



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-0945-AA16**

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

The Association of Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments 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) on the proposed modifications to 42 CFR Part 2 (proposed rule or NPRM).

ABHW serves as the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness.

Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, through our policy work, we strive to promote equal access to quality treatment and address the stark inequities created by systemic racism. We are deeply concerned about health disparities in this country in the areas of MH and SUD services and are committed to promoting health equity in the healthcare system.

We are grateful to HHS, OCR, and 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).

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 maintaining protection for patient privacy.

We appreciate that this proposed rule is intended to improve care coordination and communication between providers and other stakeholders of the healthcare system, such as payers. This NPRM will better align Part 2 with HIPAA for treatment, payment, and health care operations (TPO) purposes on various definitions such as business associate, covered entity, breach, and health care operations. However, we are concerned that anything short of full alignment with HIPAA will cause administrative burdens, continued challenges with data segmentation and may impede access to treatment. As such, we urge HHS through OCR and SAMHSA to work with Congress to remove the Part 2 consent requirement.

Please see our comments with more detail on the specific provisions below.

## I. Consent

**Single Consent for TPO:** We sincerely appreciate Congress, HHS, OCR, and SAMHSA for passing the CARES Act and drafting this NPRM, which permits 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 is a significant step forward and should help improve communication and care coordination.

We realize that HHS, OCR, and SAMHSA are limited in their regulatory authority, and this NPRM is constrained by the 42 CFR Part 2 statute that requires consent. 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 may hinder some providers from holding themselves out as substance use disorder (SUD) providers.

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 regarding 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 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. Since the proposed Part 2 consent requirements are similar to a HIPAA authorization, it might be confusing to have similar language for Part 2 consent and 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 should be incorporated into the same document at intake where feasible.

## **II. Redislosures**

ABHW members appreciate that this proposed rule allows for more flexibility with redislosures. As discussed above, this NPRM provides single patient consent for all uses and future redislosures for TPO. Where the disclosure is for TPO, a patient's consent may be redislosed in accordance with HIPAA, except for uses and disclosure for civil, criminal, and legislative proceedings 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.

**Part 2 Programs, Covered Entities, and Business Associates:** We were happy to see that this proposed rule includes specific language directing Part 2 programs, covered entities, and business associates to transmit and retransmit the Part 2 records, following the initial written consent and that no additional consents would be necessary unless the consent is revoked for TPO purposes. We request that 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, as long as the data is not redisclosed for use in civil, criminal, administrative, or legislative proceedings 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 redislosure for these proceedings.

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 is clear that once 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.

## **III. Segmentation of Part 2 Data After Transmission**

The proposed changes in the NPRM 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. 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 not be a requirement to segregate a patient's Part 2 data from the rest of a HIPAA database or record. We urge harmonization of the law that would otherwise require this segmentation.**

#### **IV. Lawful Holder**

We encourage HHS, OCR, and SAMHSA to create a regulatory definition of lawful holder so that there are better parameters around their role. If lawful holders are subject to Part 2 obligations, including the potential for penalties, they must be defined. Using this definition will help to create a mechanism to expand exceptions for the redisclosure of Part 2 records. In particular, the definition of lawful holder should provide a safe harbor for the imposition of civil or criminal monetary penalties for the unintentional redisclosure of Part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under HIPAA TPO.

HHS, OCR, and SAMHSA ask for comment on persons who are lawful holders under the current regulations and who should not be held liable under the Breach Notification Rules for compliance with the administrative requirements for protecting Part 2 records they have received. ABHW agrees with HHS, OCR, and SAMHSA that Managed Care Organizations (MCOs) would fall into this exception. 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 Act (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.

#### **V. Intermediary**

The proposed rule defines an 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 who has a treating provider relationship with the patient." For example, intermediaries are Health Information Exchanges (HIEs), Accountable Care Organizations (ACOs), and researchers, and the proposed rule suggests distinct and separate limits on redisclosures based on prior consent for intermediaries.

**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 particular accounting requirements in the NPRM for intermediaries are now duplicative of the new broader accounting requirement for all entities. At a minimum, HHS, OCR, and SAMHSA should 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. We also recommend that health plans be expressly excluded from the definition of intermediary since their role as care coordinators are ancillary to their position as health plans.**

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. Therefore, there may be a long list of entities that will need to be disclosed. Even sophisticated intermediaries such as HIEs currently find the accounting of disclosures incredibly burdensome, and patients receive unnecessary information within these disclosures. With the expanded TPO flexibility, the accounting of disclosures could become overwhelming and inevitably hinder care coordination.

## **VI. Qualified Service Organization (QSO)**

The proposed rule clarifies that business associates will be defined as Qualified Service Organizations (QSO) with respect to use and disclosures of PHI that constitute a Part 2 record when a Part 2 program is also a covered entity. Therefore, consent requirements would not apply to information exchanges between Part 2 programs and business associates when they are providing “service work “on behalf of the Part 2 program. ABHW members support this expansion, which will encourage data sharing for Part 2 programs.

## **VII. Safe Harbors for All Payor Claims Database**

We understand that this proposed rule does not preempt state law. We encourage HHS and SAMHSA to develop guidance on how this rule will interplay with state laws operationally. We also urge HHS, OCR, and SAMHSA to create a safe harbor for the imposition of civil and criminal penalties for health plans for their good faith redisclosures that comply with HIPAA but would not comply with Part 2. For example, this will be especially important for sharing information on claims databases since there are disparate state approaches to protecting and administering these records.

## **VIII. 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.**

## **IX. 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 may be beneficial in some circumstances where heightened privacy is warranted. However, it could impede care coordination because SUD counseling notes may contain clinically relevant information and help inform coordinated treatment plans. Further, some programs may have difficulty implementing the requirement and be unable to share the remainder of the record for TPO. **We encourage HHS, OCR, and SAMHSA not to create a separate category for SUD Counseling Notes but instead, allow SUD providers to determine how to best record these notes.**

## **X. Third-Party Payor**

We agree with the NPRM and support distinguishing Part 2 Third-Party Payors from health plans. Health plans are bound by their contractual obligations to Part 2 programs and need to continue to be able to redisclose Part 2 records. This interpretation follows the interpretation of the CARES Act, which only permits TPO uses and disclosures by covered entities, business associates, and Part 2 Programs. We also request that Business Associates acting on behalf of health plans be explicitly excluded from this definition.

## **XI. Notice to Accompany Disclosures & Notice Privacy Practices**

ABHW believes that a Notice to Accompany the Disclosures should be eliminated. 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. This Notice 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 the Disclosure and align with HIPAA. At a minimum, the Department should excuse covered entity and business associate recipients of the Part 2 records from the notice requirement.

Additionally, health plans should not be required to mail new Notice of Privacy Practices (NPP) to existing members. Plans that do not post an NPP online or provide an annual mailing to subscribers will incur mailing costs that can be avoided while achieving the goal of informing existing members of the NPP changes. **Specifically, we urge HHS, OCR, and SAMHSA to permit health plans to electronically notify members that a new notice is available and require health plans to send the updated language in the next three-year mailing.**

If these notices remain in the final rule, we encourage HHS, OCR, and SAMHSA to give detailed guidance on the specific contents of the notice and any requirements on how and to whom it should be delivered.

## **XII. 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 HIPAA. 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 HIPAA. 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 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.

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

### **XIV. 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 the 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 the Privacy Rule 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. We encourage HHS, OCR, and SAMHSA to simplify and clarify the definition of a Part 2 record. 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.” These provisions suggest that Part 2 records could apply to de-identified data.

### **XV. Minor Patients**

The NPRM proposes to change the verb “judges” to “determines” to describe a program director’s evaluation and ultimate decision that a minor lacks decision-making capacity to better distinguish from when a court adjudicates a patient to lack decision-making capacity. We request clarity on interrupting and implementing this change, especially when state law supersedes the Part 2 rule. This analysis will be especially useful for minors out of state and receiving SUD treatment.

We encourage HHS, OCR, and SAMHSA to issue specific guidance and technical assistance on the interplay between federal and state requirements for minors regarding Part 2 consent and SUD treatment. This guidance should also elaborate on how this rule interacts with Medicaid, the Children’s Health Insurance Program (CHIP), and similar programs that can help access minors’ SUD treatment.

#### **XVI. 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. 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.**

#### **XVII. 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 about 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, 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 to establish data integration and enhance treatment delivery.

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


We encourage HHS, OCR, and SAMHSA to study the impact and benefits of complete alignment with HIPAA. 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 stakeholders to deliver SUD services.



## Conclusion

This NPRM is a significant step towards aligning Part 2 with HIPAA. However, anything short of total alignment with HIPAA for TPO purposes will cause administrative burdens and hinder certain providers from holding themselves out as SUD providers. We encourage HHS, OCR, and SAMHSA to continue to work to align HIPAA privacy with Part 2 to eliminate operational and administrative burdens as much as possible.

Sincerely,

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

Pamela Greenberg, MPP  
President and CEO