Treatment Program Requirements

Providers  
**Buprenorphine, Buprenorphine/naloxone**

**Qualifications:** Qualified providers must obtain a waiver of authority to prescribe any medication that is a scheduled III, IV, or V and FDA approved for the treatment of opioid dependence for the purpose of detoxification or maintenance treatment of patients with opioid dependence. With DATA 2000, physicians became legally qualified to receive waiver training. In July 2016 the Comprehensive Addiction and Recovery Act was signed into law increasing buprenorphine prescription authority to also include physician assistants and nurse practitioners for 5 years (until Oct, 2021).

**Physician Waiver Eligibility:** To be eligible for a waiver, providers must have a current state medical license, a valid registration number from the US Drug Enforcement Agency (DEA), completion of 8 hours of an approved waiver training course, and one or more of the following:

* + Board subspecialty certification for addiction psychiatry (*American Board of Medical Specialties),* addiction (*American Society of Addiction Medicine*), or addiction medicine (*American Osteopathic Academy of Addiction Medicine)*

–OR–

* + Participation as an investigator in one or more trials that led to the FDA approval of buprenorphine/naloxone or another Schedule III-V narcotic medication used for the maintenance or detoxification treatment of opioid addiction

–OR–

* + Other training or experience deemed equivalent by either the state Medical Board or by the Secretary of Health and Human Services (HHS).

**NP/PA Waiver Eligibility:** To be eligible for a waiver,NPs and PAs must complete 24 hours of approved training that covers the following topics: opioid maintenance and detoxification; clinical use of all FDA-approved drugs for medication-assisted treatment; patient assessment; treatment planning; psychosocial services; staff roles; and diversion control. NPs and PAs who are approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician if required by law in their state. NP/PA will be limited to 30 patients at a time in the first year and then can apply to HHS for an extended waiver to 100.

**Referrals:** Providers must be able to refer patients to counseling or psychiatric services.

**Patient Limits:** For the first year of receiving a waiver, providers are limited to treating 30 active patients at any given time; after the first year, they are limited to treating 100 patients at any given time. (e.g., prescription written for 30 days, patient is discharged, that patient continues to count under that physician number until the end of that 30 day prescription.) To become eligible to treat up to 100 patients per provider, the provider needs to apply to CSAT for the extended waiver prior to increasing to 100 patients.

Recent legislation has expanded limits for eligible physicians to treat up to 275 patients, but the rule does not extend prescribing authority to other clinicians. Eligible physicians must complete a ‘Request for Patient Increase Form’ and receive approval prior to increase. To be eligible for a patient limit of 275, a physician must have a current waiver to treat up to 100 patients, and must have maintained that waiver for at least one year without interruption.

Physicians wishing to increase to a patient limit of 275 must also meet one of the following requirements:

* Hold a board certification in addiction psychiatry or addiction medicine
  + Certifying agencies: American Board of Medical Specialties (ABMS), American Society of Addiction Medicine (ASAM), American Board of Addiction Medicine (ABAM), American Osteopathic Academy of Addiction Medicine

–OR–

* Practice in a “qualified practice setting.”
  + A “qualified practice setting” must: provide professional coverage for patient emergencies during hours when the practice is closed, provide access to case-management services, accept third-party payment for health service costs, utilize health information technology, and be registered by their state prescription drug monitoring program where operational.

**naltrexone**

Naltrexone is not a scheduled medication and therefore does not require a special licensure, certification, or waiver to prescribe. Any individual who is licensed to prescribe medication (physician, nurse practitioner or physician assistant) may prescribe and/or administer naltrexone. There is no limit to the number of patients that a provider could legally treat with naltrexone. However, when treating patients with substance use disorders, it is important that providers understand the nature of the underlying disorder, the pharmacological properties of available medications, and the importance of patient selection and monitoring.

Nurse Care Managers (If utilizing this service delivery model)  
Licensed to practice nursing in the state for which they are practicing.

* Complete an initial 8-hour nurse care management training curriculum:   
  Office Based treatment with buprenorphine/naloxone, including the use of buprenorphine/naloxone for the treatment of opioid use disorder in the office setting, based on the TAP 30. Training regarding the use of naltrexone for the treatment of alcohol use disorder and prevention of relapse to opioid dependence.

**Curriculum Includes**:

* Legislative regulations, DEA requirements, pharmacology of buprenorphine/naloxone and naltrexone, considerations in determining patient appropriateness, induction and management procedures, guidelines for pain management, safety, storage, diversion, and psychological counseling during OBAT treatment including self-help and holistic supports, relapse, special circumstances such as pregnancy, adolescence, elderly, chronic disease, surgery, pain management, HIV, and hepatitis C.
* Attend “booster trainings” on topics relevant to OBAT program (e.g., hepatitis C treatment and management, urine toxicology screening [UTS], relapse prevention, overdose prevention education, motivational interviewing, retention, harm reduction, compassion fatigue, case discussions, materials development, and networking)

**Responsibilities**:

* Oversight of buprenorphine/naloxone and naltrexone intake assessment, induction, stabilization, maintenance and relapse management.
* Ensuring that state and federal guidelines are followed, and collaborating as needed with OBAT provider, social worker/counselors, psychiatrists, pharmacy, primary care physician, and specialty care physicians to whom the patient has been referred.
* Coordinating between OBAT provider and pharmacy: obtain medication history, assist with prescription processing and refills, prior authorizations, insurance issues, concerns of diversion, use, safety, storage, and behavioral health referrals.

Program Manager

* Provides administrative support to the team: completes state reporting requirements, assists with resolving insurance issues, prior authorizations, patient scheduling, team meetings, staffing, program issues, meetings and supervision of data coordinator and hotline coordinator.
* Manages provider files (e.g., DEA numbers, curriculum vitae, state licensure).
* Supports DEA site visits.
* Manages insurance issues, keeps current with changes and passes this information along as warranted.
* Manages lists of patients per provider to assure compliance with DEA requirements.
* Assists with program and state requests for data.
* Manages OBAT provider meetings with nurses, medical assistants, providers, medical director, project coordinator, and program director.
* Collaborates with outside agencies as needed to foster relationships with OBAT and better serve our patients (e.g., counseling services, psychiatry, Department of Children and Families, and Corrections).
* Supports specialty programs (e.g., criminally involved, pregnant women, and adolescents)

SAMHSA’s Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies

**BUPRENORPHINE ADMINISTRATIVE REQUIREMENTS**

* Certification, accreditation and waiver approval.
* Provide training for prescribers and addiction professionals on the use of medications in the treatment of opioid dependence.
* Maintain accurate provider records.
* Records on dispensation of buprenorphine and buprenorphine/naloxone must be kept in accordance with DEA regulations for controlled substances as described in 21 CFR 1304.03(b).
* Records on prescription and dispensation of medications for the detoxification and maintenance treatment of opioid dependence must be kept in accordance with DEA regulations 21 CFR 1304.03(c)
  + Maintain log to include patient identifier, name, dose, and quantity of drug prescribed/dispensed, and date.
  + Requirement may be fulfilled by keeping copies of prescriptions in the patient record. Electronic medical records where the prescription records can be accessed fills this requirement and there is no need to keep copies of the prescriptions in your office.
* For DATA 2000 compliance, DEA only needs to review records for medications used in the treatment of opioid dependence; therefore, an option is to keep separate records for these medications to facilitate the review.

Program Expectations

* Appointment frequency with nursing and provider.
* Counseling requirement and psychiatric assessment and follow-up if warranted.
* Medication refills.
* Relapse prevention and support.
* Treatment planning and review.
* Enhanced treatment as required.
* Team meetings and assessment if needed.
* Medical supports, involvement with medical team.
* Team involvement in treatment to include: nurses, program directors and administrators, providers, counselors, family or other supports if available, and psychiatric supports.
* Review and educate patient on: expected adverse events including potential for withdrawal, precipitated withdrawal, opioid antagonism and other side effects. See package inserts (See Appendix 11A)
* Review and educate patient on: safe storage, responsibilities for medication storage and lost/stolen policies (See Appendix 10D), handling, and use of medication, including pediatric exposure concerns. See Pediatric Exposure Brochure (Appendix 11D).
* Inform the patient that the initial interview is not a guarantee of treatment. Following the interview, the team must review each case, including lab results, before determining whether buprenorphine/naloxone or naltrexone treatment is an appropriate option for the patient in this outpatient treatment setting.
* Review clinic hours and times available for scheduling visits.
* If unable to meet the patient’s needs and the program requirements, site will assist in referring the patient to another treatment setting that may be better able to meet the needs of the patient.