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U.S. Department of Health and Human Services
Substance Abuse and Mental Health Services Administration,
Center for Substance Abuse Treatment
Robert Baillieu, MD, MPH, Physician and Senior Advisor
5600 Fishers Lane, Room 13-E-30
Rockville, Maryland 20857

Re: Comment on Proposed Rule to Modify Regulations for the Treatment of Opioid Use Disorder
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Dear Dr. Baillieu:

My name is Jeffrey A. Singer. I am a Senior Fellow in Health Policy Studies at the Cato Institute. I am also a medical doctor specializing in general surgery and have been practicing that specialty in Phoenix, Arizona, for over 35 years. The Cato Institute is a 501(c)(3) non-partisan, non-profit, tax-exempt educational foundation dedicated to the principles of individual liberty, limited government, free markets, and peace. Cato scholars conduct independent research on a wide range of policy issues. To maintain its independence, the Cato Institute accepts no government funding. Cato receives approximately 80 percent of its funding through tax-deductible contributions from individuals. The remainder of its support comes from foundations, corporations, and the sale of books and other publications. The Cato Institute does not take positions on legislation.

I want to thank the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment for allowing me to comment on the proposed modification to its medication regulations for opioid use disorder. I appreciate this opportunity to provide my perspective as a health care practitioner and policy analyst.

In July 2018, addiction specialists from the Boston University School of Medicine and Public Health and the Massachusetts Department of Public Health argued in the *New England Journal of Medicine* that community physicians interested in the treatment of substance use disorder should be allowed to prescribe methadone to patients they see in their offices and clinics.[1] The authors noted that primary care providers have legally prescribed methadone to treat opioid addiction in other countries for many years— in Canada since 1963, in the UK since 1968, and in Australia since 1970, for example. They stated, "Methadone prescribing in primary care is standard practice and not controversial in these places because it benefits the patient, the care team, and the community and is viewed as a way of expanding the effective delivery of an effective medication to an at-risk population."

I have written in support of the idea, which would allow practitioners to dispense take-home medication to people receiving treatment for opioid use disorder.[2] In January 2020, the National Academy of Science, Engineering, and Medicine (NASEM) made a similar plea.[3] In May of 2022, Zoe Adams et al. made a compelling case for allowing primary care practitioners and other licensed health care practitioners to treat people with opioid use disorder, prescribe take-home methadone, and follow such patients in their regular "mainstream" clinics. Pilot programs in the United States have shown that this approach can be safe and effective.[4]

To facilitate social distancing, prevent the risk of COVID-19 infection, and maintain access to medications for opioid use disorder, in March 2020, the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) relaxed some onerous regulations surrounding the use of buprenorphine or methadone. The emergency rules allowed OTPs to dispense up to 28 days of take-home methadone to "stable patients" and 14 days of take-home methadone to "less stable" patients. The agencies temporarily suspended the in-person evaluation requirement and permitted providers with DEA waivers to evaluate and prescribe buprenorphine for opioid use disorder to new patients via telemedicine.[5] The agencies also allowed (opioid treatment programs) OTPs to provide services using mobile vans. SAMHSA and DEA have since announced that these emergency measures will remain in place until one year after the end of the COVID-19 public health emergency.

Recent research, cited in the SAMHSA Notice of Proposed Rulemaking (NPRM), indicates that the flexibilities mentioned above were well-received by patients and providers alike and did not cause a significant increase in diversion. SAMHSA now proposes to make these flexibilities permanent.

SAMHSA also proposes extending the duration of interim treatment by OTPs with methadone from 120 days to 180 days. This proposal will allow people with opioid use disorder to stabilize their lives more expeditiously, assisted with methadone, even before all the programs OTPs typically provide are made available. For the same reason, I support the new proposed rule ending the requirement that a person must have been addicted to opioids for one year before admission to an OTP.

While I think the proposed modifications in the regulation of OTPs are a long-overdue step in the right direction, they don't go far enough. The policy should completely destigmatize people with opioid use disorder and allow health care practitioners with a knowledge of and interest in treating this disorder to prescribe methadone or buprenorphine and provide therapy the same way they do for people with other medical and behavioral conditions—through regular clinic visits where practitioners are free to use their best judgment to provide individualized treatment, which may sometimes include split dosing.

The proposal also calls for ending the requirement that providers who prescribe buprenorphine to 275 people with opioid use disorder must fill out detailed reports on their patients. This burden has been a disincentive to practitioners who might otherwise apply for a waiver so they can treat opioid use disorder with buprenorphine. Ending the reporting requirement is a good idea. So too, is it a good idea to extend waivers for buprenorphine to nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and nurse midwives, as this will improve access to medications for opioid use disorder to people in need.

However, while removing the reporting burden that makes it unattractive for providers to apply for buprenorphine waivers, consequently reducing access to buprenorphine for people with opioid use disorder, is a welcome step in the right direction, the most significant burden has been to require providers to apply for a waiver in the first place. Providers should not have to apply for a waiver or be subject to the restrictions and regulations attending the waiver to treat people with opioid use disorder. Along with the American Medical Association and the National Academy of Sciences, Engineering, and Medicine, I have long believed there should be no waiver requirement.[6]

Fortunately, there was bipartisan support for legislation eliminating the waiver requirement in the just concluded 117th Congress. As a result, Congress passed the Mainstreaming Addiction Treatment Act on December 23, 2022, as part of an omnibus bill that President Biden signed into law on December 29, 2022.[7] The Act "removes the requirement that a health care practitioner apply for a separate waiver through the Drug Enforcement Administration (DEA) to dispense certain narcotic drugs (e.g., buprenorphine) for maintenance or detoxification treatment (i.e., substance use disorder treatment)." The Act renders moot many of the proposed rule changes insofar as they pertain to prescribing buprenorphine for opioid use disorder.

Finally, I support making permanent the use of telemedicine that SAMHSA permits in response to the public health emergency. These changes will facilitate access to necessary medication and treatment.

I agree with the proposed changes to language and terminology that stigmatizes people with substance use disorder. We should regard people with substance use disorder no differently than people with diabetes, hypertension, bipolar disorder, or chronic obstructive pulmonary disease. But changing the language by itself will not destigmatize substance use disorder. As the saying goes, "action speaks louder than words."

Health care practitioners have, for years, prescribed methadone and/or buprenorphine to treat pain and painful conditions. This requires knowing and understanding those drugs' pharmacology, drug-drug interactions, and indications and contraindications for their rational use. The only explanation for preventing the same practitioners from prescribing the same drugs to treat opioid use disorder is that current regulations view people with substance use disorders as, somehow, less responsible and trustworthy than people with other health conditions.

Treating substance use disorder can be very challenging. But many health disorders challenge the skills and experience of clinical practitioners. Health care providers don't routinely take on patients with conditions they don't have the skills and expertise to treat. Providers swear an oath to "do no harm" and refer patients to practitioners who are better equipped to help them. In the same way, providers who don't think they have enough expertise to treat patients with substance use disorder will refer those patients to qualified and experienced practitioners.

The only way to completely destigmatize people with substance use disorder, and thus facilitate their access to care and improve the likelihood of recovery, is to remove the regulations and restrictions unique to opioid treatment programs. This includes rules affecting the use of telemedicine technology. Licensed health care practitioners should be able to prescribe opioid agonists such as methadone, as well as the partial agonist buprenorphine, to people with substance use disorder the same way the government allows them to prescribe beta

blockers to treat hypertension and insulin to treat diabetes. In short, if the Substance Abuse and Mental Health Services Administration seriously wants to destigmatize people with substance use disorder, it can start by destigmatizing how they receive treatment.

While the proposed rule modifications don't go far enough, I believe they are a welcome step in the right direction and will significantly improve access to medications and treatment for opioid use disorder and help to reduce overdose deaths.

Respectfully submitted,

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[1] https://www.nejm.org/doi/full/10.1056/NEJMp1803982
[2] https://www.cato.org/blog/methadone-mixed-messages also https://www.cato.org/blog/let-clinicians-use-methadone-treat-addiction
[3] https://nap.nationalacademies.org/resource/25626/OUD-infectious-disease-services-recommendations.pdf
[4] https://pubmed.ncbi.nlm.nih.gov/15857492/
[5] https://www.cato.org/blog/mat-regulations-relaxed-during-covid-19-pandemic-should-catalyze-further-reform
[6] https://www.cato.org/cato-handbook-policymakers/cato-handbook-policymakers-9th-edition-2022/overdose-crisis#medication-assisted-treatment-buprenorphine and https://www.cato.org/blog/will-congress-finally-x-out-x-waiver
[7] https://www.congress.gov/bill/117th-congress/senate-bill/445