



October 25, 2019

The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA—Deepa Avula
5600 Fishers Lane, Room 17E41
Rockville, MD 20857

RE: Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2 (RIN 0930-AA32)

Dear Ms. Avula,

Citizens' Council for Health Freedom, a national patient-centered, privacy-focused, free-market health policy organization located in Minnesota exists to protect health care choices, individualized patient care, and medical and genetic privacy rights. We have worked on the issue of patient privacy and consent rights for more than two decades.

We write to share our concerns about the proposed weakening of the 42 CFR Part 2 standard that today requires unequivocal patient consent for data sharing.

We are concerned about the push to align 42 CFR Part 2 with the permissive federal HIPAA data-sharing rule. Today, patients protected under 42 CFR Part 2 have the protections that every man, woman and child should have today in America. It is only because of the federal HIPAA “privacy” rule that Americans no longer enjoy the privacy and consent rights they used to have unless they live in a state with a strong (real) patient privacy law, such as the Minnesota Health Records Act. This proposal is moving away from privacy, not toward privacy. This is the wrong direction.

We are particularly concerned about the exemption for data transmitted orally, court-ordered access to patient data unrelated to a crime committed by the patient, sharing data with state government agencies for research, and the vast expansion of data-sharing that would be authorized under ‘audit and evaluation. Once the rule’s strong privacy and consent protections are breached in this way, it’s just a matter of time before they’re completely undone.

While proponents of waiving 42 CFR Part 2 say their aim is for patient safety, and make claims about the misuse and illegal use of opioids, they ignore a critical fact. The failure to protect confidentiality rights will keep these vulnerable patients from seeking the care they need, or seeking it in a timely manner. That is a safety issue of another and a higher magnitude. The proposed changes will make the hospital and doctor’s office a frightening place because the patient has no idea where his or her sensitive data could be shared, or how it could be used, or who could be given access to it. This is the antithesis of the essential confidential patient-doctor relationship that patients with sensitive and other conditions need to feel safe.

Currently, 42 CFR Part 2 prohibits disclosures of patient records concerning alcohol and drug abuse and addiction treatment by federally assisted programs without the express written consent of the patient. These individuals have the privacy that all patients should have, but do not have, due to the sweeping, but little known, plethora of permitted disclosures authorized by HIPAA.

A corporate movement is afoot to gain access to every possible piece of information on patients that can be had, including use of social media, relationships, behaviors, sleep patterns, lifestyle and so-called “Social Determinants of Health.” This race to the biggest data, without regard for the subjects of the data, is profit driven, despite claims otherwise. For example, UnitedHealth Group’s data division, OptumInsights, reported revenues of **\$8.1 billion** in 2017.

Those who have asked HHS to relax this rule do not have the care of individual patients in mind because the care of a patient includes keeping the confidences of their most private information, unless they agree to share the data. Those who want 42 CFR Part 2 relaxed are also not thinking about the rights of patients, or the rights of Americans under the Fourth Amendment of the U.S. Constitution of the United States. HIPAA provides access to a patient’s medical record to up to 2.2 million entities—an HHS number—if those holding the patient’s data choose to share it. This number does not include government agencies that can also get access. The patient’s consent is not required. This number does include 1.5 million business associates. This unconstitutionally disregards patient and citizen rights, and in the case of patient data, sharing is not caring.

Information about drug or alcohol abuse treatment is extremely sensitive and should not be shared with any third parties without patient consent, and that includes researchers and anyone who could have access under the expansive definitions proposed under the ‘audit and evaluation’ section of this proposed rule.

If people with substance abuse are really to be helped, they must have the confidence they need to be able to first walk through the door. Part 2 protections need to be protected, not eliminated. In fact, since HIPAA is not a privacy rule, the current privacy and consent protections for patients with a history of substance abuse should be expanded to every other patient with every other condition. **Advancing current 42 CFR Part 2 protections to every patient in America should be the charge of HHS, not dismantling it.**

Therefore, we call on HHS (SAMHSA) to make no changes to 42 CFR Part 2.

Sincerely,



Twila Brase, RN, PHN
President and Co-founder