National Alliance of Methadone Advocates, Inc.
d/b/a National Alliance for Medication Assisted Recovery
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SUBMITTED VIA FEDERAL ERULEMAKING PORTAL (https://www.regulations.gov/commenton/HHS-OCR-2022-0018-0001)

JANUARY 31, 2023

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

RE: Confidentiality of Substance Use Disorder Patient Records Notice of Proposed Rulemaking (HHS-OCR-0945-AA16; RIN 0945-AA16)

To Whom It May Concern:

The National Alliance for Medication Assisted Recovery (NAMA Recovery) strongly supports patient privacy rights and the confidentiality of substance use disorder ("SUD") records and offers the following comments regarding the proposed modifications to 42 CFR Part 2 ("Part 2") in the December 2, 2022 Notice of Proposed Rulemaking ("NPRM" or "proposed rule"),[1] as required by the Coronavirus Aid, Relief, and Economic Security ("CARES") Act of 2020[2] that enacted substantial changes to align Part 2 with aspects of the HIPAA Privacy Rule. We appreciate the opportunity to comment on this proposed rule.

The National Alliance for Medication Assisted Recovery (NAMA Recovery) has had the privilege and responsibility of representing the collective voices of individuals in medication supported recovery from opioid use disorder since 1988. Of the patients whose interests we represent, nearly 800,000 of them are estimated to be enrolled in federally certified Opioid Treatment Programs (OTPs) receiving methadone, buprenorphine, or naltrexone as part of their treatment for opioid use disorder. NAMA Recovery is the longest continuing and largest medication for opioid use disorder (MOUD)- specific patient advocacy organization in the world, and NAMA Recovery is the only national advocacy organization that mandates a majority of its Board of Directors be MOUD patients under its Bylaws.

[1] Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216 (Dec. 2, 2022) available at https://www.govinfo.gov/content/pkg/FR-2022-12-02/pdf/2022-25784.pdf.
[2] Coronavirus Aid, Relief, and Economic Security Act (CARES) Act, Public Law 116-136, 134 Stat. 281 (March 27, 2020).

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In order to safeguard patients' access to treatment, improve treatment outcomes, and protect patients from stigma, discrimination, and criminalization, NAMA Recovery strongly supports maintaining the core privacy protections of Part 2 for individuals' SUD treatment records. The NPRM proposes some needed changes to Part 2, including transferring the enforcement of this regulation to the U.S. Department of Health and Human Services' ("HHS") Office for Civil Rights ("OCR"), and adding a new reporting requirement for law enforcement and its use of certain court orders to access Part 2 records or place undercover officers in Part 2 programs.

However, the NPRM also proposes some modifications that will seriously compromise individuals' privacy rights and put people with SUD treatment records at risk of increased discrimination, stigma, or prosecution. These proposals include:

I. Use and Disclosure of Part 2 Records for Treatment, Payment, and Healthcare Operations with Initial Patient Consent

The proposed rule permits, but does not require, individuals to sign a single, written consent for all future uses and disclosures of SUD records for treatment, payment, and healthcare operations ("TPO") purposes, as defined in the HIPAA Privacy Rule. Once a patient signs this type of consent, Part 2 programs,[3] HIPAA covered entities, and business associates that receive the records will be able to further redisclose the records as permitted by the HIPAA Privacy Rule (with some exceptions).[4] This will dramatically expand the ways Part 2 records are used and shared without the patient's actual knowledge, including disclosures to third-parties who are not involved in the patient's actual care and may use the information to discriminate against the patient. But the proposed rule does not provide clear requirements to ensure that patients, Part 2 programs, and recipients of Part 2 records will meaningfully understand how their records will be used, disclosed, and protected, *nor* that they have the right *not* to sign that broader consent or limit disclosures for more limited TPO purposes. These rights should be clearly detailed in easy-to-understand wording in the patient's primary language. The notice prohibiting redisclosure, which accompanies records disclosed with patient consent, should clearly identify whether the records are subject to the new redisclosure permissions or still protected by Part 2.

As the representatives of methadone and buprenorphine patients (as well as having a Board of Directors that is comprised of a majority of methadone and buprenorphine patients), both within federally certified opioid treatment programs as well as office based opioid treatment variations, we can

[3] Part 2 programs include many types of SUD treatment providers, including opioid treatment programs (OTPs), many in-patient and out-patient addiction treatment providers, and some providers in integrated settings. *See* 42 CFR § 2.11 (definitions of "Part 2 program" and "program") *and* § 2.12 (definition of "federally assisted").
[4] Under the proposed rule's framework, the recipient of Part 2 records would still need patient consent or a court order before using or disclosing Part 2 records in a civil, criminal, administrative, or legislative proceeding against the individual.

definitively stat that is it essential for individuals to clearly be informed that they have a right to decide when, to whom, and how to share their (our) health records (particularly if the records contain health information of a sensitive nature (e.g., SUD, HIV, reproductive health, LGBTQ+ healthcare, STIs, mental health, etc.).

Many of us and our peers have had complex consent forms inadequately explained to us, if explained at all, only later to suffer some form of harm, including but not limited to loss of primary care physician, stigma and refusal to fill medically necessary controlled substances at our community pharmacies upon discovery of enrollment of an OTP, and negative attitudes and noticeable change in treatment from hospitalists and hospital nursing staff. It is critical that a patients' right to provide informed consent before the release of confidential and protected health information be preserved and strengthened. Some of the professionals who are most opposed to the greater protections of 42 CFR Part 2 (pharmacists, hospitalists, primary care physicians), including written consent before disclosure, are the very individuals and organizations that NAMA Recovery stakeholders and members report espouse the most stigma and negative attitudes that they encounter across the healthcare system. Many of the proponents of folding 42 CFR Part 2 ever more into HIPAA represent the very professionals that we, as SUD patients and/or MOUD patient advocates, feel most strongly necessitate its preservation.

II. Use and Disclosure of Part 2 Records in a Criminal Investigation or Prosecution, with Patient Consent

HHS proposes to allow the use and disclosure of Part 2 records in a criminal investigation or prosecution of the individual, so long as the person signed a written consent form.[5] This modification is a major departure from the established 40-year privacy standard that required a special court order to authorize the use or disclosure of SUD patient records in a criminal investigation or prosecution.[6]

NAMA Recovery remains concerned that allowing the additional method of disclosing individuals' SUD records by patient consent to law enforcement entities would exacerbate racial inequities in access to SUD treatment and ultimately treatment and recovery outcomes. For Black and brown communities, access to SUD treatment and services has historically been and continues to be denied by criminal legal systems and entities through lingering "War on Drugs" policies and other harmful strategies.[7] People should not be asked to consent to the use and disclosure of their SUD treatment records as a condition of a plea deal, sentencing, parole, or release from custody.

[5] 42 CFR § 2.12(d) (proposed).
[6] *See* 42 CFR § 2.65.
[7] *See, e.g.*, Legal Action Center, "No Health = No Justice," available at https://www.lac.org/major-project/no-health-no-justice.

Many of our Board Members as well as our stakeholders and members would have been hesitant to enter treatment if assurances of protection from criminal justice probes could not have been guaranteed. We have stakeholders that have reported the loss of these historic protections, such as the proposed changes to the use of disclosure of SUD patient records in a criminal investigation or prosecution in this NPRM, would lead them to consider leaving treatment despite no other desire or clinical appropriateness to complete care and/or taper if these changes were not being considered.

The additional method of disclosing individuals' SUD records proposed in this NPRM could be used in a coercive manner by criminal justice agencies, and it is counter to the Biden Administration's expressed desire to increase enrollment in evidence-based treatment for opioid use disorder that utilizes medications for opioid use disorder (MOUD), especially in federally certified opioid treatment programs where the protections of 42 CFR Part 2 have remained the most noticeable over recent years.

Instead, NAMA Recovery strongly recommends that HHS abandon this proposed change. **Patients should not be asked to consent to a disclosure that could potentially incriminate them, and providers should not be expected to counsel patients about the myriad constitutional and ethical considerations involved with signing such a consent form.** This change will expose both patients and providers to increased liability without any corollary benefit.

III. Weakening Patient Privacy Rights without Implementing Required Anti-Discrimination Protections

The CARES Act diminished some aspects of patients' privacy rights, but also introduced new anti-discrimination protections for individuals in a variety of settings, including healthcare, housing, and employment. The current proposed rule, however, only addresses the CARES Act's privacy changes. HHS indicates that it will propose the NPRM's anti-discrimination provisions to protect individuals from discrimination on the basis of their SUD treatment records in a separate rulemaking.[8]

While the creation of the new anti-discrimination provisions is pending, people with drug treatment records will continue to have their health information and status used against them in a number of different settings.

***NAMA Recovery* strongly encourages HHS to implement the CARES Act's corresponding anti-discrimination protections so that they go into effect at the same time as any final rule weakening the privacy protections.** The current proposed rulemaking should be delayed until the anti-discrimination

[8] 87 Fed. Reg. at 74217 (preamble).

rulemaking is completed. Individuals with drug treatment records should not be left vulnerable to discrimination that Congress intended to address solely due to a lag in HHS's rulemaking process.

IV. Additional Proposed Privacy Modifications

New Complaint Procedure for Violations of Confidentiality:

- Section 2.4 of the proposed rule requires individuals to file privacy complaints with the Part 2 program (that may be subject of the complaint or may not have any investigatory authority). Instead, patients should be able to file a complaint directly with the HHS Office for Civil Rights. The proposed changes to Part 2 should not take effect until the Office for Civil Rights has been funded and staffed to investigate and enforce Part 2 complaints, and individuals harmed by unlawful use and disclosure of their SUD records should be provided with adequate remedies.

Consent Form Changes:

- The proposed changes to the consent form requirements in Section 2.31 should prioritize transparency and preserve individuals' choice to authorize more limited disclosures of their treatment records. Ambiguous consent forms with no expiration date and vague descriptions of how information will be shared do not meaningfully promote patient understanding of how their health information will be used and shared for years to come, nor do they encourage patient-centered care. Furthermore, these changes were not required by the CARES Act. ***NAMA Recovery* supports the removal of these proposed changes.**

Safe Harbor Provision:

- The proposed rule's new safe harbor provision in Section 2.3, which safeguards investigative agencies that obtain protected SUD treatment information without authorization (because the agencies did not realize the information was from a program covered by Part 2) is unnecessary and overbroad and was not required by the CARES Act. **HHS should withdraw this proposed change, or at least should include more accurate methods of how investigative agencies can determine a provider offers SUD services (and thus may be subject to Part 2)**. HHS should remove inaccurate verification methods from the rulemaking, such as passing by the building to observe or checking a Prescription Drug Monitoring Program website ("PDMP") (since many SUD providers do not share

information with PDMPs). More accurate verification methods, such as consulting the SAMHSA Locator,[9] should be employed instead.

NAMA Recovery encourages HHS to pay greater consideration to comments for this proposed rule from directly impacted people, including people who use drugs and current and former patients at Part 2 programs, and the harm reduction and recovery organizations that represent their interests such as NAMA Recovery. **Individuals whose rights will be directly impacted by the rule should be at the center of HHS's considerations about the changes to Part 2, and their voices deserve greater weight than representatives of insurance companies or law enforcement entities.**

Thank you for your consideration of these comments and the viewpoint of methadone and buprenorphine patients across the country who stand to lose the most if some of these changes are enacted.

With best regards,

Zachary C. Talbott, MSW
President & Chairman
National Alliance for Medication Assisted Recovery

[9] HHS, Substance Abuse & Mental Health Services Administration, *Behavioral Health Treatment Services Locator*, available at https://findtreatment.samhsa.gov/.