



The Use of Buprenorphine/Naloxone for the Treatment of Opioid Use Disorder

The United States is in the midst of an unprecedented opioid epidemic. Access to treatment for patients with Opioid Use Disorder has been limited due to increasing number of patients needing treatment, limited treatment programs, and a limited number of qualified prescribers.

The number of Opioid Treatment Programs (OTP) utilizing methadone are relatively small compared to the number of patients needing treatment. Only four OTP locations in Nebraska are listed on the Substance Abuse and Mental Health Services Administration (SAMHSA) website with two sites each in Omaha and Lincoln.

Efforts are underway to address access for the treatment of Opioid Use Disorder. For decades, methadone was the mainstay of treatment for patients who were addicted to heroin or opioids. In the past ten years, more combination products which include buprenorphine have been made available for the treatment of Opioid Use Disorder (see Table 1).

In 2000, the United States Congress passed the Drug Addiction Treatment Act, also known as DATA, which waived the requirement to be registered as an OTP to expand access to treatment for Opioid Use Disorder. The law permits the Center for Substance Abuse Treatment (CSAT),

under SAMSHA, to qualify physicians (including MDs and DOs) to prescribe, administer, and dispense FDA-approved controlled substances in Schedules III, IV and V to narcotic dependent patients. Qualified physicians can initially conduct maintenance and detoxification treatment for 30 patients at a time.

Each DATA-Waived Physician (DWP) is assigned a new Drug Enforcement Administration (DEA) number, which begins with the letter “X”, for use in prescribing for opioid-dependent patients. DWPs may treat opioid dependency with approved buprenorphine products in any setting in which they are qualified to practice, including an office, hospital, health department, or correctional facility. Physicians may qualify as a DWP if they are board-certified or hold an addiction certification from the American Society of Addiction Medicine. Other physicians may qualify by completing an eight-hour training course or meeting other requirements as outlined in the DATA.

After a period of one year, DWPs are permitted to submit the need and intent to increase the patient limit from 30 patients up to 100 patients. If an increase in the patient limit to 100 is granted, a new DEA certificate is issued. Specific federal record keeping requirements apply for opioid dependency treatment with buprenorphine.

Table 1.
Combination Products for the Treatment of Opioid Use Disorder

Buprenorphine/Naltrexone Sublingual Tablet Products in mg						
Suboxone®	2/0.5	8/2				
Zubsolv®	0.7/0.18	1.4/0.36	2.9/0.71	5.7/1.4	8.6/2.1	11.4/2.9
Buprenorphine/Naltrexone Film Products in mg						
Bunavail® buccal	2.1/0.3	4.2/0.7	6.3/1			
Suboxone® sublingual	2/0.5	4/1	8/2	12/3		

DEA record keeping requirements for buprenorphine treatment go beyond the Schedule III record keeping requirements. DWPs are subject to onsite inspections by the DEA to ensure compliance with the DATA and its regulations.

To further expand access to treatment, the Comprehensive Addiction and Recovery Act (CARA) was passed in 2016. The act expanded eligible prescribers to include nurse practitioners (NPs) and physician assistants (PAs) until October 1, 2021. NPs and PAs are required to complete at least 24 hours of training to be eligible for a prescribing waiver to treat up to 30 patients under the CARA.

In addition, updates were made to the DATA 2000 allowing physicians with additional credentialing in addiction medicine or addiction psychiatry or who practice in a qualified practice setting to increase their patient limits to 275. Physicians who qualify and have prescribed buprenorphine to 100 patients for at least one year can apply for the increase.

While qualified physicians are required to have waivers to prescribe or dispense buprenorphine under the DATA 2000, pharmacists and pharmacies are not required to have credentials for dispensing these medications beyond those for other Schedule III medications. Federal laws and regulations, however, do affect pharmacy practice regarding opioid dependency treatment prescriptions. Pharmacists can verify a prescriber's DATA waiver by using the *Buprenorphine Pharmacy Lookup* tool on SAMHSA's website at <https://www.samhsa.gov/bupel/lookup-form> using his or her last name and DEA registration number.

To ensure treatment success and enhance patient compliance, patients should also participate in a comprehensive medication-assisted treatment (MAT) program which includes counseling and social support according to SAMHSA. Under federal law, MAT patients must receive counseling which can include different forms of behavioral therapy. These services are required along with medical, vocational, educational, and other assessment and treatment services. MAT has proved to be clinically effective and significantly reduces the need for inpatient detoxification services for patients with Opioid Use Disorder.

Increasing the number of patients allowed for treatment and increasing the number of qualified prescribers are part of the efforts to address the unprecedented opioid epidemic. All healthcare providers should be aware of these efforts and be part of the solution to treat patients with Opioid Use Disorder.

Resources

- SAMSHA <https://www.samhsa.gov>
- DEA <https://deadiversion.usdoj.gov>
- Bunavail Prescribing Information
- Suboxone Prescribing Information
- Zubsolv Prescribing Information

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