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Pennsylvania Recovery Organizations Alliance
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The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA - Ms. Deepa Avula
5600 Fishers Lane, Room 17E41
Rockville, MD 20857

October 14th, 2019

Re: The Pennsylvania Recovery Organizations – Alliance Comments on NPRM for 42 CFR Part II (RIN 0930-AA32)

Dear Ms. Avula:

Thank you for the opportunity to provide comment related to proposed changes to 42 CFR Part II through the rulemaking process. We are the Pennsylvania Recovery Organizations – Alliance, the statewide Substance Use Disorder (SUD) Recovery Community Organization for the state of Pennsylvania, with over 5000 members.

PRO-A, the statewide recovery community organization of Pennsylvania is adamantly opposed to the proposed rule changes within RIN 0930-AA32.

We ask SAMHSA to consider the protection of persons who would face such prosecution and discrimination as the primary consideration in any change to 42 CFR Part 2. These rules are critically important to us. We are all too well aware that there are economic interest being pursued by groups who would seek to obtain our highly sensitive and personal information and to use this information in ways that would impact our employment, housing, access to health insurance, life insurance, student loans and other benefits. **We ask you to uphold our current SUD privacy standards**.

Discrimination and the likelihood of prosecution remain a very real threat for many of us with substance use disorders, which is why the recovery community and our allies continue to strenuously advocate to protect these critically important protections that ensure access to safe care without fear of consequences to us. As our federal administration, we respectfully ask that you recognize these risks for us and stand with us. **The interest of those impacted by regulatory standards should be held as the primary consideration above all others.**

As there is a stated interest to expand access to treatment, we would respectfully suggest that focus be placed on all the people who are not getting into care through our medical care institutions. Hospitals are quite literally filled with **people who have readily apparent alcohol and other drug dependencies and very little is done to help them.** Referrals for addiction care are uncommon to rare in our hospital wards dealing with cirrhosis, esophageal cancers, strokes, heart conditions and other serious medical problems clearly related to substance use disorders. **Everyone sees it, these cases are hiding in plain sight, but virtually no one helps them.**

We see medical institutions far too often discriminate against persons who have an identified substance use disorder, people who are identified as having a substance use disorder often are treated rudely, given inferior care, have interventions withheld and are seen as less than human. Stigma and negative perceptions about us are endemic to the medical care system in the United States. **We would deeply appreciate as much or more focus on discrimination against us rather than the focus given to the erosion of our critically important patient record privacy rights.**

The truth is that many of us live in fear of medical care discrimination because of our history of substance use disorders. We would welcome a right of action to create a clear mechanism to sue and hold accountable medical care institutions and providers who use information from our records to provide inferior care or outright withhold medical interventions. **We should be focusing on discrimination against persons with substance use conditions who are treated poorly or not at all because of stigma, not yet another proposed rule change.**

Overall Comment on who can qualify to obtain and protect sensitive Part II protected information:
SAMSHA appears to be dispensing with the regulatory language related to Qualified Service Organization. We are concerned that this may inappropriately allow the broad sharing of protected information within the context of virtually any kind of contract or agreement. We see no mention of holding the receiver bound to Part II requirements in ways consistent with 42 USC 290dd. **The current QSOA language in the existing rule must be retained in order to protect persons seeking, receiving or having received treatment for a substance use disorder against legal prosecution and discrimination through the sharing of information with groups who wish to have our information and are not qualified as defined by the current rule.**

Comment on Section III.I, Research:
Allowing research disclosures of part 2 patient data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, for the purpose of conducting scientific research eliminates necessary protections that prohibit the use of patient information in ways that can result in legal prosecution or discrimination to us. **These proposed changes should be removed and the language within the existing rule remain in place to protect persons seeking, receiving or having received treatment for a substance use disorder against legal prosecution and discrimination through data gather to research substance use disorders.**

Comment on section III.A redefinition of records:
In section III.A. of this proposed rule, SAMHSA proposes to modify the existing definition of ''Records'' in § 2.11. In the current rule. The term records in the current rule is defined to mean ''any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient.'' **We are opposed to the adding at the end of the of the first sentence of the definition, the phrase**: ''provided, however, that information conveyed orally by a part 2 program to a non-part 2 provider for treatment purposes with the consent of the patient **does not become a record subject to this part in the possession of the non-part 2 provider merely because that information is reduced to writing by that non-part 2 provider**. Records otherwise transmitted by a part 2 program to a non-part 2 provider retain their characteristic as a ''record'' subject to this part in the possession of the non-part 2 provider, but may be segregated by that provider.''

- Adding this language would strip off protections that were clearly intended in the original statute. We are astounded that such a redefinition would be proposed that **clearly puts people with substance use disorders at risk and will inevitably reduce willingness to seek help – the antithesis of what we should be doing.**
- The proposed language would make a substantive amendment to the § 2.11 definition of ''records,'' and it seems **beyond any reasonable definition of a record** to propose that writing down, transcribing or rerecording information from a Part II record into a medical record does not constitute a record under 42 USC 290dd.
- **Patients must be able to access care for a substance use disorder without fear of their highly sensitive information being transferred into HIPAA records that offer less protections and open patients up to legal prosecution and discrimination under the HIPAA standards, which do not offer any protection regarding illegal drug use.**

Additional comment on Section 2.11:
SAMSHA notes that is **does not intend for abuse by providers in extensively recording information** via the proposed transcribing process that strip out Part II protections **but provides no parameters on what is permissible beyond the vague term "clinical purpose, which may well result in extensive and potentially damaging information being stripped of Part II protections," broadly shared and opening up persons with substance use disorders to legal prosecution and discrimination**. The lack of parameters in the proposed rule will inevitably result in this information being shared inappropriately and in a routine manner. **To reiterate we are opposed to changing the current definition of the term "records" under the proposed rule change.**

Comment on PDMP Section 2.36:
Allowing Opioid Treatment Programs to disclose dispensing and prescription information to PDMPs would **open up this information to law enforcement review** and would subsequently place our community at significant risk for legal prosecution and discrimination through the very act of seeking or receiving help for a substance use condition. **Sections referencing this should be removed from the proposed change and the language remain as in the current rule**. As noted by The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC): "The (PDMP) data are used to support states' efforts in education, research, **enforcement** and abuse prevention."* 42 USC 290dd identifies in section (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. **These sections should be removed as protection from view of these highly sensitive records is fundamental to 42 USC 290dd. Once information is included into records with law enforcement access, the written intent of 42 USC 290dd would be exceeded by this proposed rule.**

*Source: https://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq

Comment on proposed changes to § 2.52 and § 2.53 to allow certain disclosures without patient consent:
We are opposed to the proposed amendments to section III.I., and section III.J. to amend § 2.52 and § 2.53 to allow certain disclosures without patient consent. In section III.I. of this proposed rule, SAMHSA would modify the text of § 2.52(a) in order to allow research disclosures of part 2 data from a HIPAA covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule. **We are opposed to allowing such information shared without patient consent as persons receiving treatment for a substance use disorder would be at great risk for legal prosecution and discrimination and patients should retain control over how their information is used – it is fundamental to the originating statue.**

Comment on the addition of 252 (a)(1)(iii) to extend research disclosures to members of the workforce of a HIPAA covered entity for purposes of employer sponsored research:
This section should not be added to the rule, to protect persons seeking, receiving or having received treatment for a substance use disorder against legal prosecution and discrimination. Workplace discrimination against persons with substance use disorders is pervasive in America. Persons with substance use disorders must be able to access care for a substance use disorder without fear of information going back to their employer or others in ways that can result in loss of employment. There would be significant motivation at the employer level to use this information to discriminate against patients and there would be virtually no way for people to know that their information was used to harm them in this way.

SAMHSA proposes to expand the scope of section §2.53, to allow government agencies and third-party payer entities to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes. This is ostensibly for the improvement of care and outcomes for part 2 patients (e.g., provider education, recommending or requiring improved health care approaches); targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment. The proposed changes also include inserting a new §2.53 (c)(2) that would permit audit and evaluations under this

section that may include, but are not limited to, reviews of appropriateness of medical care, medical necessity, and utilization of services. This is very broad language that allows for the expansive sharing of information that is highly sensitive with few parameters and places government and third-party payers in the role of the clinician instead of the actual treating entity working directly with the part 2 patient. **The sad reality is that patient care information has long been used to reduce care below the appropriate level and duration of care needed, not to increase it – and resources focused on addiction are already woefully inadequate. We are opposed to these changes as broad sharing of detailed information in this way as it opens patients up for discrimination and threatens the therapeutic alliance with the treating provider while potentially eroding care.**

Patient consent must be retained for information being used from their own records to make decisions in respect to their own care and must only be shared with their expressed written consent. 42 USC 290dd clearly states in section (b) (2) (B) that patients may not be identified directly or indirectly or otherwise disclose patient identities for purposes of research in any manner. The proposed rule does not describe how granular level information that would support medical necessity, utilization and other purposes described in the section would be shared in ways that would be not disclose patient identities in any manner yet be useful for the purposes described and we see no enforcement measures in place to protect patients. **The proposed rule change exceeds 42 US Code 290dd and should be removed.**

Comment on section related to Audit and Evaluation:
SAMHSA proposes to re-designate current §2.53(c) and (d) as §2.53(e) and (f), respectively, and insert a new § 2.53(c) titled: ''Activities Included.'' The proposed new paragraph §2.53(c)(1) would specify that audits or evaluations may include periodic activities to identify actions that an agency or third-party payer entity can make, such as changing its policies or procedures to improve patient care and outcomes across part 2 programs; targeting limited resources more effectively; or determining the need for adjustments to payment policies for the care of patients with SUD. This change would clarify that disclosures of patient records by a part 2 program to an agency or third-party payer entity are permitted for these purposes **without patient consent**. 42 USC 290dd clearly states in section (b) (1) (B) that **patient consent is required** and further on under section (b) (2) (B) that **patients may not be identified directly or indirectly or otherwise disclose patient identities in any manner**. The proposed rule does not describe how granular level information would be shared between agencies or with third party payer entities in ways that would be not disclose patient identities in any manner yet be useful for the purposes described. **The proposed rule change exceeds 42 US Code 290dd and should be removed.**

Additional comment on section on Audit and Evaluation:
SAMHSA is proposing to insert a new section into the rule, §2.53(g) to **permit patient identifying information** to be disclosed to federal, state, and local government agencies, as well as their contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using deidentified information. 42 USC 290dd clearly states in section (b) (2) (B) that personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner. **The proposed rule change exceeds 42 US Code 290dd and should be removed.**

In the proposed rule change, SAMHSA notes in respect to section §2.53 that "Additionally, SAMHSA does not believe it is generally necessary to conduct these types of audits or evaluations on a routine or ongoing basis. Rather, would generally expect that they would be performed periodically, unless they are required by applicable law or other compelling circumstances exist, such as unique cases in which an oversight agency determines there is a need for ongoing review. Information disclosed for the purpose of a program audit or evaluation may not be used to directly provide or support care coordination." **We are deeply concerned about the failure to place parameters on proposed government and government vendor access allowances to these**

records. There is significant risk in this process being used quite frequently to make decisions about patient care solely on what can be found in the files through such reviews. **Virtually every use will be deemed compelling and the use of this avenue would become routine.** We see these proposed changes as opening the door for audit and evaluation processes, including data with patient identifying information to be used to reduce care as noted is the historic norm in the opening sections of this comment letter.

We believe that SAMHSA has also dramatically underestimated the training needs for these extensive and complex proposed rule changes as they have estimated one hour of training per staff to achieve proficiency in the 42 CFR part 2 regulations. We see the training needs as far more involved with significant higher costs.

In closing we ask that you stand with the persons impacted by these regulations – persons with substance use disorders, those of us in recovery as well as those who would seek help in the future who would face prosecution or discrimination related to employment, housing, access to health insurance, life insurance, student loans and other benefits.

We ask you to uphold our current SUD privacy standards.

Sincerely,

William Stauffer, CADC, LSW
Executive Director
The Pennsylvania Recovery Organizations – Alliance