THE PARTNERSHIP TO AMEND

42 CFR PART 2

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 Coffer, OCR

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

Dear Secretary Becerra, Director Fontes Rainer, and Assistant Secretary Delphin-Rittmon,

The Partnership to Amend 42 CFR Part 2 (Partnership) appreciates the opportunity to comment on the Notice of Proposed Rule Making (NPRM or proposed rule) to 42 CFR Part 2 (Part 2). The Partnership is a coalition of nearly 50 organizations committed to aligning Part 2 with the disclosure requirements and use of data obtained under the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and health care operations (TPO).

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 Part 2 with the regulatory requirements under HIPAA. We were happy to see alignment with HIPAA on various definitions such as business associate, covered entity, breach, and health care operations. However, we are concerned that anything short of complete alignment with HIPAA for TPO will cause administrative burdens and continued data segmentation challenges and may impede treatment access and safe care. As such, we will continue encouraging Congress to remove the Part 2 consent requirement.

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 as straightforward as possible to enable fully informed diagnosis and treatment of persons with a substance use disorder (SUD) or with history of SUD treatment while protecting patient privacy. Please see our comments on the specific provisions below.

I. Consent

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 records for purposes of TPO.

Single Consent for TPO: We sincerely appreciate the passage of the CARES Act and the drafting of 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 records can be shared once patient consent is obtained should help improve communication and care coordination, which is vital to providing safe care.

We understand this NPRM is constrained by the 42 CFR Part 2 statute that requires consent. However, as a result, it does not go as far as HIPAA, which allows TPO disclosures without consent or authorization. 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 may hinder some providers from holding themselves out as SUD providers. In addition, a treating healthcare provider may not have the patient's complete medical record with critical information because of data segmentation, which can impact the provision of safe care.

Additionally, HIPAA allows uses and disclosures beyond TPO with an authorization. Limiting these changes to just TPO will serve as a barrier, as Part 2 programs might be hesitant to implement changes for fear that they will violate the law by sharing a Part 2 record for a non-TPO purpose.

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 records will have more flexibility in how potential recipients of those records are described on the form. If the Part 2 record is to be disclosed directly to other organizations, then the form is not required to list all potential recipients by name 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 a HIPAA authorization but with different purposes. The consent process should be easily folded into existing HIPAA compliance processes, and the patient's Part 2 consent incorporated into the same document at intake where feasible.

II. Redisclosures Permissions

Part 2 Programs, Covered Entities, and Business Associates: 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 Part 2 record 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. HHS, OCR, and SAMHSA should work to establish

that entities should not have to continue to segment Part 2 records for civil, administrative, and legal proceedings while also maintaining those protections.

We were happy to see that this proposed rule includes specific language allowing Part 2 programs, covered entities, and business associates to transmit and retransmit the Part 2 records, following appropriate written consent, and that no additional consent would be necessary for TPO purposes unless the general consent is revoked. We understand that under this NPRM, once disclosed to a HIPAA entity under a TPO consent, a covered entity or business associate may redisclose the data for any purpose permitted by HIPAA, so long as the data is not redisclosed for use in a civil, criminal, administrative, or legislative proceeding against the patient. **We seek clarity from HHS, OCR, and SAMHSA that ensures that consent or a court order is still required for use, disclosure, and redisclosure for these proceedings.**

If the recipient is neither a HIPAA-covered entity, a business associate, or a Part 2 program, then the recipient could redisclose the information so long as the redisclosure was consistent with the terms of the consent.

Lawful Holder: Since lawful holders are subject to Part 2 obligations, including the potential for penalties, we encourage HHS, OCR, and SAMHSA to create a regulatory definition of lawful holder so that there are better parameters around their role. We recommend that the definition of "lawful holders" encompass entities with access to individual Part 2 records outside the HIPAA and Health Information Technology for Economic and Clinical Health (HITECH) Act and Part 2 confidentiality rules. We believe that HHS, OCR, and SAMHSA should clarify that mobile health apps that are business associates of covered entities would be considered lawful holders. Other healthcare interoperability applications, or mobile health apps, may fall into this space. Greater coordination is needed among HHS, OCR, SAMHSA, and the Federal Trade Commission (FTC) to determine what enforcement mechanisms would apply.

We hope these changes will improve care coordination and communication between providers and other elements of the healthcare system and expand access to claims data by ensuring that public and private payers can track the notification of consent.

We ask that the final rule clarify that if a Part 2 record has been shared with a business associate or covered entity for TPO purposes, then it should operate that general consent for those purposes also applies to those entities. We also conclude that covered entities and other payers have a right to redisclose claims data in accordance with the CARES Act and that they have received general consent for TPO purposes unless written consent indicates otherwise.

III. Segmentation of Part 2 Data After Transmission

These proposed changes will not eliminate the need to segment Part 2 data from HIPAA data because of the requirement for consent to share Part 2 records for TPO purposes. Therefore, Part 2 and HIPAA data have had to be siloed because of their different

regulatory schemes around consent. We acknowledge that complete data alignment may not be possible under the existing statute.

Once the 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.

HHS, 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 HHS, OCR, and SAMHSA to specify that once Part 2 data is transmitted or retransmitted, there should <u>not</u> be a requirement to segregate a patient's Part 2 data from the rest of a HIPAA database or record. We urge HHS, OCR, and SAMHSA to harmonize the rules requiring this segmentation while preserving protections against impermissible uses and disclosures of Part 2 records under the CARES Act.

IV. Revocations

Thank you for aligning the wording of the revocation requirements with those under HIPAA. We appreciate that the language clarifies the limits on a patient's ability to "pull back" Part 2 records from a covered entity, business associate, or Part 2 program once disclosed in alignment with HIPAA. Thus, once a Part 2 program discloses a Part 2 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 it in the same manner as permitted by HIPAA and the CARES Act. **It is essential to the Partnership that revocation of consent should only affect Part 2 record 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 applies only to additional disclosures. The sentence above would be modified to read, "once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, business associate or <u>intermediary</u> with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities." **We encourage HHS, OCR, and SAMHSA to offer subsequent guidance on the best way to flag a revocation within electronic health records and work with regulatory and technology partners to support advancements that can help achieve this objective.**

V. 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. Lastly, the CARES Act requires patient revocations of consent to be in writing. **We encourage HHS, OCR, and SAMHSA to consider the feasibility of implementing oral revocations in clinical settings.**

VI. De-identification for HIPAA

Individuals and entities subject to Part 2 may disclose Part 2 records without patient consent to public health authorities, provided that such records are de-identified in accordance with HIPAA de-identification standards. The proposed rule "should not be construed as extending the protections of Part 2 to de-identified information, as such information is outside the scope of 2.12(a)." Similarly, any person conducting scientific research using Part 2 information could report results in aggregate form if patient identifying information is de-identified in accordance with the HIPAA de-identification standard. HHS, OCR, and SAMHSA later specify that de-identification would mean "rendering patient identifying information de-identified in accordance with the requirements of HIPAA at 45 CFR 164.514(b), such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder." However, this is not the HIPAA de-identification standard. Section 2.2 defines "records" to include patient identifying information. Other provisions also appear to refer to Part 2 records as "patient identifying information" and "SUD information." **We encourage HHS, OCR, and SAMHSA to simplify and clarify the definition of a Part 2 record and what constitutes de-identified data.**

VII. 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, accountable care organizations (ACOs), electronic health record vendors, and researchers. The proposed rule suggests distinct and separate limits on redisclosures based on prior consent for intermediaries. 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.

We urge HHS, OCR, and SAMHSA to eliminate the concept of an intermediary since most are already defined under Covered Entities or Business Associates under HIPAA. The special accounting requirements in the NPRM for intermediaries are now duplicative of the new broader accounting requirement for all entities. **At a minimum, we**

request to carve out business associates from the definition of intermediary. Business associates are bound by their contractual obligations to the Part 2 programs, and this distinction will more closely align Part 2 with HIPAA.

VIII. 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 redisclose 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. This will be especially important as the healthcare system implements these new regulations.

IX. Notice to Accompany Disclosures

The Part 2 Partnership does not believe that a Notice to Accompany the Disclosures should be required. Retaining the notice to accompany the disclosure requirement will ensure that certain protections for Part 2 records continue to "follow the record," as compared to HIPAA, whereby protections are limited to protected health information held by a covered entity or business associate. It also means that the need to identify, segment, and segregate the data will persist in order to append the notice with each disclosure. **We urge HHS, OCR, and SAMHSA to eliminate the notice to accompany disclosure and align itself with HIPAA and the CARES Act. At a minimum, this NPRM should excuse covered entity and business associate recipients of the Part 2 records from the notice requirement.**

X. Breach Notifications

The Part 2 statute now applies HIPAA and HITECH Act breach notification provisions to breaches of Part 2 records. **We encourage HHS, OCR, and SAMHSA to issue robust technical assistance on when a breach would occur and need to be recorded.**

XI. 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 have until the compliance date to establish and implement policies and practices to achieve conformity. While some programs may be able to implement the rule sooner than others, we encourage a broad implementation timeline so that all impacted stakeholders have time to become familiar with the new changes. Additionally, we anticipate that the technology systems updates will be substantive.

We request that the compliance date is at least 24 months after publication, as suggested by the NPRM. Additionally, we encourage the delay of civil and monetary penalties and expanded safe harbor protections for Part 2 programs, providers, business associates, and covered entities acting in good faith for at least 36 months after publication.

XII. 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 educating stakeholders and implementing the law. Examples of TA 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, sharing of lessons learned, and best practices through implementing these Part 2 rule modifications so that all entities can continue to learn how to best carry out these provisions to establish data integration and enhance treatment delivery.

XIII. Study by HHS, OCR, & SAMHSA on Full Alignment with HIPAA

We encourage HHS, OCR, and SAMHSA to study the impact and benefits of complete alignment with HIPAA, with protections against uses and disclosures in civil, criminal, administrative, or legislative proceedings against a patient. 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 SUD treatment and the availability of SUD providers. The differences between Part 2 and HIPAA still pose significant hurdles to encouraging more providers to deliver SUD services.

Conclusion

This NPRM is a significant step towards aligning Part 2 with HIPAA for TPO. However, anything short of total alignment with HIPAA for TPO purposes will retain and reinforce the significant impediments to fully informed care for persons with a SUD or history of SUD treatment. In addition, it would cause undue administrative burdens and hinder certain providers from holding themselves out as SUD providers**.** Thank you for the opportunity to comment on this important proposed rule. Please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at Cohen@abhw.org or (617) 515-8066 with any questions.

Sincerely,

Maeghan Gilmore

Maeghan Gilmore, MPH
Chairperson, Partnership to Amend 42 CFR Part 2

Members of the Partnership

Academy of Managed Care Pharmacy · Alliance of Community Health Plans · American Association on Health and Disability · American Association of Psychiatric Pharmacists · American Health Information Management Association · American Hospital Association · American Psychiatric Association · American

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