



February 14, 2023

Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Treatment  
ATTN: RIN 0930-AA39

*Submitted via Regulations.gov*

**RE: Medications for the Treatment of Opioid Use Disorder (RIN 0930-AA39)**

Thank you for the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA) Medications for the Treatment of Opioid Use Disorder proposed rule and other policy changes. The NYS Council is a statewide, non-profit membership organization composed of 120 community-based organizations that provide recovery-focused mental health and/or substance abuse/chemical dependence and addiction treatment programs and services for New Yorkers in need. NYS Council members offer a broad array of behavioral health services designed to meet the unique needs of children and adolescents, individuals and families seeking our assistance. Our services are available in a variety of community settings including freestanding agencies, behavioral health divisions of general hospitals, and county mental hygiene programs.

The proposed Medications for the Treatment of Opioid Use Disorder (hereinafter "Proposed Rule") includes numerous revisions to the Code of Federal Regulations (CFR) and Controlled Substances Act (CSA) to increase access to medications for opioid use disorder (MOUD) and streamline processes for Opioid Treatment Programs (OTPs). The Proposed Rule seeks to reflect the evolution of accreditation and treatment environment standards for OTPs and the utilization of MOUD since the regulation's initial issuance in 2001. The above proposed updates modify certain provisions in 42 CFR Part 8 (hereinafter "Part 8") to update OTP accreditation and certification standards, treatment standards for the provision of MOUD as dispensed by OTPs, and requirements for individual practitioners eligible to dispense certain types of MOUD with a waiver.

Below, we have associated our comments with the topic sections used in the Proposed Rule, and we have placed our comments in the order in which topics appear in the Proposed Rule.

**Definitions**

The Proposed Rule revises §8.2 to update and add definitions, reflecting the evolution of substance use treatment and recovery standards since Part 8 went into effect in 2001. Notably, the definition of a "qualifying practitioner" has been expanded to reflect the Congressional mandate to expand access to services in the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The proposed definition would include "a physician,

physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a state to prescribe covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).”<sup>i</sup> Further, the Proposed Rule defines harm reduction. The proposed definition of harm reduction would include references to overdose education; testing and intervention for infectious diseases such as human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; and linkage to other public health services including peer support services. The NYS Council applauds SAMHSA’s efforts to expand access to care by ensuring current practice standards are reflected in the regulations that guide the provision of care by OTPs. An expanded definition of “qualifying practitioners” promotes expanded access to substance use disorder care through the explicit inclusion of a broad range of substance use and mental health professionals who are qualified and licensed by their states to provide OUD care through MOUD. Moreover, the agency’s acknowledgement of harm reduction services in the Proposed Rule signals the role of such services as critical, life-saving interventions in the continuum of care for individuals living with substance use disorder.

### **Accreditation Body Responsibilities**

The Proposed Rule implements a new standard for OTPs that do not meet one or more accreditation elements during survey completion. Under the new rule, OTPs would be required to take all corrective measures within 60 days of survey completion and, for OTPs with less substantial violations, accreditation shall not exceed 12 months during which time a resurvey or reinspection must occur. The NYS Council is concerned that the proposed accreditation standards could create barriers to expanded access to care in the OTP setting. The accreditation process, while worthy, can be time and resource intensive, as well as costly and the possibility of a less substantial violation resulting in a full survey or audit up to every 12 months could have a negative impact on operations and ultimately reduce access to care. The NYS Council recommends that SAMHSA collaborate with the various accreditation entities to review the specific standards they propose to use to conduct oversight of OTPs to support enhanced clinical standards and a more balanced process and timeline for accreditation. Imposing timelines on OTPs that differ significantly from other health care settings increases and reinforces the stigma and discrimination that already exists against MOUD and individuals seeking such lifesaving services.

### **Removal of the one-year requirement for OUD**

The Proposed Rule acknowledges that current OTP regulations do not reflect the evolution of treatment standards over the past 20 years and proposes several important changes to Subpart C – Certification and Treatment Standards for Opioid Treatment Programs. First, the requirement that patients must have had an addiction to opioids for at least one year prior to admission to an OTP for MOUD is removed. The Proposed Rule amends the standard by specifying that the individual should either “meet diagnostic criteria for active moderate to severe OUD; that the individual may be in OUD remission; or at high risk for recurrence or overdose.”<sup>ii</sup> The NYS Council applauds this proposed change. This change in standard promotes increased access to MOUD and removes arbitrary requirements, allowing OTP practitioners to exercise clinical judgement and provide individualized care by demonstrating that “the person meets diagnostic criteria for a moderate to severe OUD, the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose.” Notably, this policy change also applies to individuals recently released from penal institutions, pregnant patients, or previously enrolled individuals. In particular, the application of this proposed provision will positively impact previously enrolled individuals who experience recurrence of OUD symptoms by expanding

access to services to combat the high mortality risk associated with initiation of use after a period of abstinence.

### **Initiation of buprenorphine and methadone through telehealth**

In response to the emergence of the COVID-19 pandemic, the Drug Enforcement Administration (DEA) rolled back select provisions of the Ryan Haight Online Pharmacy Consumer Protection Act, originally passed in 2008, to allow for prescriptions of controlled substances without an in-person medical evaluation.<sup>iii</sup> Shortly thereafter, SAMHSA, in response to the temporary lifting of these restrictions, issued guidance on the provision of buprenorphine and methadone via telehealth during the public health emergency (PHE).<sup>iv</sup> These agency actions were significant to maintaining access to care due to workforce shortages across the behavioral health sector and ensuring both provider and patient safety during the height of the COVID-19 pandemic and throughout the PHE. Both providers and patients were able to maintain individualized care via telehealth for the treatment of OUD. Further, these circumstances created the opportunity to evaluate the impact of telehealth flexibilities during a time where overdose deaths tragically reached alarming rates. Notably, research concluded that telehealth flexibilities for buprenorphine did not lead to a rise in the share of overdose deaths involving the medication.<sup>v</sup>

The Proposed Rule seeks to make the provision of buprenorphine via telehealth permanent. It would also allow for the initiation of buprenorphine via audio-only or audio-visual telehealth technology if an OTP physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth. Additionally, the Proposed Rule would apply some of the buprenorphine flexibilities to treatment with methadone in OTPs. Program physicians, or an authorized healthcare professional under the supervision of a program physician, could utilize audio-visual telehealth for new patients seeking methadone if an adequate evaluation can be accomplished virtually. However, the Proposed Rule clarifies that it does not apply to the prescription of methadone but allows for the ordering of the medication to be dispensed at the facility under the supervision of OTP practitioners. The NYS Council supports SAMHSA's proposal to permanently expand telehealth flexibilities for the initiation of buprenorphine and is pleased to see that the Proposed Rule has been expanded to include audio-visual telehealth for new patients seeking treatment with methadone. Allowing for the initiation of MOUD through telehealth is a critical step towards curbing the devastating impact of the opioid crisis and ensuring that remote and underserved communities have access to substance use disorder care.

### **Revision of rules related to take-home doses of methadone**

Section 8.2 also revises OTP regulations regarding take-home doses of methadone. During the COVID-19 pandemic, SAMHSA has allowed states to request blanket exceptions for all "stable patients" to receive 28 days of take-home methadone doses.<sup>vi</sup> The guidance also allowed for states to request up to 14 days of take-home doses for patients who were deemed "less stable," but who the OTP believed could safely "handle the level" of take-home medication. In November 2021, SAMHSA extended this exemption for an additional year beyond the expiration of the COVID-19 PHE.<sup>vii</sup> Research from the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) demonstrate that the extended take-home dose regulations did not lead to increased deaths involving methadone.<sup>viii</sup> This study, and other research on the impact of take-home methadone flexibilities, show overall improved patient satisfaction, increased engagement in treatment, and expanded access to care.<sup>ix</sup> This is compelling data to support the benefits of making take-home methadone policies permanent beyond the PHE.

The Proposed Rule would allow OTPs to provide patients with up to 7 days of take-home doses during the first 14 days of treatment, up to 14 take home doses after 15 days of treatment, and up to 28 take home doses after 31 days of treatment. The flexibility afforded in the Proposed Rule promotes individualized care, equitable access to methadone, and continuity of care. This proposed change will help prevent disruptions in employment and daily activities often faced by patients that were previously required to visit the OTP daily in order to access methadone prescriptions. In addition, individuals who have to travel to an OTP, lack reliable transportation, or serve as caregivers will benefit significantly from the flexibility provided by take-home doses. The NYS Council values SAMHSA's promotion of practitioner autonomy in determining patient eligibility for take-home doses of methadone. OTP practitioners are best equipped to consider both individual patient characteristics and program adherence to determine eligibility for take-home doses.

### **Extending duration of interim treatment**

Section 8.12 of the Proposed Rule extends the duration of interim treatment approval from 120 days to 180 days. Interim treatment allows OTPs to provide services on a temporary basis while patients wait for access to more comprehensive services. The extension of interim treatment approval provides OTPs with the flexibility necessary to adjust to staff shortages stemming from the workforce crisis that continues to impact the behavioral health field. Additionally, the use of interim treatment may promote access to services for individuals who otherwise may not seek care. In particular, interim treatment does not require a primary counselor to be assigned to the patient but makes crisis services and information pertaining to community-based resources available. The revision also requires OTPs to institute a plan for continuing treatment beyond 180 days by the patient's 120<sup>th</sup> day in treatment, ensuring continuity of care and prioritizing a patient's transition into comprehensive treatment. The NYS Council supports this proposed change and efforts by SAMHSA to promote access to care and engagement for individuals that may be resistant to or unable to access more comprehensive services.

### **Mobile Units**

On July 28, 2021, the DEA introduced requirements for OTPs seeking to add a "mobile component" to their existing registration, eliminating a separate registration requirement for mobile medication units. SAMHSA followed with guidance on the establishment of mobile medication units and allowable services including dispensing medication for OUD treatment, collecting samples for drug testing, dispensing of take home medications, intake and medical assessments, and the initiation of methadone or buprenorphine after an appropriate medical assessment is performed.<sup>x</sup> The Proposed Rule mirrors the aforementioned guidance from SAMHSA, making permanent these provisions by allowing "OTP practitioners, contractors working on behalf of the OTP, or community pharmacists [to] dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services."<sup>xi</sup> More generally, the Proposed Rule notes that any services provided in an OTP may be provided in the mobile unit, "assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space."<sup>xii</sup> The NYS Council supports the use of mobile units and applauds SAMHSA for their efforts to make this provision permanent. Mobile units provide critical services to individuals in rural areas and to those who lack access to transportation, ensuring equitable access to care.

### **Authorization to Increase Patient Limit to 275 Patients**

The Drug Addiction Treatment Act of 2000 (DATA 2000) permitted physicians meeting certain qualifications to prescribe buprenorphine and naltrexone in treatment settings other than OTPs, such as

office-based settings. Qualified practitioners were also eligible to treat up to 30 patients in the first year and could submit notification of the need and intent to increase their patient limit to 100 after the first year concluded. With passage of the SUPPORT for Patients and Communities Act of 2018, qualified practitioners could treat up to 100 patients in the first year of holding a DATA waiver if the practitioner held additional credentials including board certification in addiction medicine or addiction psychiatry. Notably, SAMHSA released regulations in 2016 allowing eligible physicians to request approval to treat up to 275 patients after prescribing at the 100-patient limit for one year.<sup>xiii</sup> The Proposed Rule clarifies that the 275-patient waiver is limited to three years in duration and requires renewal. In addition, reporting requirements for these practitioners are removed. While the NYS Council supports and appreciates the additional access to lifesaving OUD treatment provided by the proposed rule, Sec. 1262 of the Consolidated Appropriations Act, 2023 removes the federal requirement for a DATA waiver to prescribe medications such as buprenorphine and naltrexone. The passage of the omnibus bill and notice from SAMHSA that waiver applications will no longer be accepted, renders this section of the Proposed Rule unnecessary.<sup>xiv</sup>

The NYS Council appreciates the opportunity to provide these comments. If you have any questions or wish to further discuss the recommendations described here, please contact Lauri Cole at 518-461-8200 or at lauri@nyscouncil.org. Thank you for your time and consideration.

Sincerely,



Lauri Cole  
Executive Director

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<sup>i</sup> <https://public-inspection.federalregister.gov/2022-27193.pdf>

<sup>ii</sup> <https://public-inspection.federalregister.gov/2022-27193.pdf>

<sup>iii</sup> <https://www.deadiversion.usdoj.gov/coronavirus.html>

<sup>iv</sup> <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>

<sup>v</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?source=email>

<sup>vi</sup> <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>

<sup>vii</sup> <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance>

<sup>viii</sup> <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2793744>

<sup>ix</sup> <https://public-inspection.federalregister.gov/2022-27193.pdf>

<sup>x</sup> <https://www.samhsa.gov/sites/default/files/2021-letter-mobile-component.pdf>

<sup>xi</sup> <https://public-inspection.federalregister.gov/2022-27193.pdf>

<sup>xii</sup> <https://public-inspection.federalregister.gov/2022-27193.pdf>

<sup>xiii</sup> <https://nasadad.org/2019/01/bupecap/>

<sup>xiv</sup> <https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement>