

BUPRENORPHINE PATIENT LIMITS: HISTORY AND OVERVIEW

What are buprenorphine patient limits ?

Buprenorphine (or “bupe”) is a partial agonist medication used to treat opioid use disorder (OUD). Practitioners who can prescribe buprenorphine to patients for the treatment of OUDs are limited to a certain number of patients at any given time.

DATA 2000

The Drug Addiction Treatment Act of 2000 (DATA 2000) permits physicians who meet certain qualifications to treat OUD with FDA-approved narcotic medications in treatment settings other than opioid treatment programs (OTPs), such as office-based treatment settings.

The legislation waives the requirement for obtaining a separate Drug Enforcement Administration (DEA) registration as an OTP for qualified physicians to prescribe FDA-approved Schedule III, IV, and V medications for OUD treatment.



HISTORY OF PATIENT LIMITS

After passage of DATA 2000, waived physicians could treat 30 or 100 patients at any one time, dependent on individual authorization from SAMHSA’s Center for Substance Abuse Treatment (CSAT). After one year of prescribing at the 30- patient limit, physicians could submit a second notification of the need and intent to increase the patient limit from 30 patients up to 100 patients.

EVALUATION OF THE DATA 2000 WAIVER PROGRAM

Results from a 2005 congressionally mandated evaluation study of the DATA 2000 waiver program found that: the waiver program increased the availability of medication-assisted treatment (MAT) for OUD; treatment provided under the waiver program has been safe and effective; and the 30-patient limit on physicians, as well as continuing cost and reimbursement issues, have dampened the full potential of buprenorphine to improve access to treatment.



COMPREHENSIVE ADDICTION & RECOVERY ACT OF 2016

Section 303 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 (P.L. 114-198) expanded the definition of a “qualifying other practitioner” beyond physicians to include nurse practitioners (NPs) and physician assistants (PAs) who meet certain criteria. Although Congress considered raising the patient limit in CARA, ultimately lawmakers did not amend it, and instead noted in the legislation that the Secretary of HHS may change the patient limit by regulation.

RAISING THE CAP BY REGULATION

In July 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) released its final rule on MAT for Opioid Use Disorders, which allows eligible physicians to request approval to treat up to 275 patients after prescribing at the 100-patient limit for one year and meeting other criteria. The final rule allows for physicians with a 100-patient waiver who are not otherwise eligible for a 275-patient waiver to request a temporary increase to treat up to 275 patients for up to 6 months in an emergency situation.

SUPPORT ACT OF 2018

Section 3201 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 (P.L. 115-271) adds to the category of “qualifying other practitioner” clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives from October 1, 2018-October 1, 2023.

Section 3202 of the SUPPORT Act ensures physicians who have graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements, can apply for a waiver to prescribe MAT.

The SUPPORT Act allows qualified practitioners to treat up to 100 patients (instead of 30) in the first year of holding a DATA waiver if the practitioner holds additional credentialing (board certification in addiction medicine or addiction psychiatry), or the practitioner provides MAT in a qualified practice setting.

CURRENT STATUS

Who can be considered a qualifying practitioner?

If they meet certain criteria (e.g., 8 hours of training for physicians, 24 hours of training for NPs, PAs, CNSs, CRNAs, and CNMs), the following types of practitioners can apply for a DATA waiver in order to offer MAT:

- Physicians (including osteopathic and allopathic doctors)
- Nurse practitioners
- Physician assistants
- Clinical nurse specialists*
- Certified registered nurse anesthetists*
- Certified nurse midwives*



*Note: With the passage of the SUPPORT Act, CNSs, CRNAs, and CNMs were extended prescribing privileges for the treatment of OUD with buprenorphine.

What's the current patient limit?

Qualifying physicians can treat 100 patients in the first year if they meet the criteria outlined in the SUPPORT Act (see previous section), and 275 after one year of prescribing at the 100-patient limit.

If a physician does not meet the criteria to treat 100 patients in the first year, they would have to prescribe at the 30-patient limit for one year before requesting an increase to 100 patients, and then treat at the 100-patient limit for one year before requesting an increase to 275 patients.

RESOURCES:

DEA Requirements for DATA Waived Physicians:
https://www.dea diversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

Evaluation of the Buprenorphine Waiver Program:
https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/evaluation-impact-data-waiver-program-summary.pdf

Final Rule on Medication Assisted Treatment for Opioid Use Disorders:
<https://www.federalregister.gov/documents/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders>

Comprehensive Addiction and Recovery Act: A Section-by-Section Summary:
<http://nasadad.org/wp-content/uploads/2016/07/CARA-Section-by-Section-July-2016-1.pdf>

SUPPORT Act: A Section-by-Section Summary:
<http://nasadad.org/wp-content/uploads/2018/11/SUPPORT-Act-Section-by-Section-Summary-11.9.18-1.pdf>

QUESTIONS?

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