American Academy of Addiction Psychiatry
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February 15, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration (SAMHSA)

**Comments in response to RIN 0930-AA39: Medications for the Treatment of Opioid Use Disorder**

Dear Secretary Becerra and Assistant Secretary Delphin-Rittmon,

On behalf of the American Academy of Addiction Psychiatry (AAAP), thank you for the opportunity to comment on the proposed modifications to 42 CFR Part 8 (proposed rule) regarding the use of medications for opioid use disorder (MOUD) in Opioid Treatment Programs (OTPs). AAAP is the preeminent professional organization representing specialists in Addiction Psychiatry and other healthcare professionals who treat patients with substance use disorders (SUDs) and co-occurring mental illness. We appreciate the thoughtful approach to update OTP accreditation and certification standards by drawing on experiences and data gathered during the COVID-19 Public Health Emergency (PHE). Since the last update of 42 CFR Part 8 more than 20 years ago, evidence has been gathered to support patient-centered recovery and improve the quality of care of people receiving MOUD. However, caution must still be given to ensure a balanced approach is achieved between reducing barriers to MOUD and creating unintended harm to individual patients and communities. We urge ongoing evaluation to ensure care is improved without new harms emerging. ***Since the PHE will be ending on May 11, we urge the Administration to quickly provide individual patient exceptions for patients receiving PHE flexibilities in take-home doses (THD) to ensure a safe transition from the PHE while careful consideration can be given to any permanent rule changes going forward.***

AAAP supports the following proposed changes to modernize Part 8 regulations with additional funding to evaluate the public health impact of these changes:

- Adding evidence-based delivery models of care such as split dosing, telehealth and harm reduction activities.
- Removing such outdated terms as “detoxification”.
- Strengthening the patient-practitioner relationship through promotion of shared and evidence-based decision-making and allowing greater use of clinical judgement.
- Removing the one-year requirement for opioid addiction before admission to an OTP, in favor of focusing on the patient’s diagnosis of OUD and risks and benefits of methadone versus other options for MOUD.
- Expanding the medical examination to include assessment of behavioral health needs and risk of self-harm.
- Continuing telehealth flexibilities regarding buprenorphine and methadone.

AAAP does not support the following proposed change to Part 8 regulations:

- **Expanding scope of practice for nonphysicians in MMT**: Expanding the definition of providers who make decisions for MMT admission, dosing and discharge from a "qualified physician" with board certification in addiction psychiatry or addiction medicine or one-year experience in addiction treatment to include ''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).

  AAAP affirms the benefits of an interdisciplinary team-based approach to MOUD. ***However, before eliminating the requirement that the team is led by a qualified physician, we strongly urge HHS to continue to fund research to determine whether and under what guidelines independent management of MMT by nonphysicians would be safe and effective.***

Lastly, AAAP urges for the final rule to take a cautious approach to easing restrictions on methadone take home doses (THD), especially during the initiation stage when people are most at risk for overdose.

- Studies should be considered that highlight patient risks and areas of inconclusive evidence. For example, a 2017 Cochrane Review of "Supervised dosing with a long-acting opioid medication in the management of opioid dependence" (Saulle 2017) determined that there was insufficient evidence to make any conclusions about the effectiveness of supervised dosing compared to dispensing of medication as THD and recommended further research in this area. In addition, while PHE-related flexibilities in methadone THD from OTPs provided the flexibility for physicians to authorize up to 28-days of THD for stable patients and up to 14-days of THDs for unstable patients when the physician determined that the benefits of unsupervised self-administration outweighed the risks, research indicates that few patients realized changes in their THDs(Krawczyk 2022, Wu 2022). Wu reported that many OTPs granted THDs to additional patients who newly qualified for THDs under existing rules because of new PHE-related housing availability and that some OTPs quickly rolled back PHE-related THD flexibility because of the need for clinic visits to maintain reimbursements to remain financially viable. Krawczyk et al reported that while most surveyed OTPs indicated that they offered extended methadone THDs following the new PHE regulations, the majority of patients did not receive 14-day THDs and very few patients received 28-day THDs. In fact, 71% of OTPs surveyed reported that none of their patients received 28-day THDs and of those OTPs that offered 28-day THDs, none reported that a majority of patients received 28-day THDs.

  Current 42 CFR Part 8 guidelines state that patients can receive one unsupervised THD per week on days that the clinic is closed at initiation of methadone treatment. Individuals meeting criteria can receive one additional take-home dose per week every 90 days of continuous treatment, and patients can receive up to 14 and 28 take-home doses after one and two years of treatment, respectively. However, due to challenges achieving stable recovery, receiving higher amounts of take-homes often takes longer. ***AAAP agrees that the schedule for allowing***

***THD can likely be safely accelerated, but we are concerned that the proposed schedule for THD escalation starting during initiation of MMT is not supported by the medical evidence to date.***

Furthermore, there is evidence that prematurely introducing large numbers of THD per week, especially early in treatment, would increase the risk of premature death that accompanies initiation of methadone. A meta-analysis of MOUD associated mortality risk by Sordo and colleagues of 19 cohorts following 122,855 people treated with methadone and 15,831 people treated with buprenorphine conducted prior to the PHE found that there is an increased risk of mortality in the first month of initiating methadone, but no similar increase in mortality when initiating buprenorphine (Sordo 2017). There was an increased risk of death after discontinuation of both medications. Methadone's pharmacology is quite different from buprenorphine. Methadone has a slow onset of action that peaks hours after a dose is taken and a long elimination half-life which means that the full effect of any dose change is not realized for five to seven days later. Because methadone is a pure mu opioid agonist, it can cause fatal overdoses when taken alone or in combination with other sedating substances, including alcohol. Methadone also prolongs conduction of electrical signals in the heart which can lead to fatal cardiac arrhythmias even at therapeutic doses. Other medications and substances such as stimulants or cannabinoids that cause cardiac arrhythmias can increase this risk (Thomas 2014, Mayet 2011, Wallner 2008). Thus, it is imperative for patient safety that patients initiating methadone be closely monitored during initiation and dose changes (McCance-Katz 2008). The current practice of daily clinic visits for medication administration during initiation encourages recommended close medical monitoring. The lack of a dramatic increase in methadone-related overdose deaths in the United States during the pandemic is likely attributable to continued careful monitoring of methadone administration at initiation and for patients for whom risks of self-administration outweighed the benefits. In the United States, methadone was much less likely to be involved in drug overdose deaths than prescription opioids or illicit opioids both before and during the COVID-19 pandemic in the United States where initiation and ongoing methadone treatment has continued uninterrupted throughout the pandemic and has continued to be closely monitored through OTPs (Ahmad, 2021).

In contrast, the French pandemic experience with increasing MOUD access through pharmacy administration of methadone provides a cautionary tale. In France where methadone has been dispensed from pharmacies by prescription since 2008, data from 2008 to 2017 by the French Addictovigilance Network shows that methadone was increasingly involved in drug overdoses and deaths even before the pandemic disrupted medication dispensing (Frauger, 2019). In France, methadone was the most common substance involved in drug overdoses during the COVID-19 pandemic lockdown (Lapeyre-Mestre, 2020). This was attributed to methadone's pharmacology and a combination of pandemic-related factors including interruptions in methadone dispensing from pharmacies with unsupervised restarting of the medication by the intended patient, combining of methadone with other drugs, and diverted methadone obtained by naïve users and through the illicit market.

AAAP shares the agency's concern that there are racial and ethnic disparities in access to MOUD (Suen 2022). We are concerned that because minoritized persons are overrepresented in MMT,

the medical and public health risks of prematurely accelerating THDs of methadone will be born disproportionately by these communities. Again, we agree that the current schedule for TDHs could likely be safely accelerated from current regulations. ***However, we advocate for a more cautious approach in establishing rules that may become the new standard of care. For example, take home doses should be gradually increased in increments of one additional TDH dose weekly beginning no sooner than the fourth week of MMT and based on the patient's clinical stability in recovery from OUD and co-occurring disorders. We strongly recommend that HHS fund prospective research to determine the best practices in initiation and discontinuation of MOUD and in granting of TDHs to ensure that a proposed accelerated schedule is safe and effective in achieving the goals of improving MOUD access while reducing OUD-related mortality and improving quality of life for individual patients and their communities.*** As mentioned previously, we urge the Administration to quickly provide individual patient exceptions for patients receiving PHE flexibilities in take-home doses (THD) to ensure a safe transition from the PHE while careful consideration can be given to any permanent rule changes going forward.

Thank you for consideration of our comments and your work to improve access to effective care for people with substance use disorders.

Sincerely,

Karen Drexler
AAAP Medical Director