



ASAM American Society of
Addiction Medicine

Public Policy Statement on the Regulation of Office-Based Opioid Treatment

Background

Office-based opioid treatment (OBOT) commonly refers to outpatient treatment services provided outside of licensed Opioid Treatment Programs (OTPs) by clinicians to patients with addiction involving opioid use, and typically includes a prescription for the partial opioid agonist buprenorphine, the provision of naltrexone, or the dispensing of methadone, in concert with other medical and psychosocial interventions to achieve and sustain remission. The initial model of office-based opioid treatment using methadone was first devised as a pathway to expand the reach and capacity of methadone treatment in the 1980's.^{1,2} In the United States today, the most common type of OBOT uses the partial opioid agonist buprenorphine and was made possible by the Drug Addiction Treatment Act of 2000 (DATA 2000). The law provided a pathway for qualified physicians to apply for a waiver separate from the Drug Enforcement Administration (DEA) registration requirements that licensed OTPs must meet. DATA 2000 allowed physicians to use certain Schedule III-V controlled substances approved by the Food and Drug Administration (FDA) for the treatment of patients with addiction involving opioid use. In 2002, the FDA approved the use of buprenorphine, a Schedule III opioid, for this purpose and has subsequently approved several different buprenorphine formulations designed to deter its misuse. When compared with methadone maintenance treatment (MMT), OBOT permitted more physicians the opportunity to treat and bill for the treatment of opioid addiction within their regular medical practice. This provided for expanded access to treatment, potential payment mechanisms for physicians in practice as is appropriate for the treatment of chronic diseases, and a more private treatment experience for the patient with an opioid use disorder. The Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded on DATA 2000 to allow nurse practitioners (NPs) and physician assistants (PAs) to become eligible for a waiver as well.

DATA 2000 and CARA have greatly expanded access to evidence-based treatment for patients with addiction involving opioid use. Relative to treatment without medication, office-based opioid treatment with buprenorphine improves six-month treatment engagement, significantly reduces cravings, illicit opioid use and mortality, and improves psychosocial outcomes.^{3,4} Importantly, agonist therapy has been shown to decrease mortality by approximately 50% among persons with opioid-use disorder.⁵ However, because its use in addiction treatment has increased, concerns have risen about the possible role of OBOT in buprenorphine diversion. In preliminary data from 2016, buprenorphine was the ninth most common drug, and fourth most common prescription opioid, among drugs secured in law enforcement operations and analyzed by federal, state or local forensic laboratories.⁶ While the risks of morbidity and mortality are low for buprenorphine, efforts should be made to address diversion, which may possibly be mitigated with some enhanced practices. In fact, studies have shown that the lack of treatment availability is directly linked to the increase in diversion.^{3,4}

In 2015, to define and support high-quality treatment for addiction involving opioid use, the American Society of Addiction Medicine (ASAM) released the *National Practice Guideline on the Use of Medications to Treat Addiction Involving Opioid Use* (Practice Guideline). The Practice Guideline covers all FDA-approved medications available to treat addiction involving opioid use and opioid overdose, and aims to help clinicians make evidence-based decisions when prescribing these medications to patients with opioid use disorders. Since studies have shown that lack of treatment access is a risk factor for buprenorphine diversion,⁷ and diverted buprenorphine is often used to manage symptoms by persons who cannot access treatment,⁸ increasing access to evidence-based treatment as described by the Practice Guideline may be the most effective policy solution to reduce diversion.

To ensure an appropriate quality of care for patients receiving office-based opioid treatment and reduce the diversion of buprenorphine, several states have proposed or begun to regulate the practices of physicians who offer OBOT. The regulatory schemes vary by state, but generally involve a licensing requirement and associated inspections and fees, and may include requirements related to staff training, types of services offered, and/or limits on buprenorphine dosages and formulations. This policy statement aims to inform the creation and implementation of OBOT regulations so that they are evidence-based and do not dissuade clinicians from offering OBOT services, nor create environments unattractive to patients because of unnecessary and unhelpful regulatory burden.

Regulatory Considerations

ASAM believes that OBOT is a positive development in that it promotes the treatment of addiction in the primary care setting. As such it does not support the exclusive licensing of these sites but rather supports oversight from state medical boards and departments of health as superior to specific licensing. However, ASAM understands that the use of controlled substances to treat the disease of addiction introduces the possibility of misuse and diversion of the very medications used for treatment. Given this, some states may seek to regulate the practices that deliver such treatment to patients with addiction. If a state feels thus compelled, any regulatory framework should be developed from the perspective of what is best for the patient and feasible for the provider while not neglecting the safety of a household or the community at large. Thus, the development of such regulations should include perspective from all of those involved including patients, so that successful balancing can occur between feasibility of implementation and maintenance of safety in these environments. It is vital that timely access to addiction treatment occurs, and thus unnecessary and over-burdensome barriers to treatment should be avoided.

ASAM recommends:

- States and local jurisdictions should not enact non-evidence-based oversight of OBOT, such as required mandatory medication taper schedules or limits on dosages.
- States seeking to regulate OBOT should consult with addiction specialist physicians in designing regulations which balance treatment effectiveness with patient and public safety.
- States that choose to regulate OBOT should study the effects of its regulations on access to treatment and diversion of buprenorphine.
- Any licensing should be overseen by the state board of medicine and/or department of health.
- Providers that treat 100 or fewer patients should be exempt from any additional regulatory requirements beyond what it is included in the Drug Addiction Treatment Act of 2000, as amended by the Comprehensive Addiction and Recovery Act of 2016.

- Providers who are approved to treat up to 275 patients should be subject to no more than the reporting requirements specified by the Substance Abuse and Mental Health Services Administration (SAMHSA).
- Clinicians should consider adopting diversion control measures, such as drug testing, reviewing reports from the prescription drug monitoring program (PDMP) and recall visits for pill counts.
- Restrictions on buprenorphine mono-product, if justified, should exclude implantable or depot formulations.

Level of Training

Prescriber (MD, DO, NP, PA)

Delivering addiction treatment can be a complicated process in any environment. In a primary care setting this difficulty can be amplified by the heterogeneity of the patient population and the pace and volume of work. Thus, the training demands on the individual prescribing medication for opioid use disorders should be sufficient but not excessive given time constraints and available resources in what are often challenging clinical settings.

ASAM recommends:

- Clinicians should obtain training covering buprenorphine, methadone and naltrexone and any other topics that align with current federal policy.
- Clinicians should voluntarily continue their knowledge with annual CME focused on treating addiction, including the use of all FDA-approved medications, evidence-based pain treatment and properly addressing behavioral health screening and intervention.

Treatment Continuum of Care Including Components, Structure, and Intensity

ASAM recognizes the place that OTPs hold in the continuum of care by providing highly structured treatment environments. The clinical, social, and public health benefits of methadone maintenance administered in federally-licensed and accredited OTPs have been repeatedly demonstrated in clinical research studies and are irrefutable.⁹ In addition, recent studies of medical maintenance support both the feasibility and efficacy of transferring stable patients to office-based physician care. If transferred or started on evidence-based medications in the OBOT setting, other major treatment components should be available either directly or through referral. Examples of other major treatment components can include counseling (individual and group), general medical care, psychiatric services, programs for family members, educational/vocational counseling, financial counseling, and legal services, as well as monitoring progress and adherence through laboratory testing and prescription drug monitoring programs. It is important to note that many services are not available in all communities, and that this should not preclude patients from accessing the treatment components that are available. Generally, unstable patients in early treatment require both more structured treatment and greater intensity of such services than patients who are stable and are actively managing their disease. ASAM recognizes that patients who prove unstable in office settings may likely require the level of structure and intensity of integrated services available in an OTP, either with buprenorphine or methadone, if a higher level of structure cannot be obtained in the OBOT setting.¹⁰ However, in areas where such services are not available, such as areas where there are no OTPs, pharmacological treatment alone with support of the treating clinician results in improved outcomes for some patients.¹¹

ASAM recommends:

- That OBOT physicians, affiliated or independent, and OTPs establish a collaborative relationship that permits patients to be referred between programs, providing differing models and intensities of treatment, according to clinical needs.
- Clinicians should document provision of or referral for additional psychosocial treatment if indicated.
- Clinicians should be required to register for their state PDMP and check the PDMP at treatment initiation and once per quarter or per their state requirement thereafter regardless of level of care.
- Clinicians should co-prescribe naloxone to patients receiving OBOT, both as a risk-reduction measure and so that buprenorphine is not incorrectly used to treat opioid overdose, regardless of level of care.

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¹ O'Connor PG, Fiellin DA. Pharmacologic treatment of heroin-dependent patients. *Ann Intern Med.* 2000; 133:40-54.

² Salsitz EA, Joseph H, Fran B, et al., Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice – a summary report (1983-1998), *Mount Sinai Journal of Medicine* 2000; 67(5-6); 388-397

³ American Society of Addiction Medicine, Treatment Research Institute. (2013). FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness and Cost-Effectiveness. Chevy Chase, MD: American Society of Addiction Medicine. Available at http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addictiontreatment_final.

⁴ Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database of Systematic Reviews* 2014, Issue 2. Art. No.: CD002207.

⁵ Schuckit MA. Treatment of Opioid-Use Disorders. *N Engl J Med* 2016; 375:357-368.

⁶ U.S. Drug Enforcement Administration, Office of Diversion Control. (2017). National Forensic Laboratory Information System: 2016 Midyear Report. Springfield, VA: U.S. Drug Enforcement Administration. Available at: https://www.nflis.dea/diversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS_MidYear2016.pdf

⁷ Lofwall MR and Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug Alcohol Depend.* 2012; 126:379-383.

⁸ Yokell MA, Zaller ND, Green TC, Rich JD. Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review. *Current drug abuse reviews.* 2011;4(1):28-41.

⁹ Saxon AJ, Special Issues in Office-Based Opioid Treatment, Chapter 5, *Principles of Addiction Medicine 5th Ed. 2014* (Ries, Fiellin, Miller & Saitz, Ed.s), pp. 778-795.

¹⁰ Mee-Lee D. et al., Eds., *The Asam Criteria 3rd Ed.*, 2013, ASAM

¹¹ Fiellin DA, Pantalon MV, Chawarksi MC, et al. Counseling plus Buprenorphine–Naloxone Maintenance Therapy for Opioid Dependence. *N Engl J Med* 2006; 355:365-74.