



Terminal Distributor License for Office-Based Opioid Treatment

Updated 4-24-2017

On January 4, 2017, SB 319 was signed by Governor Kasich. A provision of this new law 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 classification. Please be advised that there are some exemptions to this requirement (see below).

The requirement to obtain a license as a terminal distributor with an office-based opioid treatment classification takes effect on **August 4, 2017**.

The application for licensure is available by visiting: www.pharmacy.ohio.gov/OBOTapplication

On or after August 4, 2017, any facility treating more than thirty individuals with controlled substances for opioid dependence or addiction without being properly licensed as a terminal distributor will be in violation of Ohio law (unless exempted – see below). Penalties for failure to obtain proper licensure include monetary fines of up to \$5,000.

NOTE: 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 at a pharmacy.

Exemptions to the Licensure Requirement

Under the law, the following are excluded from the office-based opioid treatment licensing requirements: (1) hospitals, (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), or (6) programs or facilities that are licensed or certified by the Ohio Department of Mental Health and Addiction Services.

Physician Ownership Requirement and Waivers

As with pain management clinics, the law requires the 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. Instructions for obtaining a waiver are included as part of the [application](#).

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 are required to submit to a criminal records check to ensure that no person is employed who has previously been convicted of or pleaded guilty to any felony theft or drug offense. Instructions for this process is outlined in the [application](#).

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.

An individual is considered a patient of the prescriber until the controlled substance prescription for the treatment of opioid dependence or addiction has expired or the timeframe in which the medication quantity should have been depleted in accordance with prescription instructions has elapsed.

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.

For More Information

A copy of the OBOT license application is available here:

www.pharmacy.ohio.gov/OBOTApplication

A copy of the OBOT rules (OAC 4729-18) can be accessed here:

www.pharmacy.ohio.gov/OBOTrules

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>.

For a summary of SB 319, please visit:

<https://www.legislature.ohio.gov/download?key=6079&format=pdf>