



January 31, 2023

U.S. Department of Health and Human Services  
Office of the Secretary  
Office for Civil Rights (OCR)  
Substance Abuse and Mental Health Services Administration (SAMHSA)  
Attention: Lester Coffey, OCR

Re: Confidentiality of Substance Use Disorder (SUD) Patient Records Notice of Proposed Rulemaking (NPRM), Docket No. HHS-OCR-2022-0018

Dear Secretary Becerra and Assistant Secretary Delphin-Rittmon,

On behalf of the American Academy of Addiction Psychiatry (AAAP), thank you for the opportunity to comment on the proposed modifications to 42 CFR Part 2 (proposed rule). AAAP is a professional organization representing specialists in Addiction Psychiatry and other healthcare professionals who treat patients with substance use disorders (SUDs). AAAP is focused on delivering quality care to patients with substance use disorders and co-occurring mental illness. To best treat people with SUDs, clinicians need to be able to coordinate care with other health professionals to meet patients' whole health needs without fear of stigma and discrimination. This rule will help to better meet this need.

We are grateful to the Department of Health and Human Services (HHS), through the Office for Civil Rights (OCR) and the Substance Abuse and Mental Health Services Administration (SAMHSA) for this proposed rule that seeks to implement Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) to better align the Confidentiality of Substance Use Disorder Patient Records regulations under 42 CFR part 2 (Part 2) with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) for purposes of treatment, payment and operations (TPO). However, we are concerned that technological limitations will result in administrative burdens, continued challenges with data segmentation, and may impede access to treatment. Thus, we support regulatory and legislative changes that further align Part 2 with 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.

At a time when opioid overdoses and deaths are increasing, coupled with the impact of the ongoing coronavirus pandemic, care coordination must be as streamlined and straightforward as possible while protecting patient privacy. Please see our comments on the specific provisions below.

**I. Consent - § 2.31**

Consistent with the CARES Act, the proposed rule leaves in place the requirement that Part 2 programs generally must obtain patient consent prior to disclosing Part 2 information for purposes of TPO.

*Board of Directors*

**Larissa Mooney, MD**  
President

**Kevin Sevarino, MD, PhD**  
Immediate Past President

**Shelly F. Greenfield, MD, MPH**  
Chair, Past Presidents Council

**John Mariani, MD**  
President Elect

**Tim Fong, MD**  
Vice President

**Rebecca Payne, MD**  
Treasurer

**Kevin Gray, MD**  
Secretary

**Carol Weiss, MD**  
Member at Large

**Kathryn Cates-Wessel**  
Chief Executive Officer

**Karen Drexler, MD**  
Medical Director

**Alena Balasanova, MD**  
AMA Liaison

**Adina Bowe, MD**  
Chair, Diversity, Equity, and Inclusivity Committee

**Michael Hoefler, MD**  
Chair, Education Committee

**Thomas Kosten, MD**  
Editor-in-Chief, *The American Journal on Addictions*

**Frances Levin, MD**  
Grant Liaison

**David Lott, MD**  
APA Liaison, Assembly

**David Marcovitz, MD**  
Chair, Early Career Committee

**Sanchit Maruti, MD**  
Director, Addictions and Their Treatment Course

**Inbal Gafni, MD**  
Chair, International Committee

**Thomas Penders, MD**  
Chair, CPD Committee

**Ismene Petrakis, MD**  
Chair, Area Directors

**John A. Renner, Jr, MD**  
APA Liaison, Council on Addictions

**Richard N. Rosenthal, MD**  
Chair, Public Policy

**Lewei (Allison) Lin, MD, MSc**  
Chair, Research Committee

**Corneliu Stanciu, MD**  
Editor, AAAP Newsletter

**Jose Vito, MD**  
Chair, Membership Committee

**Nitigna Desai, MD**  
Chair, Scientific Program Committee

**Laurence Westreich, MD**  
Chair, Law and Addiction

**Will Rutland, MD**  
Trainee Representative

**Ebony Caldwell, MD, MPH**  
Trainee Representative

**Single Consent for TPO:** We sincerely appreciate Congress, HHS, OCR, and SAMHSA for passing the CARES Act and drafting these proposed rules, which permit Part 2 programs to use and disclose Part 2 records for future TPO uses and disclosures based on a single consent signed by the patient. This new flexibility regarding how Part 2 information can be shared once patient consent is obtained should help improve communication and care coordination.

We understand this NPRM is constrained by the 42 CFR Part 2 statute that requires consent. However, as a result, this NPRM does not go as far as HIPAA, which is more permissive and allows TPO disclosures without consent or authorizations. The new flexibility to share TPO with consent is a step in the right direction and will encourage more information sharing. However, since the Part 2 consent requirement remains, it is inconsistent with HIPAA and will cause administrative burdens around data segmentation. This likely will hinder some providers from holding themselves out as substance use disorder (SUD) providers.

**Revised Consent Requirements:** The proposed rule intends to align the Part 2 written consent requirements with the consent requirements for a valid HIPAA authorization. Under the proposed rule, a person who obtains a patient's written consent for the disclosure of that patient's Part 2 data will have more flexibility regarding how potential recipients of that data are described on the form. If the information is to be disclosed directly to other organizations, then the form is not required to have all potential recipients named but instead may contain a description of a class of persons who may receive the information. We appreciate that this alleviates the burden on patients and providers to list all potential recipients. Operationally, since the proposed Part 2 consent requirements are similar to a HIPAA authorization, it might be confusing to have similar language for a Part 2 consent and separate 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.

#### I. Redisclosures Permissions

**Part 2 Programs, Covered Entities and Business Associates:** Following Section 3221 of the CARES Act, the rule indicates that if the recipient is a HIPAA-covered entity, a business associate, or another Part 2 program, such recipient may redisclose the information so long as such redisclosure complies with HIPAA and the information was not shared for use in a civil, criminal, administrative, or legislative proceeding against the patient. ***We urge the final rule make it clear, on a consistent basis, that such 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 patient consent for that purpose. AAAP 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.***

#### II. 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 retained in a separate database or segregated from a patient's overall health record. It is difficult for integrated systems or Health Information Exchanges (HIEs) to manage the consent process for separate databases for Part 2 programs and their other systems. For example, many HIEs have declined to accept Part 2 data because modifying their systems was too costly and prevented people with SUDs from participating.

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.

***We urge the HHS and SAMHSA to specify that once Part 2 data is transmitted or retransmitted, there should not be 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.***

### **III. Revocations**

Thank you for aligning the wording of the revocation requirements under HIPAA. We appreciate that the language clarifies the limits on a patient's ability to "pull back" Part 2 information from a covered entity, business associate, or Part 2 program once disclosed, in alignment with the Privacy Rule. Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, or business associate with prior written consent, a revocation would only be adequate to prevent additional disclosures to those entities. It would not prevent a recipient Part 2 program, covered entity, or business associate from using the previously disclosed record for TPO or redisclosing the record in the same manner as permitted by the Privacy Rule. ***It is essential that revocation of consent should only affect data sharing from the point of revocation going forward.***

To be consistent with other proposed changes, we recommend that intermediaries be included in the list of entities where revocation of consent only affects additional disclosures. The sentence above would be modified to read: "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." We encourage the HHS OCR and SAMHSA to offer subsequent guidance on the best way to flag a revocation within electronic health records and highlight technological advancements that can help make this more seamless.

### **IV. Oral Revocations**

Many Part 2 programs ensure that revocations are documented in writing to be tracked as valid

and enforceable. Additionally, HIPAA revocations must be in writing and are only effective once the covered entity receives them.

## V. Intermediary

The rule proposes a definition for intermediary as a person who has received records under a designation of general written patient consent to be disclosed to one or more of its member participants with a treating provider relationship with the patient.” For example, intermediaries are HIEs, ACOs, and researchers. The proposed rule suggests distinct and separate limits on redisclosures based on prior consent for intermediaries.

**Accounting of Disclosures:** The current regulation ensures that a patient has the right to receive a list of Part 2 disclosures from an intermediary. However, the scope of disclosures from an intermediary will likely be much broader with the proposed rule, given that a single consent for TPO would be implemented, and therefore, there will be a long list of entities that will need to be disclosed. Even sophisticated intermediaries such as HIEs find the accounting of disclosures incredibly burdensome, and patients need more information. With the expanded TPO flexibility, the accounting of disclosures could become overwhelming and inevitably hinder care coordination.

## VI. SUD Counseling Notes

Creating 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 could be beneficial. This category would provide greater protection for SUD Counseling Notes and limit the notes from being shared under TPO. This may make adopting this provision easier since parties are already familiar with how to comply with Psychotherapy Notes under HIPAA; we have heard that some clinicians do not separate psychotherapy notes because they have to generate multiple records of the encounter. We encourage the SAMHSA and the OCR to ensure clear guidance is issued 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 additional administrative burden.

## VII. Safe Harbors

We encourage extending safe harbor protections against civil and monetary penalties to Part 2 programs, providers, business associates, and covered entities acting in good faith when they disclose and redisclose Part 2 data for at least 34 months, following the 60-day effective date period (36 total months). This protection is essential to encourage providers to hold themselves out as SUD providers and other entities to support Part 2 programs. This will be especially important as the healthcare system implements these new regulations. **However, AAAP opposes the proposed the safe harbor for investigative agencies as written.** As written, the proposed safe harbor could reduce access to care if Part 2 programs or providers 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, AAAP also urges SAMHSA to revisit the definition of a Part**

**2 program to create an objective standard rather than subjective (“holds itself out as”); for example, the definition could include only those that are state-licensed SUD treatment providers.**

#### **VIII. Notice to Accompany Disclosures § 2.32**

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 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, then AAAP agrees with a recommendation to eliminate the notice to accompany disclosures.***

##### **I. Breach Notifications**

The Part 2 statute now applies the HIPAA HITECH ACT breach notification provisions to breaches of Part 2 records. Since HIPAA allows TPO disclosures without consent, it is unclear how easy it will be to apply the HIPAA HITECH four-factor test to a violation of Part 2 that would not be a violation of HIPAA. We encourage HHS, OCR, and SAMHSA to clarify in regulation and subsequent guidance when a breach would occur and need to be recorded.

#### **IX. Compliance Date – 24 months after publication**

The proposed rule states that the effective compliance date would be 22 months after the effective date and 24 months after publication. Entities subject to a final rule would have until the compliance date to establish and implement policies and practices to achieve compliance. ***We encourage a broad implementation timeline so that all impacted stakeholders have time to become familiar with the new changes. While some programs may be able to implement the rule sooner than others, we request that penalties are not enforced until at least 24 months after publication.***

#### **X. HHS, OCR & SAMHSA Technical Assistance of Part 2 Rule**

We urge HHS, OCR, and SAMHSA to work with stakeholders and offer robust technical assistance (TA) as they work on unpacking and implementing the law. Examples of technical assistance could be collaborations to create multiple learning modalities, including webinars, written sub-regulatory guidance, sample wording, and public awareness campaigns.

We encourage the tracking, monitoring, and sharing of lessons learned and best practices through implementing these Part 2 rule modifications so that all entities can continue to learn how to carry out these provisions best and enhance treatment delivery.

**XI. Study by HHS, OCR, and SAMHSA on Full Alignment with HIPAA**

We encourage the HHS OCR and SAMHSA to study the impact and benefits of complete alignment with the HIPAA Privacy rule. This study should focus on access, availability, and quality of healthcare treatment services, including but not limited to SUD. As we have discussed, this proposed rule is a significant step forward, but retaining two separate sets of partially aligning authorities remains challenging. Ultimately, Congress, HHS, OCR, and SAMHSA share our goal to increase access to substance use disorder (SUD) treatment and the availability of SUD providers. The differences between Part 2 and HIPAA still pose significant hurdles to encouraging more to deliver SUD services.

**XII. Antidiscrimination Prohibitions.**

AAAP 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.

**Conclusion**

Thank you for consideration of our comments and your work to reduce barriers to care for people with substance use disorders.

Sincerely,

A handwritten signature in black ink that reads "Larissa Mooney". The signature is written in a cursive, flowing style.

Larissa Mooney, MD  
AAAP Board President