



Ohio Revised Code

Section 4729.553 Office-based opioid treatment; licensure.

Effective: December 16, 2020

Legislation: House Bill 341 - 133rd General Assembly

(A) As used in this section:

(1) "Advanced practice registered nurse" has the same meaning as in section 4723.01 of the Revised Code.

(2) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(3) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.

(4) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled substance.

(5) "Physician" means an individual who is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(6) "Physician assistant" means an individual who is licensed under Chapter 4730. of the Revised Code.

(B)(1) Except as provided in divisions (B)(2) and (3) of this section, no person shall knowingly operate a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than thirty patients or that meets any other identifying criteria established in rules adopted under this section without holding a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.

(2) Division (B)(1) of this section does not apply to any of the following:

(a) A hospital;



- (b) A facility for the treatment of opioid dependence or addiction that is operated by a hospital;
 - (c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;
 - (d) A facility that conducts only clinical research and uses 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 protection programs, inc.;
 - (e) A facility that holds a category III terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code for the purpose of treating drug dependence or addiction as part of an opioid treatment program and is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11;
 - (f) A program or facility that holds a license or certification issued by the 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;
 - (g) A federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;
 - (h) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
 - (i) 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;
 - (j) Any other facility specified in rules adopted under this section.
- (3) A patient who receives treatment on-site for opioid dependence or addiction through direct



administration of a drug by a physician, physician assistant, or advanced practice registered nurse shall not be included in determining whether more than thirty patients are being provided office-based opioid treatment in a particular facility, clinic, or other location that is subject to division (B)(1) of this section.

(C) To be eligible to receive a license as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification, an applicant shall submit evidence satisfactory to the state board of pharmacy that the applicant's office-based opioid treatment will be operated in accordance with the requirements specified in division (D) of this section and that the applicant meets any other applicable requirements of this chapter.

If the board determines that an applicant meets all of the requirements, the board shall issue to the applicant a license as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification.

(D) The holder of a category III terminal distributor license with an office-based opioid treatment classification shall do all of the following:

- (1) Be in control of a facility that is owned and operated solely by one or more physicians, unless the state board of pharmacy waives this requirement for the holder;
- (2) Comply with the requirements for conducting office-based opioid treatment, as established by the state medical board in rules adopted under section 4731.056 of the Revised Code;
- (3) Require any person with ownership of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the state board of pharmacy for review and decision under section 4729.071 of the Revised Code;
- (4) Require each person employed by or seeking employment with the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code;
- (5) 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, unless the state board of pharmacy permits the person to be employed by waiving this requirement for the facility:

(a) 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;

(b) A felony drug offense, as defined in section 2925.01 of the Revised Code.

(6) Maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list.

(E) No person subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification shall knowingly fail to remain in compliance with the requirements of division (D) of this section and any other applicable requirements of this chapter.

(F) The state board of pharmacy may impose a fine of not more than five thousand dollars on a person who violates division (B) or (E) of this section. A separate fine may be imposed for each day the violation continues. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(G) The state board of pharmacy shall adopt rules as it considers necessary to implement and administer this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.