

Opioid/Medication Assisted Treatment License & Oversight

What is licensed by DBHDS?

Opioid treatment services (OTP) where:

1. Methadone and buprenorphine products are dispensed onsite; and
2. Treatment is combined with outpatient services such as counseling sessions (required) assessments, therapy, psychotherapy, etc; and
3. The physician is operating within/under a DBHDS licensed entity.

***Please note: Opioid treatment services that are provided under a waived physician license and involve dispensing of buprenorphine only during the induction phase does NOT require a license by DBHDS. See below for more information.**

"Medication assisted treatment (Opioid treatment service)" means an intervention strategy that combines outpatient treatment with the administering or dispensing of synthetic narcotics, such as methadone or buprenorphine, approved by the federal Food and Drug Administration for the purpose of replacing the use of and reducing the craving for opioid substances, such as heroin or other narcotic drugs.

Specific DBHDS Licensing Regulations for OTP/MAT Providers:

12VAC35-105-925. through 12VAC35-105-1050.

Applicable DBHDS Definitions:

"Outpatient service" means treatment provided to individuals on an hourly schedule, on an individual, group, or family basis, and usually in a clinic or similar facility or in another location. Outpatient services may include diagnosis and evaluation, screening and intake, counseling, psychotherapy, behavior management, psychological testing and assessment, laboratory and other ancillary services, medical services, and medication services. "Outpatient service" specifically includes:

1. Services operated by a community services board or a behavioral health authority established pursuant to Chapter 5 (§ 37.2-500 et seq.) or Chapter 6 (§ 37.2-600 et seq.) of Title 37.2 of the Code of Virginia;
2. Services contracted by a community services board or a behavioral health authority established pursuant to Chapter 5 (§ 37.2-500 et seq.) or Chapter 6 (§ 37.2-600 et seq.) of Title 37.2 of the Code of Virginia; or
3. Services that are owned, operated, or controlled by a corporation organized pursuant to the provisions of either Chapter 9 (§ 13.1-601 et seq.) or Chapter 10 (§ 13.1-801 et seq.) of Title 13.1 of the Code of Virginia.

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“Medication administration” means the direct application of medications by injection, inhalation, ingestion, or any other means to an individual receiving services by (i) persons legally permitted to administer medications or (ii) the individual at the direction and in the presence of persons legally permitted to administer medications.

12VAC35-105-930. Registration, certification, or accreditation. The opioid treatment service shall maintain current registration or certification with:

1. The federal Drug Enforcement Administration (DEA);
2. The federal Substance Abuse and Mental Health Services Administration (SAMHSA); and
3. The Virginia Board of Pharmacy.

What are the staffing requirements for DBHDS Opioid Treatment Service License?

Demonstrate that there are sufficient personnel available to meet the following staffing requirements and qualifications:

1. The program director shall be licensed or certified by the applicable Virginia health regulatory board or by a nationally recognized certification board or eligible for this license or certification with relevant training, experience, or both, in the treatment of individuals with opioid addiction;
2. The medical director shall be a board-certified addictionologist or have successfully completed or will complete within one year a course of study in opiate addiction that is approved by the department;
3. A minimum of one pharmacist;
4. Nurses;
5. Counselors shall be licensed or certified by the applicable Virginia health regulatory board or by a nationally recognized certification board or eligible for this license or certification; and
6. Personnel to provide support services

What is a Buprenorphine Waivered Practitioner? What is an OBOT (Opioid-Based Outpatient Treatment)?

Waivered practitioners operating under OBOTS do not have to be licensed by DBHDS.

Qualified practitioners who are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications (medications that have a lower risk for abuse, like buprenorphine) in settings other than an opioid treatment program (OTP) such as a methadone clinic. Opioid treatment services that are provided under a waivered physician and involve dispensing of buprenorphine during the induction phase only would NOT require a license by DBHDS; these are services that are covered under the physician’s license under the Board of Medicine.

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DMAS currently defines this in 12VAC30-130-5020 . "Office-based opioid treatment" or "OBOT" means addiction treatment services for individuals with moderate to severe opioid use disorder provided by buprenorphine-waivered practitioners working in collaboration with credentialed addiction treatment practitioners providing psychosocial counseling in public and private practice settings. For more information regarding DMAS definitions and regulations, please see [DMAS ARTS Information Website](#).

OBOTs do not need a DBHDS OTP/MAT license if they:

1. Are providing opioid treatment under the license of a buprenorphine-waivered practitioner;
2. Will not be dispensing methadone or other opioid treatment medication on site **or** will only dispense buprenorphine products during induction, and;
3. Will provide prescriptions for buprenorphine products to patients after the induction.

Under the [Drug Addiction Treatment Act of 2000 \(DATA 2000\)](#), qualified practitioner may apply for waivers to treat opioid dependency with approved buprenorphine products in any settings in which they are qualified to practice, including an office, community hospital, health department, or correctional facility. A "qualifying physician" is specifically defined in DATA 2000 as one who is:

- Licensed under state law (excluding physician assistants or nurse practitioners); and
- Registered with the Drug Enforcement Administration (DEA) to dispense controlled substances; and
- Required to treat no more than 30 patients at a time within the first year and then required to complete the [Online Notification Form to Increase Patient Limit](#) (to SAMHSA) at least one year after initial waiver was approved; and
- Qualified by training and/or certification.

In addition, in order to maintain a waiver, a physician must be capable of referring patients to counseling and other services.

What is the process to become waived?

In order to prescribe or dispense buprenorphine, physicians must [qualify for a physician waiver](#), which includes completing eight hours of required training, and [applying for a physician waiver](#). Physicians can complete the [Online Request for Patient Limit Increase](#).

- **Physicians are also required to complete [buprenorphine training](#) and provide their training certificate after completing the Waiver Notification Form.**
- These waiver applications are forwarded to the DEA, which assigns the physician a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the physician's regular DEA registration number.
- SAMHSA reviews waiver applications within 45 days of receipt. If approved, physicians receive a letter via email that confirms their waiver and includes their prescribing identification number.

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- SAMHSA is finalizing the criteria for Nurse Practitioners and Physician Assistants to qualify for a buprenorphine waiver.

Why doesn't DBHDS license Buprenorphine (Suboxone) Waiver Physicians?

- DBHDS does not have statutory authority to regulate physicians.

Which agencies regulate buprenorphine waived physicians?

- The Virginia Board of Medicine
- The federal Substance Abuse and Mental Health Services Administration (SAMHSA)
- The federal Drug Enforcement Agency (DEA)

Which agencies regulates pharmacies that dispense Buprenorphine (Suboxone)?

- The Virginia Board of Pharmacy
- DEA