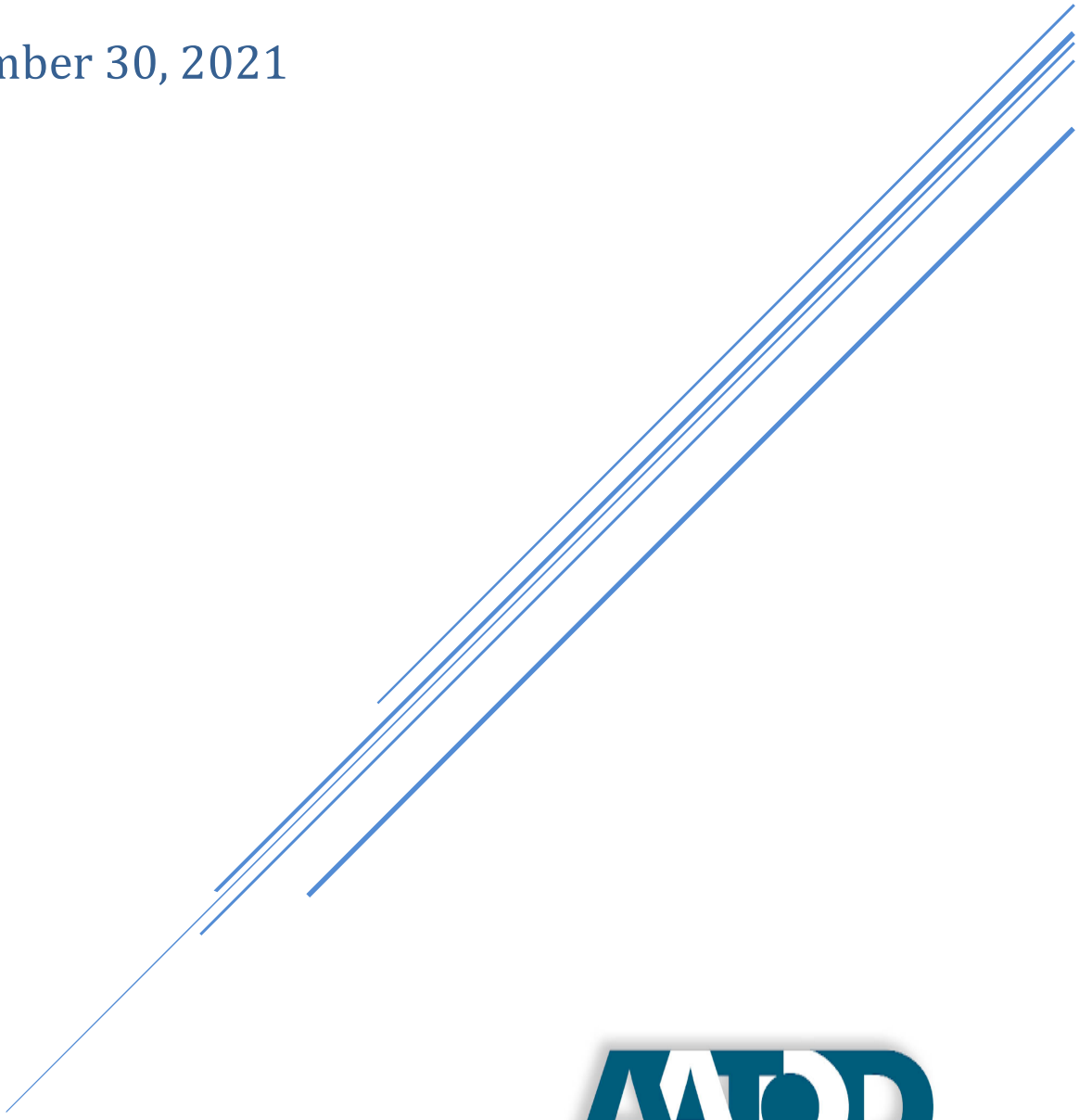
Regulatory Reform and Policy Initiatives for OTPs in a Post Covid-19 World

September 30, 2021



American Association for the Treatment of Opioid Dependence, Inc.

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Introduction

On behalf of the American Association for the Treatment of Opioid Dependence (AATOD), which represents over 1,200 Opioid Treatment Programs (OTPs) throughout the United States, we write this to advocate the need to improve access to comprehensive evidence-based treatment of opioid use disorder in the face of a global pandemic. We work closely with our partners in the World Federation for the Treatment of Opioid Dependence (WFTOD), representing over 600 OTPs worldwide. The World Federation represents substance use treatment programs in Europe and works cooperatively with other treatment centers throughout the world. Together with the World Federation, AATOD works with the United Nations Office on Drugs and Crime (UNODC) and the World Health Organization (WHO) in disseminating policies and practices to treat opioid use disorder. Since our founding in 1984, we have also worked with federal and state agencies across the United States that have jurisdiction in this policy area. AATOD has produced nationally recognized training conferences from 1984 to the present and have worked with policy and treatment partners through other national organizations.

Our experience in these matters is substantial. We produced the first *Treatment Improvement Protocol* (TIP) for the Substance Abuse and Mental Health Services Administration (SAMHSA) in cooperation with our associates at the American Society of Addiction Medication (ASAM) and released by SAMHSA in 1993 (State Methadone Treatment Guidelines).[1] We worked with the Drug Enforcement Administration (DEA) to produce the first *Best Practice Guideline*, published by the DEA in 2000.[2] Both documents provided guidance to OTPs in understanding the best evidence-based clinical practices in treating patients with opioid use disorder and achieving a high degree of compliance with federal regulatory requirements.

The Combined COVID-19 Pandemic and Opioid Use Epidemic

The opioid epidemic began with prescription opioid misuse, which morphed into heroin use and, at present, to increased fentanyl use. Our country has also entered an era of increased stimulant use, particularly with methamphetamine. It is also fair to indicate that COVID-19 lasted for far longer than any reasonable person could have anticipated. Both situations have had tragic results and have ushered in an era of policy considerations about how we should increase access for the treatment of opioid use disorder and how we should evaluate existing regulatory oversight in an era that has been reshaped by these combined public health challenges. A goal of this policy initiative is to expand access to care through innovations that do not sacrifice the quality or the integrity of the treatment experience throughout the continuum of care.

Brief Historical Background

The original concept of methadone maintenance to treat opioid use disorder developed from the early research work of Drs. Vincent Dole, Marie Nyswander and Mary Jeanne Kreek at Rockefeller University in the mid-1960s.

> "An effective pharmacologic intervention had to meet stringent conditions to successfully treat narcotic addiction. It must eliminate the euphoric appeal of heroin and the abstinent symptoms that draw addicts back to drug use; it must be sufficiently free from toxic dysphoric effects that patients will continue with treatment; it must be orally effective, long-acting, medically safe and compatible with normal performance at work and at school with responsible behavior in society." [3]

Methadone treatment expanded quickly in the late 1960s based on the success of their research efforts. In the book, *Addicts Who Survive: An Oral History of Narcotic Use in America, 1923-1965*, Dr. Dole wrote,

> "The problem was one of rehabilitating people with a very complicated mixture of social problems on top of a specific medical problem, and that [practitioners] ought to tailor their programs to the kind of problems they were dealing with. The strength of the early programs as designed by Marie Nyswander was in their sensitivity to individual human problems. The stupidity of thinking that just giving methadone to solve a complicated problem seems to me beyond comprehension" [4]

In our judgment, Dr. Dole's comment is especially relevant given current policy considerations in treating opioid use disorder with medications. Dr. Dole's comment reflects the importance of the assisted part of treatment.

In 1972, the Food and Drug Administration (FDA) published regulations for methadone treatment programs. No formal clinical guidelines were available to operate OTPs until SAMHSA published the above referenced treatment improvement protocol, State Methadone Treatment Guidelines, in 1993.[5]

It is important to point out that a damaging and influential series of articles "Methadone, The Deadly Cure" was published by the *Sun Sentinel* in Florida during June of 1983.[6] A quote from the editor follows:

> "the public doesn't care very much about methadone patients. They don't enjoy a very good reputation, nor do they get much sympathy. Indeed, the nationwide program to treat heroin addicts with methadone was not set up with the idea that it was being done to help addicts. It was being touted as a way of protecting society and keeping addicts from committing crimes."

An objective observer could reasonably argue that such stigma, as represented in this quotation, is just as pervasive at present, which is why one of our Association's recommendations is to develop a long-term national education campaign about the value of medications in the treatment of patients with opioid use disorder.

The importance of this reference from the *Sun Sentinel* is that it would lay the groundwork among federal legislators to request that the General Accounting Office (GAO) develop a report on this topic. In response, the GAO did publish a report in March 1990 - *"Methadone Maintenance – Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed"*.[7] This report was sent to Chairman Congressman Charles B. Rangel of the House Select Committee on Narcotics Abuse and Control/House of Representatives and underscored the great disparity of quality care being offered to patients through OTPs, including subtherapeutic dosing and insufficient program services. It also highlighted that the FDA was not fulfilling its responsibilities in regulating the system. The GAO reviewed the practices of twenty-four OTPs operating in eight states. As a result, the House Select Committee on Narcotics Abuse and Control/House of Representatives immediately convened a hearing and was sharply critical of the FDA.

Following the release of this report, the FDA commissioned the Institute of Medicine (IOM) to conduct a comprehensive review of federal regulations for methadone treatment programs. The IOM published its report in 1995[8] and recommended that the federal oversight of methadone treatment programs should change from process-oriented regulations to a more patient-centered outcome driven approach. The IOM also concluded "the need exists to maintain certain enforceable requirements in order to prevent substandard or unethical practices that have socially undesirable consequences."

Following the release of the IOM report, the Department of Health and Human Services (DHHS) implemented a strategy to transition federal oversight from the FDA to SAMHSA. After years of interagency federal discussions, SAMHSA would assume the responsibilities of providing oversight to OTPs in 2001[9] through approved accreditation bodies, which continues to the present.

The Impact of COVID-19 on OTPs

During the COVID-19 pandemic, several major developments transformed clinical and operational practices in OTPs. Beginning in March 2020, and under emergency exemption policies promulgated by SAMHSA in collaboration with the State Opioid Treatment Authorities (SOTAs), OTPs were approved to provide more take-home medications to patients. Forty-two states filed for emergency exemption requests for take-home medication; published reports are referenced in this paper.[10] Markedly few reports of misuse are seen in take-home medication given the scope and number of increased take-home medication. Many of the OTPs in the United States suspended toxicology screenings to protect the safety of the staff and patients. However, more toxicology reports were found to be positive with heroin and fentanyl once OTPs reinitiated testing. Fortunately, few reports of methadone related overdoses were attributable to patients consuming take-home medication prematurely. This development has opened the door to rethinking how take-home medication can be implemented with greater flexibility in treating clinically stable and unstable patients. SAMHSA also needs to make clearer distinctions with regard to clinically unstable patients if there is any attempt to reevaluate the existing regulatory criteria for dispensing take-home medications.

We believe SAMHSA's OTP regulatory oversight policies should be cautiously reevaluated and based on evidence and clinical practice. Clearly, OTPs need to have greater flexibility to make ongoing care less burdensome for the patient. The COVID-19 pandemic also compelled OTPs to be more creative in providing patient care. The "real-world" experience of OTPs clinician and patients makes a case that SAMHSA consider a change in take-home requirements.

Expanding the Footprint of OTPs in United States

What follows are a number of AATOD policy recommendations with regard to OTP development and oversight. We believe it is important to expand the footprint of OTPs throughout the United States, especially in suburban and rural areas. In considering such matters, it is important to point out that to have a positive impact in how OTPs function in a post COVID-19 environment, changes in state oversight need to be aligned with

changes in federal oversight. This alignment is an important recommendation since a number of state regulations are not necessarily based on evidence-based practices. Illustratively, some state regulations require that OTPs use pharmacists to administer and/or dispense medication. In an environment of shortages in pharmacists, such regulations are burdensome and significantly add to the cost of treatment. No one has provided any evidence to support how pharmacists offer superior care in the OTP setting when compared to nursing or clinical personnel. Additionally, a number of state agencies or Medicaid authorities require patient-to-staff ratios without providing any particular rationale for doing so. Some state agencies/licensing bureaus have strict requirements in siting OTPs, especially if they are located near business districts, churches or learning centers. Additionally, some states have census capacity limits for OTPs, which are not based on occupancy standards. Federal and state oversight must also be aligned with third-party reimbursement practices including Medicare, Medicaid and private insurance. This integration is especially daunting but essential to guarantee success in any sweeping policy change in this sector. Accordingly, the following recommendations are primarily focused on OTP development.

Funding

SAMHSA grants are appropriated by Congress and go to Single State Alcohol and Drug Abuse Authorities. However, current "language" does not allow these funds to be awarded to or used by for-profit proprietary OTPs. This policy needs to be changed since approximately 60% of the OTPs are operated by for profit entities. State Alcohol and Drug Abuse Authorities are currently able to contract with such entities with specific operating requirements and deliverables. However, this procedure needs to be more transparent so that OTPs, regardless of ownership status, will benefit from opportunities to expand. Fortunately, SAMHSA has already begun to move in this policy arena. In a communication dated August 4, 2021,[11] Miriam E. Delphin-Rittmon, Assistant Secretary for Mental Health and Substance Use, provided guidance to State Alcohol and Drug Abuse Directors to use SAMHSA funds for both nonprofit and for-profit OTPs through appropriate mechanisms and to use such funds to purchase mobile vans. The use of mobile vans is particularly vital to serving patients in rural areas as well as prisons and

jails where research shows a large majority of the patients with OUD exist. AATOD recommends that SAMHSA continue to support the expansion of mobile vans connected to OTPs wherever they are needed, and to monitor how states will use such funds to treat opioid use disorder.

Mobile Vans

Brian Chan and his colleagues recently published a paper titled "Mobile Methadone Medication Unit: A Brief History, Scoping Review and Research Opportunity"

> "Mobile methadone medication units ("methadone vans") emerged in the late 1980s to respond to the spread of HIV infection among people who use drugs and the need to enhance access to opioid treatment programs. The purpose of the vans was to facilitate access to care in rural communities and in urban areas when communities opposed the opening of fixed site opioid treatment programs (OTPs). The Drug Enforcement Administration (DEA) approved the first "clinic on wheels" as a medication unit serving communities in Southeastern Massachusetts 1988." [12]

AATOD has worked with the DEA with regard to permitting/allowing the use of mobile vans to work under the aegis of licensed and accredited OTPs.

After several years of consideration, the DEA released new mobile van regulations on June 28, 2021.[13] In our judgment, AATOD sees three broad applications in using such vans. The first pertains to the more standard use of such vans, which extends the reach of OTPs in surrounding communities. The DEA has simplified the process of acquiring such vans, although other issues must be considered, including the purchase price of these mobile components, grant support to the OTPs to purchase the vans, and the services provided through such vans.

The second broad application is how such vans could work with the justice system. In this case, the OTPs would work with the State Opioid Treatment Authorities as well as

the Departments of Corrections. The goal would be to have the OTP dispatch such vans to correctional facilities, including jails and prisons, where the OTP van personnel would induct patients onto one of the three federally approved medications to treat opioid use disorder and would maintain inmates on these medications until the time of their release. These patients/inmates would also receive additional clinical services to support the use of these medications during their period of incarceration and transition back into the community. Van personnel or correctional program personnel would work in cooperation with program personnel to coordinate a seamless handoff to a community-based provider so patients can be admitted into the OTP or a DATA 2000 practice upon release in an effort to continue treatment.

The third application would be to use such vans to provide, expand, and enhance access to care for people with opioid use disorder in residential settings. These settings could include recovery homes, which are classified as medication free facilities, skilled nursing facilities and nursing homes, in addition to many other site needs. It is understood that such mobile vans are expensive, and AATOD recommends that federal and state funding be used to assist OTPs to purchase such vans. We emphasize the importance of the SAMHSA communication of August 4, 2021.

> "SAMHSA supports the use of the Substance Abuse Prevention and Treatment (SAPT) Block Grant funds for mobile units for the purpose of providing substance use disorder outreach, screening, assessment, treatment and recovery support services." [14]

The Department of Agriculture appears to have funding ability for OTPs to purchase such vans as long as the services would operate in a rural population of 50,000 people or less. AATOD completely supports these funding initiatives in this policy arena.

Satellite Medication Units

According to SAMHSA's Federal Guidelines for Opioid Treatment Programs (March 2015), a satellite medication unit

> "must have a separate and unique DEA registration. SAMHSA only requires notification via submission of an updated on-line SMA-162 (http://dpt2.samhsa.gov/sma162/); no additional certification is needed. Such a unit is intended to facilitate access to medication-assisted treatment for patients who would otherwise have to travel great distances. Other required services must still be provided at the certified OTP" [15]

AATOD recommends that expanded satellite medication units work in conjunction with licensed OTPs. We also recommend that SAMHSA coordinate this effort with the DEA and State Opioid Treatment Authorities. We reiterate that the use of telehealth services to assess and induct new methadone patients enhances the ability of such satellite units to admit patients. In this case, and unlike mobile vans, the satellite medication unit is a brick-and-mortar facility, which can be located in the general vicinity of the OTP, or some distance away, depending on the treatment gaps in the county or region of the state. SAMHSA's current regulations allow for the implementation of satellite medication units. To date, such units are considerably underutilized, and we are of the judgment that this opportunity would also expand access to care with the OTPs acting as hub sites. The care would be coordinated through the OTP hub site as a means of monitoring the treatment the patient would receive. SAMHSA needs to amend the existing regulatory guidance to OTPs from 2015 and clearly define what services can be provided in satellite medication units.

Telehealth Services Through OTPs

Telehealth services expanded significantly at OTPs, and we learned that many patients did not have the technology for visual/two-way exchange, leaving them with audio-only opportunities. This experience has also compelled a review of how such services can be incorporated into updated OTP policy. Our Association is renewing its recommendation

to have SAMHSA change the ability of OTPs to admit new patients to treatment with methadone via telehealth. This will be especially important to the recommendations that follow.

Increased Access to Interim Care through an OTP

SAMHSA supported the development of interim care services as a method of responding to delays in patient's seeking admission to OTPs. A recently published article by Dennis McCarty and his associates, "Interim Methadone – Effective but underutilized: A Scoping Review," provides an important reference for this policy section.

> "The initial interim services demonstration led to a 1993 amendment to the Federal methadone regulations authorizing interim methadone services. The amended regulations, however, added three requirements to the delivery of interim services (i.e., a letter from the state health officer authorizing interim services, approval from SAMHSA, and patients must be enrolled in counseling within 120 days) and two restrictions (i.e., for-profit OTPs may not deliver interim methadone, and take-homes are not permitted – the OTP must be open 7 days a week for dosing)." [16]

It is important to point out that the underlying premise of interim maintenance was based on patient waiting lists to gain access to OTPs. AATOD worked closely with the Department of Health and Human Services to develop criteria for interim maintenance to better ensure that patients could get immediate access to care in an OTP when waiting lists existed. In this case, the OTP would need to demonstrate a waiting list was created for patients to get into treatment and would work with the State Opioid Treatment Authority to inform SAMHSA that such programs were beginning to admit patients without providing a full array of services. We were concerned that patients would leave treatment prematurely during an early stabilization period if they did not get access to support services while they were also getting their medications. Additionally, when New York City was considering use of interim care several years ago when several OTPs were closed for regulatory reasons, patient advocacy groups objected to the use of interim care

because they wanted access to full services. From our point of view, we see two existing barriers with regard to interim maintenance: 1) restricting the operation of such care to nonprofit entities, and 2) requiring that all interim maintenance patients attend the OTP seven days per week. We advise SAMHSA to eliminate these two barriers.

Dispensing Methadone Through Pharmacies

We received reports from Scotland about diversion of methadone in pharmacy distribution and it led to several considerations by their parliaments about ending access to methadone treatment entirely. This challenge to continue providing access to methadone maintenance to treat opioid use disorder in these countries motivated the World Federation for the Treatment of Opioid Dependence to write a letter to the Scottish Parliament and members of the Irish Parliament to forestall such legislative considerations.

It is also important to reference an article by Graham Gauthier, Joseph K. Eibl and David C. Marsh, published in *Alcohol and Drug Dependence* during 2018, "Improved Treatment-Retention for Patients Receiving Methadone Dosing within the Clinic Providing Physician and Other Health Services (Onsite) Versus Dosing at Community (Offsite) Pharmacies". This original research included 3743 patients, and compared methadone dispensed through a clinic to methadone prescriptions through a pharmacy.

> "The findings of this study suggest that patients receiving methadone dosing within the MMT clinic have an increased likelihood of being retained in care as compared to patients choosing to obtain observed dosing in a community pharmacy. We advocate that both the physician and patient should be aware that in-clinic methadone dosing correlate with improved treatment retention." [11]

At the present time, we do not recommend the use of pharmacies dispensing methadone hydrochloride products through physician prescribing.

Recommended Changes in Federal and State Oversight for OTPs

Currently, many organizations are being compelled to focus on changing policies to make take-home medication more flexible for patients, both stable and unstable, during the COVID-19 pandemic. A good deal has been written about the complexity and comprehensive nature of SAMHSA's regulations and guidelines for OTPs, especially in the March 2015 Federal Guidelines for OTPs and the fact that it is 79 pages in length. OTPs have followed these guidelines since the SAMHSA regulations were published in 2015 and when SAMHSA released its OTP regulations during May 2001. For the most part, they provide guidance to the field, based on years of proven clinical practice standards and evidence-based care. While they are extremely detailed and should be considered for some modification, as a whole, they provide useful guidance to the field.

The existing SAMHSA criteria in determining take-home doses should be cautiously reevaluated even though the existing requirements appear to be reasonable and based on years of clinical practice. It is also reasonable to change the current regulation paradigm, which cites that the medical director is making the determination of the patient's ability to receive take-home medication and expanding this decision-making responsibility to program medical practitioners to make such determinations.

SAMHSA criteria for patient take-home doses

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinical attendance outweighs the potential risks of diversion.

Some states currently require that OTPs be open seven days a week, especially in treating newly admitted or unstable patients. Once again, changes in federal regulations should be woven into the policy tapestry and aligned with state regulatory agencies and reimbursement entities. AATOD recommends that SAMHSA work with State Alcohol and Drug Abuse Authorities in addition to the State Opioid Treatment Authorities to provide greater flexibility in how OTPs provide take-home medication based on the lessons learned during COVID-19. Current regulatory criteria with regard to time and treatment, to be eligible for take-home medication, must be carefully reevaluated.

Additionally, a review of state regulatory policies is needed regarding staffing to patient ratios, the use of pharmacists in preparing onsite and take-home medications, and the use of lockboxes when patients do get take-home medication. The use of lockboxes creates a number of difficulties for the patient, especially since it becomes more obvious to other parties that the patient is carrying such a box. If the treatment program trusts that the patient will use such take-home medication appropriately, the use of a lockbox becomes questionable. Obviously, the circumstances are different if clinically unstable patients are being provided with take-home medication. This is why such regulatory issues need to be better resolved.

Moving Forward with Innovative Change

The realities of an ongoing opioid epidemic, combined with the lessons learned from the COVID-19 pandemic, provide creative and responsible opportunities to improve, enhance, and expand the role of OTPs. Policymakers should be careful when considering such changes as opportunities to embrace harm reduction principles along with research and evidence-based clinical practices to ensure that patients receive evidence-based care that is most appropriate and relevant to their needs.

A good deal has been debated on how comprehensive patient care should be. It has been demonstrated over the course of 60 years that patient outcome improves when medications are part of a coordinated and comprehensive range of other support services.

Effective treatment needs to be able to respond to the therapeutic interests of our patients as well as determining, among other considerations, the right medication in response to their particular needs. This is especially true in an era of fentanyl and stimulant use. As a general principle, we should provide a complement of services based on the needs of the individual and should be careful not to condition the patient's participation in treatment by requiring many services, to the exclusion of giving the patient access to essential medications to treat their opioid use disorder. This is a delicate clinical balancing act, and policymakers need to be careful to not be overly doctrinaire when providing such policy recommendations. It is also important to reference the seminal work of Dr. John Ball and his colleagues, published in 1988. This important research focused on the treatment program rather than the patient as the unit of study.

Dr. John C. Ball and his associates, in the article "Reducing the Risk of AIDS through Methadone Maintenance Treatment," published in the 1988 *Journal of Health and Social Behavior*, cited findings from a three-year NIDA-funded study of six methadone treatment programs in three Eastern cities that addressed program effectiveness:

> "Although we had anticipated that there would be minor variations in outcome due to program differences, we thought that the dominant influence upon treatment success would be patients' characteristics, such as length of addiction, employment history, prior criminality and severity of psychiatric symptoms. This expectation was not substantiated by the research findings; instead we found program treatment variables to be of paramount importance in reducing IV usage. It is a major finding that some methadone maintenance programs are markedly more effective than others in reducing IV drug use and needle sharing among their patients because these differences in treatment outcome are related to definite program variables. The more effective programs have high patient retention rates (especially long-term retention rates), high rates of scheduled attendance, a close, consistent and enduring relationship between staff and patients, and year-to-year stability of treatment staff. Conversely, the less-effective programs are characterized by poor patient attendance, inadequate

> methadone medication, and high rates of staff turnover. Effective and ineffective programs, however, did not differ with regard to patient characteristics." [18]

The importance of this reference is to underscore that patients are more likely to improve during the course of their treatment in an OTP if the programs are under stable management with adequate funding and well-trained personnel.

Workforce Shortages and Development

AATOD has received reports from OTPs throughout the United States with regard to workforce shortages. This is especially true for physicians and other medical practitioners, in addition to nursing personnel and counseling positions. This workforce shortage has grown increasingly significant throughout the COVID-19 epidemic due to concerns about working in such healthcare environments. AATOD recommends that SAMHSA work in conjunction with DHHS, ONDCP and other federal agencies, to give individuals in the health profession the opportunity to work in OTPs to fulfill their obligations in loan forgiveness programs. This approach has been used with great success in other environments and should be used for opioid treatment programs. It is not possible to expand access to care unless we have a workforce that can meet the challenges of admitting more patients into the treatment system. It is also important to point out that personnel salaries and benefits also need to be competitive to attract and retain staff, in addition to expanding the use of recovery coaches as part of the OTP workforce.

Finally, the entire field has an opportunity to move forward and ensure that treatment is available to all people who would benefit from such care. We also work in a highly stigmatized environment, which can only be overcome by consistent education, especially when explaining to the American public why medications are used to treat opioid use disorder. Until a comprehensive education campaign is developed and sustained, we will not have broad public support when treating our patients. Such a campaign would include public service announcements in various media networks throughout the country in addition to developing the kind of campaign during President

Reagan's time in office but without the use of pejorative terms like "just say no." This campaign would need to explain how people get into trouble with opioids whether it is an overuse of prescription opioids or moving on to heroin and fentanyl use. The campaign needs to include how the three primary FDA-approved medications to treat opioid use disorder are used, breaking through commonly perceived myths. This campaign should include individual stories of patient recovery through the use of medication-assisted treatment. Once again, it is important to balance the interest of increasing access to medication-assisted treatment to treat opioid use disorder without compromising the quality and integrity of services that are provided to the patients in treatment. These recommendations can only be achieved and sustained through a coordinated effort with federal agencies working together in addition to working with the State Alcohol and Drug Abuse Agencies and the State Opioid Treatment Authorities. The OTPs have an obligation to ensure the care they provide is informed and delivered by compassionate and knowledgeable personnel, whose sole interest is providing the best care possible to the patients, who put their trust in our ability to guide them on their path to recovery.

Recommendations

1. The "real-world" experience of OTPs and patients suggests that SAMHSA considers a change in take-home requirements.
2. Our Association is renewing its recommendation to have SAMHSA change the ability of OTPs to admit new patients to treatment with methadone via telehealth.
3. Changes in state oversight need to be better aligned with changes in federal oversight.
4. CMS Medicare/Medicare in addition to state Medicaid reimbursement rates need to be aligned as changes are made to federal and state oversight requirements.
5. AATOD recommends SAMHSA continue to monitor how states use funds to ensure the expansion of mobile vans connected to OTPs wherever they are needed to expand access to care to treat opioid use disorder.
6. AATOD recommends SAMHSA remove the two primary barriers in expanding access to interim maintenance treatment, which include removing the restriction

for for-profit entities and allowing patients to have take-home medication during the period of interim maintenance.

7. AATOD recommends the expanded use of satellite medication units to work in conjunction with licensed OTPs. We recommend that SAMHSA coordinate this effort with the DEA and State Opioid Treatment Authorities. We believe SAMHSA needs to amend the existing regulatory guidance to OTPs from 2015 and clearly define what services can be provided in satellite medication units.
8. AATOD recommends that federal and state authorities develop additional and creative/innovative options to treat our patients. Such innovations include deliveries to home bound patients during times of crisis in addition to working with an expanded number of partners in mental health and residential settings. With regard to creating such innovative change, it is important to reference the three whitepapers that AATOD developed for SAMHSA during 2016/2017: "Models of Integrated Patient Care through OTPs and DATA 2000 Practices," "Integrated Service Delivery Models for Opioid Treatment Programs in an Era of Increasing Opioid Addiction, Health Reform, and Parity" and "Increasing Access to Medication Assisted Treatment for Opioid Addiction in Drug Courts and Correctional Facilities and Working Effectively with Family Courts and Child Protective Services."
9. AATOD recommends SAMHSA encourage states to widen flexibilities in regard to staffing ratios so OTPs can balance the needs of patients with both their level of risk and the availability of various workforce components (i.e., physicians, physician extenders, nurses and counselors/therapists) in a way that, while not always ideal, allows for the provision of adequate care under various environmental conditions.
10. AATOD recommends a review of patient admission criteria. Illustratively, the current regulations indicate the following: "A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment." These provisions should be eliminated.

11. AATOD recommends SAMHSA work with the approved accreditation entities with regard to how such entities are interpreting SAMHSA regulations and guidelines.

12. AATOD recommends against the use of pharmacies dispensing methadone hydrochloride products through physician prescribing.

13. AATOD recommends SAMHSA work in conjunction with other agencies within DHHS, ONDCP and other federal agencies, which have the ability to create loan forgiveness opportunities so that individuals in the health profession are given the opportunity to work in OTPs to fulfil their obligations in receiving student loans.

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