



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-2022-0018

Dear Secretary Becerra and Assistant Secretary Delphin-Rittmon:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the proposed rule regarding the confidentiality of substance use disorder (SUD) patient records. Specifically, the rule 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).

NAACOS is a member-led and member-owned nonprofit of more than 400 accountable care organizations (ACOs) in Medicare, Medicaid, and commercial insurance working on behalf of health systems and physician provider organizations across the nation to improve quality of care for patients and reduce health care cost. NAACOS represents more than 8 million beneficiary lives through Medicare's population health-focused payment and delivery models, including the Medicare Shared Savings Program (MSSP) and the ACO Realizing Equity, Access, and Community Health (REACH) Model, among other alternative payment models (APMs). We applaud efforts to align HIPAA and Part 2. NAACOS is committed to improving our health system through accountable care models, which help to control rising costs by increasing coordination and improved outcomes.

ACOs are provided claims data at least monthly, and sometimes weekly, through Claim and Claim Line Feed (CCLF) files. These data lack SUD-related information because of previous privacy restrictions around Part 2 data. Without access to such claims data, ACOs and other APM participants risk treating the whole patient with only part of their data, potentially harming patient care and outcomes. Furthermore, we believe it was Congress's intent to allow the sharing of this important information.

**The final rule should make clear that if SUD data or a Part 2 record has been shared for purposes of treatment, payment, and health care operations (TPO) with a business associate or covered entity, it should operate that general consent was given.** NAACOS believes it would be lawful for HHS to release SUD-related claims data, particularly after the CARES Act. Part 2 law requires patient consent to bill for services rendered. This proposed rule does not provide an exemption for providers to bill CMS or other

payers if they fail to obtain patients' written consent. Thus, if a payer is billed for such SUD services, then payers, including CMS, should assume patients gave consent for their Part 2 data to be shared with others for purposes of TPO. Currently, other payers are sharing such claims data with providers in value-based arrangements. Similarly, **CMS should release SUD-related claims data to ACOs.**

Additionally, NAACOS urges HHS to specify that once Part 2 data is transmitted, there should not be a requirement to segregate a patient's Part 2 data from the rest of a HIPAA database or patient record. Currently, many SUD programs are integrated into primary care sites. Once the Part 2 data is transmitted, it is critical that there not be an additional requirement that the Part 2 data be retained separately. Such a requirement to segregate a patient's Part 2 data would place tremendous burden on ACOs and their partners to manage the consent process for separate databases for Part 2 programs and their other systems. Unless this change is made in the final rule, Part 2 and HIPAA data will continue to be siloed.

Our members are committed to population-health management, including addressing public health crises like the opioid epidemic. Unfortunately, ACOs lack access to the full suite of necessary information that allows them to achieve the goals of well-coordinated patient care, improved quality, and preventive care that will realize HHS's goals of limiting the spread of opioid overdose deaths. We urge HHS take the appropriate next steps to provide ACOs with the information they need to achieve our collective goals. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at [aisha\\_pittman@naacos.com](mailto:aisha_pittman@naacos.com).

Sincerely,



Clif Gaus, Sc.D.  
President and CEO  
NAACOS