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February 13, 2023

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration (SAMHSA)
5600 Fishers Lane, Room 13-E
Rockville, MD, 20857

Re: 42 CFR Part 8, RIN 0930-AA39

SUBMITTED VIA PORTAL ON February 13, 2023

Dear Assistant Secretary Delphin-Rittmon:

Thank you for the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) 42 CFR Part 8, published in the December 16, 2022, Federal Register. The National Association of State Alcohol and Drug Abuse Directors, Inc. (NASADAD) is the national association representing the government agencies that administer the publicly-funded prevention, treatment and recovery systems in the 50 states, District of Columbia, and U.S. territories. We have worked collaboratively with the Substance Abuse and Mental Health Services Administration (SAMHSA) for many years, and this partnership has been further strengthened during the current national opioid crisis. One critical aspect of this partnership is the work between our association's component group, the Opioid Treatment Network (OTN), which consists of the State Opioid Treatment Authorities (SOTAs), to ensure that patients in Opioid Treatment Programs (OTPs) have access to safe and effective medication and services. We believe many of the proposed rule changes will further strengthen this goal.

Comments on the Proposed Rule:

We support the emphasis in the proposed rule on treatment that is clinically focused and patient-centered, and that requires assessment and treatment planning that is tailored to meet the needs of individual patients. Additionally, NASADAD supports removing the eligibility requirement that individuals seeking medication for opioid use disorder (MOUD) be addicted for one year, and removing restrictions to treatment for individuals who are younger than 18 years of age to remove barriers to MOUD in OTPs. We strongly agree with the NPRM explicit requirement to give priority admission for pregnant patients to all OTPs and the accompanying requirements concerning the care of these patients. We concur with the emphasis in the proposed rule that the Medical Director is ultimately responsible for oversight of patient care, and the attention given to mid-level providers in the definitions.

NASADAD supports updating terminology consistent with public health practice (e.g., MOUD and withdrawal management).

We also support the strengthened communication between the accrediting bodies and SAMHSA, the inclusion of a physician experienced in treating Opioid Use Disorder (OUD) on the survey team, and the increased role of the provider in making treatment decisions in the OTP application process.

Schedule for Take-Home Medication.

NASADAD understands the utility of the proposed schedule for take home medications, especially in certain situations in which the patient is not able or free to move around in the community, or where patients who previously demonstrated responsible use of MOUD have had to stop MOUD and are returning to treatment, or who are in living situations that do not support frequent visits to the OTP. Examples might include patients who are returning to treatment after incarceration and who are otherwise stable, a patient who is anticipating a short period of incarceration in a jail facility that will cooperate with safely storing medication for the patient to self-administer, or a patient who needs to be in a residential program for additional therapeutic support where the program can provide safe storage of medication for the patient to self-administer. In addition, we are aware that states and OTPs may institute their own policies regarding access to take-home medications.

We note that the NPRM is proposing a more liberal take-home schedule than is allowed under the Public Health Emergency (PHE). We also note that while the revised take home policies allowed under the PHE were evaluated, we know of no similar set of evaluations of the proposed take home policies outlined in the NPRM. Therefore, we suggest that the **regulations require that all patients have an individual documented evaluation for their ability to safely manage take-home medications and that this documented evaluation be a required part of the clinical record.** This requirement would safeguard against blanket policies that prevent an individual assessment of a patient's ability to safely manage or inability to currently self-manage their medications.

Screening and Evaluation.

We appreciate the intent to reduce "bottlenecks" that occur in some OTPs because the medical provider is not available to conduct a screening and evaluation prior to initiation of MOUD. However, we are concerned that many non-OTP medical practitioners may lack basic knowledge regarding substance use disorders and the skills necessary to screen or evaluate someone to initiate MOUD prior to the OTP Medical Director reviewing the results of the screening and/or full examination. It should be noted that several state directors are actively working with community providers to increase their knowledge and skill in this area, including working with Federally Qualified Health Centers (FQHCs) and developing "bridge" programs with community emergency departments to utilize the three-dose 72-hour allowance permitted by the Drug Enforcement Administration (DEA). However, MOUD are powerful medications, and we are concerned that the external examination may not be adequate for initiation of medication. The NPRM requires that the OTP practitioner verify the examination, but does not provide a timetable for doing so. **We are recommending, therefore, that the regulation**

require the OTP Medical Director (or their appropriately licensed proxy) document a review and approval of the written patient evaluation conducted by a non-OTP practitioner in the OTP clinical record within a reasonable time period after initiating MOUD.

Elevate screening for imminent risk of harm to self or others.

We are pleased to see that language requiring assessment of these risks is included in the NPRM, however, the current language indicates that these issues are not addressed until the assessment occurs. **We recommend that the regulations require that an assessment for imminent risk of harm to self or others be raised in the initial screening.**

Utilizing audio-only devices for the screening of new patients if a licensed practitioner registered to prescribe controlled substances is present.

We believe that utilizing assessments conducted via audio-only devices should be utilized only in exceptional circumstances. Therefore, we are **recommending that the regulation explicitly state that audio-only evaluations should only be allowed in situations documented in the patient's record to demonstrate difficulty in accessing an in-person or telehealth assessment by the OTP medical practitioner, and that examples be provided in the regulation. In addition, we are recommending that the regulations require the Medical Director to verify the assessment within a reasonable time period after initiating MOUD in the patient's clinical record. Finally, we recommend clarifying the meaning of "present" during instances when the use of audio-only devices for screening may be appropriate.**

Staff credentials.

The current NPRM language requires that "qualifying practitioners and other licensed/certified health care providers ... comply with... credentialing and maintenance of licensure and/or certification requirements of their respective profession." **We recommend that the language be amended to also include the credentialing or licensing requirements of the respective state or territory in which qualifying practitioners are practicing, including interstate compacts that allow reciprocity of staff requirements.**

The Role of the State Opioid Treatment Authority (SOTA).

The NPRM defines the SOTA as "an agency," however, we **recommend that the regulation define the SOTA as "a position" and clarify its relationship to the Principal Agency as defined in 45 CFR 96.121.**

We noted several instances in which the position of the SOTA was specifically recognized in the NPRM and view this addition as positive. However, we noted several instances in which we thought that the regulation should explicitly include the SOTA or where language such as "appropriate State Authority" should be replaced by "SOTA." These instances include the following:

- Accreditation bodies responsibilities. In Section 8.11, there are several references to communication between the Secretary and the accreditation body when an OTP is not meeting standards. **We recommend that the regulations require the accreditation**

body to include the SOTA in these communications and that information concerning the nature of the deficiencies noted by the accreditation body be shared with the SOTA.

- Withdrawal of approval of accreditation bodies. In the instance in which the Secretary withdraws approval or places an accreditation body on probation, we **recommend that the regulations require the Secretary to notify the SOTAs in affected States or Territories.**
- Opioid Treatment Certification. We **recommend that the reference to “the appropriate state authority” be replaced with “the SOTA” in references to Action on application, Requirements for certification, and Exemptions.**
- Comprehensive treatment for persons under age 18. We **recommend that the reference to “the relevant state authority” be replaced with “the SOTA.”**

Definitions.

We would like to state our concern with the use and definition of the term “behavioral health services” and seek clarification regarding the split dosing and practitioner allowances.

- Behavioral health services. The definition provided for this term is extremely generic and lacks any reference to services that are specific to substance use disorders. Given that MOUD are a medical intervention for a substance use disorders, clarification is required. Moreover, the definition does not reference recovery support services which have been demonstrated to be integral to successful treatment and recovery of substance use disorders. We would recommend that specific definitions be provided for mental health services (if that is the intent) and for substance use disorder services, and that recovery support services be included as a part of these definitions.
- Split dosing. It is not clear from the proposed rule if utilizing split dosing will still require approval through the Exception Request process.
- Practitioner. It is not clear from the proposed rule if the use of mid-level practitioners will still require SAMHSA approval.
- Accreditation Bodies. Language concerning the members of the survey team indicates that “members of the accreditation team with conflicts of interest (either actual of the appearance of) must be able to recuse themselves.” **We recommend that the language be changed to state that these members shall recuse themselves.**

Thank you for the opportunity to comment on the proposed rule. NASADAD looks forward to working closely with SAMHSA to ensure successful implementation. If you have any questions about the comments, feel free to email me at: rmorrison@nasadad.org or by phone at (202) 292-4862.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert I.L. Morrison". The signature is fluid and cursive, with a large initial "R" and "M".

Robert I.L. Morrison
NASADAD Executive Director