



## **Terminal Distributor License for Office-Based Opioid Treatment**

**Updated 11-18-2017**

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### **SPECIAL NOTICE REGARDING OBOT PROVIDERS:**

*The Board recognizes that those providing office-based opioid treatment (including prescribers, nurses and counselors) may have a history of substance-use disorder. Such a history does not automatically preclude a provider from practicing/working at a facility or serving as the responsible person for the facility (i.e. physician) if that provider complies with the terms of the provider's applicable probation or consent agreement and can demonstrate a pattern of sustained recovery.*

*Information documenting a provider's recovery should be submitted along with all copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions) with the facility application.*

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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 has been extended (see resolution at the end of this document) and now takes effect on **November 30, 2017**. The extension of the licensure deadline will allow the Board additional time to review and process license applications while not disrupting access to care.

**IMPORTANT UPDATE:** On November 13, 2017, the Board authorized the Executive Director, or the Director's designee, to grant an extension of the licensure requirements **only if** the facility has applied for a terminal distributor of dangerous drugs with an office-based opioid treatment facility license on or before November 30, 2017. Extensions issued are only valid until January 15, 2018.



The application for licensure is available by visiting: [www.pharmacy.ohio.gov/OBOTapplication](http://www.pharmacy.ohio.gov/OBOTapplication)

On or after November 30, 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); (6) programs or facilities that are licensed or certified by the Ohio Department of Mental Health and Addiction Services; (7) detoxification programs operated by a state or local correctional facility (see resolution at the end of this document).

### **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](#).

**Note: The Board has approved a waiver process that would permit the issuance of a license for a facility that employs an individual who has previously been convicted of or pleaded guilty to any felony theft or drug offense. Waivers will be granted on a case-by-case basis as determined by the Board. A copy of the resolution can be found at the end of this document and instructions for submitting the waiver have been added to 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](http://www.pharmacy.ohio.gov/OBOTapplication)

OBOT rules (OAC 4729-18) can be accessed here: <http://codes.ohio.gov/oac/4729-18>

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>

**Board Resolution: Extension of Office-Based Opioid Treatment Facility License**

**Adopted October 10, 2017**

The Board hereby extends the effective date for licensure, as required in section 4729.553 of the Revised Code, to November 30, 2017. The extension of the licensure deadline will allow the Board additional time to review and process license applications.

**Board Resolution: OBOT License Extension for Applicants**

**Adopted November 13, 2017**

The Board hereby authorizes the Executive Director, or the Director's designee, to grant an extension of the licensure requirements in section 4729.553 of the Ohio Revised Code only if the facility has applied for a terminal distributor of dangerous drugs with an office-based opioid treatment facility license on or before November 30, 2017. Extensions issued in accordance with this resolution are only valid until January 15, 2018.

**Board Resolution: Waiver for Employees with Felony Convictions for a Terminal Distributor of Dangerous Drugs with an Office-Based Opioid Treatment Facility Classification**

**Adopted July 12, 2017**

Pursuant to section 4729.25 of the Revised Code, the State of Ohio Board of Pharmacy finds that it is in the public interest to grant an application for a terminal distributor of dangerous drugs with an office-based opioid treatment facility (OBOT) classification for an entity employing a person who has previously been convicted of, or pleaded guilty to, an offense listed in division (D)(4) of section 4729.553 of the Revised Code, if all the following are met:

- 1.** Upon submission of an application, the applicant requests a waiver by the Board for the employee who has previously been convicted of, or pleaded guilty to, an offense listed in division (D)(4) of section 4729.553 of the Revised Code. **NOTE: THE REQUEST SHOULD BE ON A SEPARATE SHEET OF PAPER THAT ACCOMPANIES THE APPLICATION.**
- 2.** The applicant includes the employee's title, duties, and responsibilities, a detailed account (including date, place, circumstances, and disposition of the matter), and copies of relevant documents (such as court pleadings or orders). Additional information, including an in-person appearance before the Board or staff, may be requested.
- 3.** The Board will review the facts and circumstances related to each waiver request to determine the criminal background's potential nexus, if any, to the issuance of a license. Such factors may include, but are not limited to, the following:
  - a. Whether the facility plans to possess drugs on-site;
  - b. Supporting documentation from employers;
  - c. The employee's role in the provision of office-based opioid treatment;
  - d. The type and severity of the felony conviction;
  - e. The time that has elapsed since the conviction;

- f. If applicable, the employee's progress in completing the terms of probation from the employee's licensing agency;
  - g. A pre-inspection of the facility;
  - h. Any additional factors deemed appropriate by the Board.
4. If granted a waiver by the Board, the waiver shall be deemed in effect specific to the Board-reviewed OBOT employee for as long as the employee is employed by the license holder. The licensee shall inform the Board if the individual that obtained the waiver is no longer employed by the facility.

**Board Resolution: Detoxification in State and Local Correctional Facilities**

**Adopted October 10, 2017**

The Board hereby clarifies that detoxification using a controlled substance in a state or local correctional facility, as defined in section 5163.45 of the Ohio Revised Code, that is currently licensed as a category III terminal distributor of dangerous drugs, does not require licensure in accordance with section 4729.553 of the Ohio Revised Code.