

Buprenorphine Patient Limit

“We’ve got a problem when it’s easier for Americans to get heroin than it is for them to get help to break their addiction.”

- U.S. Senator Sherrod Brown (January 12, 2015)

Evolving Requirements for Opioid Use Disorder

Waiver Requirement

The Drug Addiction Treatment Act of 2000 (DATA 2000) amended the Controlled Substances Act (CSA) to make it possible for qualified physicians who meet certain training and educational requirements to apply for a waiver from federal opioid treatment program registration requirements.

The DATA 2000 waiver allows practitioners to prescribe or dispense buprenorphine to individuals with opioid use disorder (OUD) in an office-based setting.

The Comprehensive Addiction Recovery Act of 2016 (CARA) expanded the types of providers who may treat individuals with buprenorphine for OUD to include nurse practitioners and physician assistants.

The SUPPORT Act of 2018 enables clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to also prescribe buprenorphine for OUD.

Patient Limit

DATA 2000 established limits on the numbers of patients that a waived practitioner may treat at a time in an effort to prevent buprenorphine diversion and abuse.

Originally, DATA 2000-waived practitioners were only permitted to treat 30 patients with buprenorphine at a time.

Congress recognized that the limit was too restrictive to meet the need for treatment. In 2006, DATA 2000 was amended to increase the patient limit so that qualified practitioners could treat 30 patients at a time during their first year of receiving the waiver and 100 patients thereafter.

In 2016, the U.S. Department of Health and Human Services (HHS) implemented regulations that allow certain practitioners who have had a waiver to treat 100 patients at a time for at least one year to become eligible to treat up to 275 patients at any one time.

The SUPPORT Act also allows certain qualified DATA 2000-waived practitioners (e.g., addiction specialists or practitioners who provide medication assisted treatment (MAT) in qualified practice settings) to immediately start treating 100 OUD patients at a time with buprenorphine.

CARA gives the Secretary of HHS the authority to exempt practitioner-administered buprenorphine products from the DATA 2000 patient limit.

Remaining Barriers to Treatment

Amendments to DATA 2000's patient limit are a step in the right direction, but they do not go far enough to meet the high demand for OUD treatment provided by well-qualified practitioners.

As of November 19, 2019, there were approximately 76,103 DATA 2000-waived practitioners in the United States. Yet, many prescribers have waitlists, and some DATA-waived practitioners choose not to prescribe buprenorphine at all.

- Consequently, patients are being turned away.
- Individuals seeking treatment can remain on waitlists for months, during which time they are at substantial risk for substance use, criminal activity, infectious disease, overdose, and premature death.
- Individuals who cannot obtain MAT might seek buprenorphine on the black market to self-medicate.

What Can Be Done to Increase Access to Treatment?

- The buprenorphine patient limit could be adjusted to meet the high demand for treatment associated with the opioid abuse epidemic.
- More DATA-waived practitioners could be encouraged to prescribe buprenorphine, when medically appropriate, and to maximize their patient limits.
- The X the X Waiver movement to eliminate these prescribing restrictions is gaining traction.
- The Mainstreaming Addiction Treatment Act, introduced July 10, 2019, would amend the CSA to allow doctors and physicians to prescribe buprenorphine for addiction without the DEA waiver.

To learn more about the buprenorphine patient limit and proposals for reform, visit CUSP's X the X Waiver Initiative.