

Recovery organization PRO-A comments on Part 2 NPRM

The U.S. Department of Health and Human Services (HHS) has proposed significant changes to 42 CFR Part 2, known as Part 2, in a Notice of Proposed Rulemaking (NPRM) issued last year (see <https://onlinelibrary.wiley.com/doi/10.1002/adaw.33678>, <https://onlinelibrary.wiley.com/doi/10.1002/adaw.33661>, <https://onlinelibrary.wiley.com/doi/10.1002/adaw.33637>, <https://onlinelibrary.wiley.com/doi/10.1002/adaw.33628>).

The deadline for comments, as we have stated repeatedly, was last week, Jan. 31. *ADAW* has obtained some of the submitted comments. Below is one from William Stauffer, executive director of the Pennsylvania Recovery Organizations – Alliance (PRO-A).

Stauffer and many others have noted that getting rid of strong confidentiality regulations for people who seek treatment for substance use disorders (SUDs) will only discourage people from seeking such treatment. In this NPRM, the threat of using those records in criminal proceedings looms large.

The below is from PRO-A.

“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 anti-discrimination 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 anti-discrimination 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 is critical for them to [be able to] understand any potential risks they may face [with] 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.
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 people’s 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 [of] 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 note that persons who can afford to self-pay may not wish to face the risks [of] 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 [HHS] 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

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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 nation's 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, [and] 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 programming in the public sector.

Trust

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 risk 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

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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.

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 that 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." •

Recovery advocate: News from Minnesota, and the country

Randy Anderson is a well-known figure in the small world of recovery advocates; he travels across the country to trainings and his organization, Bold North Recovery, is a [Connecticut Community for Addiction Recovery] CCAR-certified trainer for peers in recovery. *ADAW* talked to him last month about his work in the field.

Of his travels, "99% of what I do is paid for by me and Bold North Recovery," he said, having just returned from a meeting on the CCAR Multiple Pathways of Recovery Conference in Florida.

He said he is grateful to have a grant from the Minnesota Department of Human Services, but that is only for work done specifically in the state. One of Anderson's goals is to make sure that pharmaceutical companies pay for the harms of the opioid epidemic. In 2019, he worked to help pass a law in Minnesota that increases licensing fees "for everybody who touches narcotic medications," resulting in about \$13 million a year. And this law, which implements the Opioid Epidemic Response Advisory Council, is on top of more funding coming to recovery organizations,

he said, noting that "it's outside of the money we'll be receiving from opioid resettlement funds."

Before 2019, pharmaceutical companies in Minnesota "had a licensing fee of \$235, which is a ridiculous amount," he said.

ADAW asked whether methadone and buprenorphine — both opioids — for the treatment of opioid use disorder (OUD) were included in the increased licensing fees. He said yes, even though this was a point of contention. "We didn't want to make it more difficult for people to prescribe medications for OUD, but they were subject to the same licensing fee increase," he said.

"When I talk about recovery, and I'm not a fan of the opioid epidemic, but what's happening in our country, is an addiction crisis," Anderson told *ADAW*. "It's easy to relate to the opioid epidemic as the problem, because your loved one is here today and gone tomorrow, unlike with other substances, which take a lot longer to kill someone," he said. "But addiction is a much bigger issue than just opioids."

Anderson noted that there are still two distinct camps in the recovery community. "To me, it's about discontinuing problematic substance use," he said. "Then there's the more extreme, and this is just my opinion, but to the 'ultra-harm reduction' community, there is a distinction. This group might say, for example, that someone is in recovery if they say, 'I've stopped using heroin and now I just smoke weed.'"

"I'm not sure how I feel about overdose prevention centers," said Anderson. "I realize no one has ever died inside one of these sites, but I'm still not convinced. That is something I need to look more into. From what I've seen around harm reduction, in much of this country, it's like hospice care and we are just preparing people to die. 'Here are some safe-use supplies, we'll keep supplying you until you're ready to stop using.' How do we move people out of the using phase and into the stop-using phase?"

One thing Anderson said he is learning from the recovery conferences across the country is "new, creative ways for people to think