



U.S. Department of Health and Human Services,
Office for Civil Rights, Attention: SUD Patient Records,
Hubert H. Humphrey Building, Room 509F,
200 Independence Avenue SW,
Washington, DC 20201

January 11, 2023

Public comment on HHS proposal to modify regulations to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

Thank you for the opportunity to provide comment related to proposed changes for section 3221 of the CARES Act through the rulemaking process. We are the Pennsylvania Recovery Organizations – Alliance, the statewide substance use disorder (SUD) Recovery Community Organization, with over 5,000 members.

- These proposed changes to federal privacy regulations for SUD treatment records, 42 CFR Part 2, as required by the CARES Act of 2020 enacted substantial changes to align 42 CFR Part 2 with the HIPAA Privacy Rule.
- We believe that the proposed changes will seriously compromise individuals rights and put people with SUD treatment records at risk of increased discrimination, stigma, and prosecution.
- We are proposing that further changes to the regulations are made to ensure greater protections from discrimination, stigma, and prosecution. We also believe it is vital to empower patients through informed consent so every person who is considering accessing services covered by these rules can make informed choices and understand the risks of their information being used in ways that can potentially harm them.

We suggest these six modifications to the regulations:

- 1. Place this regulatory process on hold until the proposed antidiscrimination regulations are published -** Even though Congress introduced the changes at the same time, the current rulemaking only implements the changes weakening patient privacy rights, without the corresponding anti-discrimination protections. As individuals' SUD treatment information is used and disclosed in new ways and with increasing frequency, it will be even more important for the antidiscrimination protections required by the CARES Act to take effect.
 - It is important to note that historically there has been spotty enforcement of laws protecting persons with SUDs from discrimination, stigma, or prosecution and these measures are all that stand between people seeking help and discriminatory practices across our society.
 - Allowing commenters to see the two sets of rules side by side will allow an improved review process in order to comment on how the two sets of proposed rules interrelate.
 - There are several portions of the rules, including the conditioning of treatment on consent and the newly open door that permits patient consent for records for use in criminal, civil, administrative, and legislative proceedings that require side by side comparison to ensure people seeking help for an SUD are properly protected under the law.
- 2. Require an informed consent process -** Informed consent for patients in regard to their privacy rights are critical for them to understand any potential risks to they may face in respect to what may occur to their highly personal information. This information typically includes illegal drug use, and patients must understand the potential for that information to end up being used to discriminate, stigmatize, or prosecute them, either through improper data sharing, data loss, data theft or consented release, including the potential for coercive consent through the newly opened door created by the proposed rules.

- Honesty and openness are foundational to the SUD treatment and recovery process. Many people who experience a substance use disorder are members of marginalized and oppressed communities.
 - The proposed rule does not create clear enough requirements to ensure that patients, Part 2 programs, and recipients of Part 2 records will meaningfully understand how records will be used, disclosed, and protected, nor that they have the right not to sign that broader consent or limit disclosures to more limited Treatment, Payment, and Operations purposes.
 - If we are not forthright about potential risks that they may experience as a result of their information being used in ways that can harm them, many patients will not place sufficient trust in the process to develop a therapeutic alliance and will avoid seeking help when they learn of the potential risks they face by choosing to disclose their highly sensitive information that often includes illegal drug use.
 - An informed consent should be required by regulation to contain a plain language description of their privacy rights and what happens to their information including how information is stored, used, disclosed, and legally protected and what rights they have to limit disclosure.
 - Informed consent should specify as required by regulation that conditional consent is limited to the minimum necessary to accomplish the intended purpose. This includes language specifying that in no way can treatment be conditioned for funding and other purposes to require whole records as the information permitted to be disclosed is limited by law to the minimum necessary to accomplish the intended purpose.
3. **Protect consented release.** HHS proposes to permit the use and disclosure of Part 2 records in a criminal investigation or prosecution of the patient, so long as the patient signs a written consent form.
- This marks a major departure from the long-standing privacy protections for individuals with substance use disorder treatment records; for the last 40 years, only a special court order could authorize the use or disclosure of patient records in a criminal investigation or prosecution until now.
 - We request that the regulations specify that recipients of consented release for criminal, civil, administrative, and legislative proceedings are considered as lawful holders under the regulations and expressly bar these records or patient information to be used in ways that discriminate against the patient or to peoples records or information obtained in this manner to prosecute them.
 - We believe that failure to do so will seriously compromise people’s willingness to seek help, particularly members of marginalized communities.
4. **Remove or modify the section on the conditioning of treatment on consent.** The proposed regulation clearly sets up two sets standards, one for persons of means who can pay for their own care and the other for the rest of Americans who would have no alternative but to sign a consent as a condition of treatment.
- The regulations condition treatment on consent, which as noted in the regulations may be required to make referrals to other providers, obtain payment from a health plan, or conduct quality review of services provided.
 - For self-pay clients, the proposed regulations actually notes that persons who can afford to self-pay may not wish to face the risks restrictive health plan coverage policies, employers and others finding out they are being treated for an SUD, a privilege afforded only to those who can afford to pay for care and avoid these very real risks. We should not subject most Americans to these very real risks while acknowledging that persons of means can avoid them.
 - Broadly conditioned releases will effectively eliminate the choice not to consent in order to seek help for this life-threatening condition and should be removed or at minimum specifically limited by the regulation to the purposes needed for the consent and made clear that it is not a whole record consent.
5. **Protect highly sensitive counselor notes** – The proposed regulations note that the Department is considering whether to create a new definition similar to psychotherapy notes that is specific to the notes of

SUD counseling sessions by a Part 2 program professional. Such notes would be Part 2 records but could not be disclosed based on a general consent for Treatment, Payment, and Operations. Counselor notes should only be disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information.

- Counseling notes should be so protected using a new definition similar to psychotherapy notes and require a specific consent and not combined with a consent to disclose any other type of information.
- These notes often contain highly sensitive information that supports therapy. Limiting access to these notes is critical to protect the therapeutic alliance due to the unique risks that patients face due to the risks of inappropriate sharing of highly sensitive information in these notes.

6. Fund the associated administrative burden – The nations SUD workforce has been in a severe workforce crisis for over a generation, and recent strains are crippling it beyond the breaking point.

- The proposed regulations call for complaint and record tracking requirements to be added. While the capacity of patients to exert some influence on the use of their information is important, it is yet another administrative burden being placed on programs struggling to stay open.
- The SUD public treatment infrastructure is woefully underfunded, this creates an undue burden for program compliance, particularly in smaller, more rural programming.
- Funding and training should be allocated to programs to ensure the ability to comply with an emphasis on programing in the public sector.

We respectfully ask HHS to consider the protection of persons who would face such prosecution and discrimination as the primary consideration for these rules, it is why 42 U.S. Code § 290dd was initially intended. These rules are critically important to us. We are all too well aware of interest groups who routinely seek to obtain our highly sensitive and personal information and to use this information in ways that impact our employment, housing, access to health insurance, life insurance, student loans and other benefits.

The interest of those impacted by regulatory standards should be held as the primary consideration above all others. 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.**

We see medical institutions and funders 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 under the far too often false premise of improving care for us.

Respectfully submitted,



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