



Terminal Distributor License for Office-Based Opioid Treatment

Updated 12/8/2020

[Section 4729.553 of the Ohio Revised Code](#) requires any location where a prescriber is treating more than thirty individuals for opioid dependence or addiction using a controlled substance to obtain a license as a terminal distributor of dangerous drugs with an office-based opioid treatment (OBOT) classification.

Treatment of opioid dependence or addiction using a controlled substance does not necessarily mean that such medication must be on-site. It can also apply to practices where prescriptions for controlled substances are issued for opioid addiction/dependence and the patient receives medication from a pharmacy.

Be advised that the following entities are exempt from licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment (OBOT) classification:

1. Hospitals registered with the Ohio Department of Health under section 3701.07 of the Revised Code.
2. Facilities for the treatment of opioid dependence or addiction that are operated by a hospital.
3. Physician practices owned or controlled, in whole or in part, by a hospital or an entity that owns or controls, in whole or in part, one or more hospitals.
4. Facilities that only conduct clinical research and use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the Association for the Accreditation of Human Research Protections Programs, Inc.
5. Facilities that hold a category III terminal distributor of dangerous drugs license for the purpose of treating drug dependence or addiction as part of an opioid treatment program and are already subject to certification by the U.S. Substance and Mental Health Services Administration (SAMHSA).
6. A program or facility that holds a license or certification issued by the Ohio Department of Mental Health and Addiction Services under Chapter 5119. of the Revised Code if the license or certification is approved by the State Board of Pharmacy. **On 3/4/2019, the Board approved General Services Certification issued by the Ohio Department of Mental Health and Addiction Services (R-2019-173).**
7. A federally qualified health center or federally qualified health center look-alike, as defined in [section 3701.047 of the Revised Code](#).
8. A state or local correctional facility, as defined in [section 5163.45 of the Revised Code](#).
9. **Effective 12/16/2020:** A facility in which patients are treated on-site for opioid dependence or



addiction exclusively through direct administration by a physician, physician assistant, or advanced practice registered nurse of drugs that are used for treatment of opioid dependence or addiction and are neither dispensed nor personally furnished to patients for off-site self-administration.

To apply for a license, visit: <https://elicense.ohio.gov>. Supplemental application forms and eLicense guides can be accessed here: <https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

IMPORTANT: Unless exempted, any facility treating more than thirty individuals with controlled substances for opioid dependence or addiction without being properly licensed will be in violation of Ohio law. Penalties for failure to obtain proper licensure include monetary fines of up to \$5,000.

Physician Ownership Requirement and Waivers

The law requires an OBOT facility be owned and operated solely by one or more physicians authorized by the State Medical Board to practice medicine or osteopathic medicine. However, the law provides that the Board has the authority to waive this requirement. The waiver form is available for download under the FORMS section of the terminal distributor licensing page:

<https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

Criminal Records Checks

The law also requires any person with ownership of the facility to submit to a criminal records check and send the result directly to the Pharmacy Board for review.

Additionally, the law requires all employees of the facility to submit to a criminal records check to ensure that a person is not employed by the facility if the person, within the ten years immediately preceding the date the person applied for employment, was convicted of, or pleaded guilty to, either of the following:

- A theft offense, described in division (K)(3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the United States; or
- A felony drug offense, as defined in section 2925.01 of the Revised Code.

NOTE: A licensee or applicant may apply for a waiver for an employee who has previously been convicted of or pleaded guilty to any felony theft or drug offense within the ten years immediately preceding the date the person applied for employment.

Waivers will be granted on a case-by-case basis as determined by the Board. The waiver form is available for download under the FORMS section of the terminal distributor licensing page:

<https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

Frequently Asked Questions

What if I already have a terminal distributor license?

You will need to apply for a license as a terminal distributor of dangerous drugs with an office-based opioid treatment classification. The office-based opioid treatment license will take the place of your existing terminal distributor license.

I work in a multi-physician practice where each physician provides office-based opioid treatment to 30 or fewer patients. Is my practice required to obtain licensure?

No. The law requires licensure for any location where *a prescriber* is treating more than thirty individuals for opioid dependence or addiction using a controlled substance.

If a prescriber has multiple practice locations and treats more than 30 patients at each location, then each location will need its own terminal distributor license.

Will patients prescribed buprenorphine for chronic pain be included in each prescriber's patient count?

No. Patients treated for chronic pain using controlled substances will not be counted towards a prescriber's patient count and will not be used to determine if licensure is required.

I treat patients with long-acting injectable buprenorphine, am I required to obtain licensure?

Facilities that exclusively treat patients with long-acting buprenorphine are exempt from having to obtain a terminal distributor of dangerous drugs license with office-based opioid treatment classification. However, a standard terminal distributor license is required if long-acting controlled substances are maintained on-site. For more information on prescriber clinic licensing, visit: www.pharmacy.ohio.gov/prescriberTDDD.

REMINDER: Patients that receive prescriptions for buprenorphine that are administered outside of the facility are still counted towards the patient limits established under the law and may still require licensure as an OBOT.

For More Information

The Board has developed an inspection guide for TDDD-OBOT facilities. The guide can be accessed by visiting: www.pharmacy.ohio.gov/OBOTinspect

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: <http://www.pharmacy.ohio.gov/contact.aspx>.