American Association for the Treatment of Opioid Dependence, Inc.

Expanding Access to Quality Opioid Use Disorder Treatment Services
since 1984

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Rahul Gupta, MD, MPH, MBA, FACP
Director of National Drug Control Policy
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear Dr. Gupta,

I am writing in response to your request for feedback concerning the President's National Drug Control Strategy. At the outset, it is important to point out that this is a truly comprehensive plan in confronting the challenges that we face with opioid related overdose deaths and the need to expand access to treatment. We are also supportive of your strategy, which provides a number of balancing mechanisms in dealing with prevention, treatment and enforcement, which have long been the cornerstone principles of effective substance use policy.

Since we represent over 1,300 opioid treatment programs throughout the United States, we will focus on the treatment related aspects of the National Drug Control Strategy.

Mortality Crisis versus Opioid Use Crisis

While opioid related mortality is connected to the increasing use of opioids when combined with other drugs, there are different policy implications depending on where you sit. As an example, there are over 105,000 opioid related deaths in a 12-month reporting period, which is clearly tragic. While these deaths are connected to the use of opioids, especially fentanyl, there are very different policy initiatives and interventions to deal with each issue. Illustratively when trying to reduce opioid related mortality it is important to saturate communities with Naloxone and have as many people as possible trained in how to properly use Naloxone to reverse an opioid overdose incident. Equally important is to have emergency room personnel able to respond to the needs of the patient. Additionally, the ER needs to be connected to treatment resources and access availability so a referral can be seamlessly made if need be.

Dealing with the opioid use crisis is a different matter, which obviously deals with supply reduction, which is in the province of the DEA and other enforcement agents in addition to expanding access to treatment with the support of the Substance Abuse and Mental Health Services Administration in conjunction with State Alcohol and Drug Abuse Directors and Authorities.

Expanding Access to Treatment

Historically, the term used to describe the work of substance use treatment when medications were deemed necessary was "Medication Assisted Treatment." This term was coined by SAMHSA over 10 years ago and was meant to describe the use of medications in addition to other clinical services. This term was based on over 50 years of NIDA funded research that would repeatedly demonstrate that patient outcome would improve when medications were combined with clinical counseling and support services.

More recently, Medication Assisted Treatment has been replaced by "*Medication for Opioid Use Disorder*." While this seems like a slight change, it has significant implications. The term Medication Assisted Treatment reflects over fifty years of clinical evidence, which demonstrates that treatment outcomes are most effective when medications and clinical and support services are provided together. In effect, the emphasis on the use of medications to treat opioid use disorder exclusive of clinical and support services suggests a significant shift in treatment philosophy.

Additionally, the question that naturally comes to surface is how do you expand access to treatment and what are the essential elements of comprehensive treatment. This is an important point because, in your strategy, expanding access to treatment seems to be defined as providing a medication and not providing access to other valuable services that ensure engagement, retention and recovery. We also know that our patients present with a long history of significant psychiatric comorbidity with depressive and anxiety disorder, a great deal of trauma as well as homelessness, Hepatitis B&C in addition to HIV infection and AIDS. Such comorbidities cannot be treated with medication alone.

Expanding the Number of OTPs in the Country

OTPs have been significantly expanding over the last several years (see attached map). I am referencing a technical brief: Census of Opioid Treatment Programs, which our Association published with the National Association of State Alcohol and Drug Abuse Directors (NASADAD) during September 2022. This report, Substance Abuse and Mental Health Services Administration funded initiative through the Opioid Response Network, provided the most current patient census information for opioid treatment programs. It described the number programs that were responding to the survey (1,547) and the numbers of patients in treatment. The State Opioid Treatment Authorities were extremely helpful in capturing these data from the OTP and we found that there were 512,000 patients in treatment, representing a 85% response rate from the sample. The majority of the patients were using methadone maintenance, due to the fact that over 80% of new patient admissions are using fentanyl. Approximately 33,000

patients were using buprenorphine. Clinicians report that buprenorphine is not as clinically effective as methadone in treating such chronic fentanyl using patients in OTPs. Finally, these data were collected as of January 1, 2021.

Expansion of Mobile Vans

Our Association worked successfully with the Drug Enforcement Administration as they released the new mobile van regulations during June of 2021. Our Association has produced two webinars on this topic and the most recent was convened on May 31, 2023. I am including a link to the three presentations that were made in support of mobile van expansion (Presentation 1, Presentation 2, and Presentation 3.)

The main goal for supporting the expansion of such vans is to reach rural and other underserved areas of the country. I am happy to report that more vans are being developed and I am attaching a recent listing by the Substance Abuse and Mental Health Services Administration that confirms this expansion. In spite of the success, we need to advocate for even greater mobile van development and it is our hope that the Office of National Drug Control Policy will continue to support this important initiative. Part of the barrier will lie in state approval processes and part will result from lack of provider capability due to staff shortages. This notwithstanding, it is important to increase access to such mobile vans throughout the United States and SAMHSA has been very supportive and responsive in ensuring that funding is made available to OTPs when they have an interest in accessing such vans monies through State Alcohol and Drug Abuse Directors and State Opioid Treatment Authorities. At the present time, these vans can cost up to $400,000.00.

Medication Assisted Treatment for Opioid Use Disorder in Correctional Facilities

Additionally, there is interest in having such vans provide services to correctional facilities and providing access to care for their opioid using population. It is a matter of fact that incarcerated individuals need access to Medication Assisted Treatment during their period of incarceration. We are involved in providing training to such correctional facilities. Illustratively, the New York State legislature passed a law in 2021, requiring all correctional facilities to provide access to Medication Assisted Treatment for those that are using opioids. I am attaching a copy of this legislation in the hope that ONDCP will be able to work with other state legislatures in order to expand this utilization. From our Association's point of view, it is critically important to provide access to OUD medications during incarceration with a direct handoff to outpatient treatment programs upon release. It has been established that when such an opportunity exists, post release mortality for such intimates is reduced by more than 50% and recidivism is also reduced by a factor of 55%. This is

based on work done by our colleagues in the CODAC treatment facilities in Rhode Island.

This is why our Association has joined with other national organizations in supporting recent legislation, which would remove the Medicaid exclusion for people entering correctional settings. Again, we hope that ONDCP will also work with members of Congress to remove this Medicaid restriction.

Revising Federal Regulations

We have supported SAMHSA's interest in providing greater clinical flexibility to OTP clinicians when determining the best course of treatment for our patients. I am attaching my communication to Dr. Robert Baillieu of SAMHSA, dated February 10, 2023, which clearly supports their intent to induct patients with methadone through audio visual telehealth. We also appreciate SAMHSA's interest and support in working with state regulatory authorities for better alignment between federal and state regulatory standards and appreciate working with CMS Medicare/Medicaid to ensure that third party reimbursement aligns with federal and state regulatory standards.

You will note in reading through this correspondence that we remind SAMHSA about our concerns and implications for eliminating the term "Medication Assisted Treatment" in favor of *medications for the treatment of opioid use disorder*. This was part of my introduction in this communication and there is no need to explain this further in addition to what is in the enclosed letter.

We understand that SAMHSA is working to revise these regulations and we have urged our associates to be clear in order to leave as little room for interpretation as possible. While we wish to expand access to standards of care that will offer patients greater opportunities for stability and flexibility, we also need to be sure that we are responding to the patient's presenting needs.

The Prescribing of Methadone Outside of the Scope of OTPs

This policy initiative has taken on increasing focus and urgency from various quarters. We certainly understand why this matter has taken on such urgency but reflect serious concerns about the fact that this could result in inadvertent and considerable harm. This is why our Association has opposed the Modernizing Opioid Treatment Access Act (MOTAA) and have explained this to many members of the House and Senate. We remind you of the five methadone mortality reports that were published between 2003 and 2010.

- Methadone-Associated Mortality: Report of a National Assessment. (2003, Center for Substance Abuse Treatment)

- Methadone Diversion, Abuse, and Misuse: Deaths Increasing at Alarming Rate.

  (2007, US Department of Justice, National Drug Intelligence Center)

- Methadone Mortality – A Reassessment: Report of the Meeting.

  (2007, Center for Substance Abuse Treatment)

- Methadone Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them.

  (2009, U.S. Government Accountability Office)

- Methadone Mortality – A Reassessment.

  (2010, Center for Substance Abuse Treatment)

Although these studies are focused on methadone prescribed for pain, these data demonstrates the risk that occurs for inadvertent overdose death even when prescribed to a broader population including those with and without a prior diagnosis of OUD.

I am also attaching two more recent articles, which discuss this as well. The first is the "Examination of Methadone Involved Overdoses during the COVID-19 Pandemic". The authors, Daniel Kaufman, Amy L. Kennalley, Kenneth L., McCall and Brian J. Piper, come to the conclusion that "overdoses involving methadone significantly increased by 48.1% in 2020 relative to 2019. Therefore, robust policy changes that were implemented following the COVID-19 pandemic involving methadone take homes may warrant further study before they are made permanent".

I am also attaching the article "Methadone-involved Overdose Deaths in the United States Before and During the COVID-19 Pandemic" as authored by Robert Kleinman and Marcos Sanches. Their conclusion is equally compelling, "methadone-involved overdose deaths, both with and without other synthetic opioid co-involvement, increased during the 12-month period after March 2020, compared with prior trends. These results provide a cautionary addition to previous findings of no or limited methadone-related harms after the US regulatory changes during the COVID-19 pandemic."

There is also a profound misunderstanding in comparing how OTPs make determinations of take-home medication as opposed to an individual practice setting. It is true that most of the OTPs in the United Staes provided additional flexibility in how take-home medications were used during the height of the

COVID-19 pandemic. Many of these programs suspended toxicology collections as a further means of protecting the patients from being infected. As the pandemic eased and OTPs returned to collecting toxicology profiles, take-home medication would be adjusted if toxicology reports were positive for the use of other drugs. One cannot assume that the same practice would be used by individual practitioners, especially if they are not collecting any toxicology samples to make more informed clinical determinations. It is important to point out that OTPs involve a team of clinicians when making decisions about providing take-home medication to the patient. Medical practitioners in solo practices do not have the benefit of such team decision making. In our judgment, providing a prescription for methadone products to a clinically unstable patient is not only unwise but it is also dangerous, especially when treating unstable fentanyl using patients. This will certainly lead to increased methadone diversion and overdose.

There is also a great difference in giving a patient buprenorphine versus methadone. Buprenorphine is a schedule III medication with a favorable safety profile, while methadone is a schedule II medication. Methadone is an effective medication when used properly and is an unforgiving medication when not used properly.

Conclusion

It is recognized that there are divergent policy perspectives confronting the two crises as discussed at the beginning of this letter: the mortality crisis and opioid use crisis. In our considered judgment, we need to be thoughtful about negative unintended consequences of some policy recommendations. While it is critical that we find solutions to decrease opioid related mortality and to increase access to treatment, it is important to protect the integrity of the treatment experience for the patient without denying access to care but ensuring that the care that is provided is safe and of good quality.

While we are increasing access to mobile van services in different parts of the country in addition to medication units, which are directly affiliated with full service opioid treatment programs and an increase in access to care for the justice system, we need to be certain that treatment leads to improving the health and well-being of the patients whom we serve.

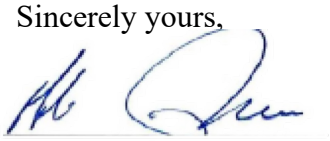
It is also important to be careful not to promulgate national policy that will ultimately destabilize current treatment systems. This is not a simple task.

Finally, there is the need to provide proper reimbursement for the services that are rendered to the patients. While there has been an interest in providing inexpensive treatment for the last 50 years, the question becomes how cheap can treatment be and at what cost to patient care? Right now, it is well known that

some State Medicaid Authorities do not provide adequate reimbursement to OTPs.

We deeply appreciate ONDCP's leadership and coordination in these policy areas. Our cautions have been clearly expressed as we are concerned about the future of effective treatment. We think it is unwise to separate services that are helpful to the patient from the medications that are provided. Throughout our history, we have emphasized the need for comprehensive services, and we do not think that the present policy recommendations should deny the evidence that has been collected for such a long period of time. As always, we are happy to meet with you and discuss these matters at greater length.

Sincerely yours,



Mark W. Parrino MPA
President