co-occurring conditions, thank you for the opportunity to provide comments on the above-referenced notice of proposed rulemaking (the "NPRM"), proposing modifications to 42 CFR Part 2 ("Part 2") to implement statutory amendments to section 290dd-2 of title 42 United States Code enacted in section 3221 of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. For decades, ASAM members have dedicated their careers to treating patients with addiction and strive to provide high quality care that respects patients' privacy and safeguards their sensitive health information. Accordingly, ASAM continues to support regulatory and legislative changes that further align Part 2 with the Health Insurance Portability and Accountability Act ("HIPAA") for the purposes of health care treatment, payment, and operations ("TPO") while leaving in place certain, critical Part 2 prohibitions on use and disclosure of records outside the healthcare system. Thus, I am grateful for this opportunity to provide ASAM's comments to the NPRM.

ASAM applauds the efforts of Congress and the Administration in further aligning Part 2 with HIPAA. However, so long as privacy rules governing the medical records of patients with substance use disorder (SUD) retain significant differences with

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respect to their handling within the healthcare system, the access, availability, and quality of SUD services will be negatively impacted. **Therefore, ASAM recommends that HHS conduct a study of the impact of full alignment with HIPAA on access, availability, and quality of SUD services, coupled with strengthened HIPAA protections against uses, disclosures, or redisclosures of SUD and other medical records outside the healthcare system.**

In the meantime, ASAM encourages HHS, through OCR and SAMHSA, to consider the following modifications and clarifications to the proposed rule:

- **Revised Consent Requirements:** Operationally, since the proposed Part 2 consent requirements are like a HIPAA authorization, it might be confusing to have similar language for a Part 2 consent and HIPAA authorization but with different purposes. The consent process should be easily folded into existing HIPAA compliance processes, preferably with the patient's acknowledgment of HIPAA practices and the patient's Part 2 consent incorporated into the same document at intake where feasible.

- **Redisclosure Permissions:** The proposed rule indicates that if the recipient is a HIPAA-covered entity, a business associate, or another Part 2 program, such recipient may redisclose the Part 2 record, without the patient's consent, to the extent the HIPAA Privacy Rules permits such disclosure. **ASAM strongly urges the final rule make it clear, on a consistent basis, that Part 2 records may <u>not</u>, however, be used, disclosed, <u>or redisclosed</u> for civil, criminal, administrative, or legislative proceedings against the patient in the absence of a court order or a specific, written patient consent for that purpose. ASAM also recommends that the final rule take additional steps to ensure that no patient is coerced, tricked, or forced into signing such a specific written consent for that purpose. ASAM recognizes that such protections are acutely important for pregnant people who use substances in the wake of the decision in *Dobbs v. Jackson Women's Health Organization* to overturn *Roe v. Wade*.** In addition, ASAM asks for clarity on how recipients of Part 2 records will know whether the Part 2 program received general consent for TPO purposes. The final rule should make clear that if a Part 2 record has been shared for TPO purposes with a business associate or covered entity, then it should operate that general consent for those purposes was given (unless a copy of a written patient consent indicating otherwise was provided with the disclosure).

- **Segmentation of Part 2 Data After Transmission:** Once Part 2 data is transmitted to a covered entity or business associate, it is critical that there not be an additional requirement that the Part 2 data be segregated from a patient's overall health record. Health Information Exchanges have declined to accept Part 2 data because modifying their systems was too costly. OCR and SAMHSA state that the NPRM's "expanded ability to use and disclose Part 2 records would facilitate greater integration of SUD treatment information with other protected health information (PHI)." It is unclear how the proposed rule will help integrate Part 2 data with other systems and enable subsequent treatment providers' access. **ASAM recommends that the final rule make it clear that**

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Part 2 data may be transmitted or retransmitted without a requirement to segregate a patient's Part 2 data from the rest of a HIPAA database or record, but that Part 2 records may not, however, be used, disclosed, or redisclosed for civil, criminal, administrative, or legislative proceedings against the patient in the absence of a court order or a specific, written consent for that purpose, as well as how both things can be accomplished.[1]

- **Revocations:** ASAM recommends that oral revocations not be permitted, aligned with the text of the CARES Act. In addition, to be consistent with other proposed changes, ASAM recommends that, to the extent the concept of an intermediary is retained, intermediaries be included in the list of entities where revocation of consent only affects additional disclosures. Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, business associate or intermediary with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities.

- **SUD Counseling Notes:** ASAM would have no objection to the creation of a new category of SUD records identified as "SUD Counseling Notes" that are handled in the same manner that Psychotherapy Notes are treated under HIPAA. This category would provide greater protection for SUD Counseling Notes and limit the notes from being shared under TPO. Parties are already familiar with how to comply with Psychotherapy Notes under HIPAA. If such a category is created, then ASAM encourages SAMHSA and OCR to issue clear guidance to make the segregation of these counseling notes as easy as possible so that Part 2 programs do not have to take repetitive actions that will add administrative burden.

- **Safe Harbors/Part 2 Program Definition:** ASAM recommends safe harbor protections against civil and monetary penalties to Part 2 programs acting in good faith when they use, disclose, or redisclose Part 2 records for at least 34 months, following the 60-day

[1] Since facilitating greater integration of SUD treatment information with other PHI is a goal, HHS may want to reconsider whether its proposed rule is consistent with the text of the CARES Act and that goal. Specifically, the CARES Act provides in subsection (b)(1)(B) that a covered entity, business associate, or Part 2 program may use or disclose the Part 2 records for TPO, following written consent, and that any information so disclosed may then be redisclosed in accordance with HIPAA. However, the immediately following subsection (b)(1)(C) of the CARES Act provides that it shall be permissible for a patient's prior written consent to be given once for all such future uses or disclosures for purposes of TPO, until such time as the patient revokes such consent in writing. Whether "all such future uses or disclosures" includes the aforementioned "redisclosures" - and, therefore, limits such redisclosures for purposes of TPO in accordance with HIPAA - is a plausible interpretation. An interpretation of the CARES Act which limits uses, disclosures, *and redisclosures* of Part 2 records to TPO, following a patient's prior written consent, may serve to facilitate integration of PHI into Part 2-compliant SUD treatment information databases – thereby, allowing for integrated information that can be used, disclosed, and redisclosed for TPO purposes – all while still preserving the CARES Act's clear prohibition against using and disclosing Part 2 records in various proceedings (as well as protections against non-TPO uses and disclosures).

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effective date period (36 total months). This protection is essential to encourage providers to hold themselves out as SUD providers. This will be especially important as the healthcare system implements these new regulations. **However, ASAM opposes the proposed safe harbor for investigative agencies as written.** As written, the proposed safe harbor could reduce access to care, especially if Part 2 programs feel more at risk for acting in good faith than the investigative agencies that do not provide patient care. **To further clarify the scope of Part 2, ASAM also urges SAMHSA to revisit the definition of a Part 2 program to create an objective standard rather than a subjective standard (i.e., "holds itself out as").**

- **Notice to Accompany Disclosures:** Retaining the notice to accompany disclosure requirement means that the need to identify, segment, and segregate the data will persist to append the notice with each disclosure. **If, and only if, the final rule makes it clear, on a consistent basis, that such Part 2 records may <u>not</u>, however, be used, disclosed, <u>or redisclosed</u> for civil, criminal, administrative, or legislative proceedings against the patient in the absence of a court order or a specific, written consent for that purpose, then ASAM agrees with a recommendation to eliminate the notice to accompany disclosures.**

- **Breach Notifications:** ASAM encourages HHS, through OCR and SAMHSA, to clarify in regulation and subsequent guidance where a breach would occur and needs to be recorded.

- **Disclosures to Prescription Drug Monitoring Programs:** ASAM applauds the proposal to the extent it allows a Part 2 program or other lawful holder to report addiction medications prescribed or dispensed by the Part 2 program to the applicable state prescription drug monitoring program if required by applicable state law.

- **Antidiscrimination Prohibitions.** ASAM urges the Administration to coordinate the effective date of the proposed rule with the non-discrimination rule as mandated by the CARES Act to protect SUD data from discriminatory uses.

Finally, ASAM encourages HHS, through OCR and SAMHSA, to offer robust technical assistance regarding rule implementation. ASAM encourages the tracking, monitoring, and sharing of lessons learned and best practices through implementing Part 2 rule modifications so that all entities can continue to learn how best to carry out the final rule to establish data integration and enhance treatment delivery, while preserving greater protections against using, disclosing, or redisclosing records in civil, criminal, administrative, and legislative proceedings against patients.

Again, ASAM is grateful for the opportunity to comment on this NPRM. ASAM will continue to advocate for the highest treatment standards and the most compassionate care for patients with addiction. We must ensure our patients can easily access state-of-the-art treatment within our

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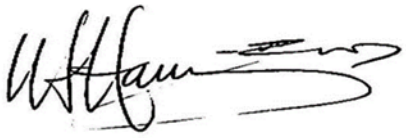
healthcare system, and HHS's efforts in this regard are greatly appreciated. If you have any questions or concerns, please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@asam.org or at 301-547-4111.

Sincerely,



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