

Situation: HHS Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder changed on April 28, 2021. Practitioners with DEA number are now eligible to apply for an X-waiver to treat up to 30 patients by submitting Notice of Intent (NOI) without required training.

Background: Previously qualified prescribers with DEA number had to complete 8-24 hours of training in order to be able to obtain an X-waiver to prescribe buprenorphine for OUD.

Assessment/Recommendation:

- 1) Follow link to: <https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php>.
- 2) Complete 2 screens below.

The first screenshot shows the SAMHSA Buprenorphine Waiver Notification interface. It includes a header with the SAMHSA logo and the title 'Buprenorphine Waiver Notification'. Below the header is a blue box with the text 'Renew 275-Patient Waivers and File Annual Reports Using This Same Interface'. Underneath, it says 'Before you begin' and 'Before starting this application, please make sure you have' followed by a list: 'Your DEA Number', 'Your State Medical License Number', and 'Your Training Certificate Information (Only Required for new Waivers)'. Below this is a question: 'Do you work for the US military, Veterans Administration, Indian Health Service, or otherwise work as a Direct Federal Employee?' with radio buttons for 'Yes' and 'No', and a 'Next' button. At the bottom, there is contact information for the SAMHSA Center for Substance Abuse Treatment's (CSAT's) Buprenorphine Information Center.

The second screenshot shows the 'Check your waiver eligibility' section. It has a blue header with the title 'Check your waiver eligibility' and the instruction 'Enter your information below to check your waiver eligibility and get started.' Below this is a section for 'Select your practitioner type:' with radio buttons for 'MD/DO', 'APRN (NP/NS/CN/A/CNM)', and 'PA'. There is a 'Licensing State:' dropdown menu. Below that are three text input fields: 'State Medical License Number:' (with a note 'Letters and numbers only. No spaces or dashes.'), 'DEA Registration Number:' (with a note 'Letters and numbers only. No spaces or dashes.'), and a 'Back' button. At the bottom, there is a 'Submit' button and the same contact information as the first screenshot.

- 3) Next screen: Choose 30-patient limit.
- 4) Complete CERTIFICATION OF QUALIFYING CRITERIA SECTION.
 - a) APRNs and PAs: check SAMHSA's Providers Clinical Support System (PCSS) in "CERTIFICATION OF QUALIFYING CRITERIA," then enter "practice guidelines" in the text box for the date. (see below page for photos for APRNs/PAs)
 - b) Physicians: Select "Other" in "CERTIFICATION OF QUALIFYING CRITERIA," then enter "practice guidelines" in the text box for the city of the training. The training date should be the application date.
- 5) SAMHSA reviews applications within 45 days of receipt. Once the application process is complete and the application is approved, SAMHSA will email an approval letter to the practitioner indicating their waiver level with certification date, and informing them they will receive their x-designation from the DEA within seven to ten business days.
- 6) Should you want to increase your patient limit beyond 30 persons, qualified practitioners who undertake required training (8 hours for physicians, 24 for APRN/PAs) can treat up to 100 patients using buprenorphine for the treatment of opioid use disorder (OUD) in the first year if they possess a waiver under 21 U.S.C. § 823(g)(2) (i.e., a DATA 2000 waiver) and meet certain conditions.

APRN/PA submission photos

When providing maintenance or detoxification treatment, I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the Federal Drug Administration for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.

8. CERTIFICATION OF QUALIFYING CRITERIA

NEW NOTIFICATION - I certify that I am either a nurse practitioner or physician assistant who satisfies the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv), as amended by the Comprehensive Addiction and Recovery Act of 2016.

NEW NOTIFICATION - I certify that I am either a clinical nurse specialist, certified registered nurse anesthetist or certified nurse midwife who satisfies the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv), as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, and I am aware that clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives, will be included in the definition of a "qualifying other practitioner" under 21 U.S.C. § 823(g)(2)(G)(iv) until October 1, 2023.

I certify that I am licensed to prescribe Schedule III, IV, or V medications for the treatment of pain under State law.

I certify that I am NOT required by State law to be supervised by OR work in collaboration with a qualifying physician to prescribe Schedule III, IV, or V medications.

OR

I certify that I am required by State law to be supervised by OR work in collaboration with a qualifying physician to prescribe III, IV, or V medications.

Supervisory/Collaborating Physician Name

Buprenorphine Waiver Notification

I certify that I have completed the required 24 hours of training for the treatment and management of opioid-dependent patients described under 21 U.S.C. § 823(g)(2)(G)(iv)(II)(aa), which covered the following topics: opioid maintenance and detoxification; appropriate clinical use of all drugs approved by the FDA for the treatment of opioid use disorder; initial and periodic patient assessments (including substance use monitoring); individualized treatment planning, overdose reversal, and relapse prevention; counseling and recovery support services; staffing roles and considerations; and diversion control. I am therefore a qualifying other practitioner. Check and provide copies of documentation (e.g., certificates of completion for the 8- and 16-hour MAT training courses) for all that apply.

Completion of:

- American Society of Addiction Medicine (ASAM)
- American Osteopathic Association (AOA)/American Osteopathic Academy of Addiction Medicine (AOAAM)
- American Academy of Addiction Psychiatry (AAAP)
- American Medical Association (AMA)
- American Psychiatric Association (APA)
- The American Association of Nurse Practitioners (AANP)
- The American Academy of Physician Assistants (AAPA)
- SAMHSA's Providers' Clinical Support System (PCSS)
- American Nurses Credentialing Center (ANCC)
- American Psychiatric Nurses Association (APNA)

Please Provide Date(s) of Completion:

SECOND NOTIFICATION FOR 100 PATIENTS - I certify that my qualifications from my initial notification request have not changed.

NEW NOTIFICATION TO TREAT 100 PATIENTS - I certify that I provide medication-assisted treatment with covered medications (as such terms are defined under 42 C.F.R. § 8.2) in a qualified practice setting as described under 42 C.F.R. § 8.615.