



Ohio Revised Code

Section 4729.553 Office-based opioid treatment; licensure.

Effective: August 4, 2017

Legislation: Senate Bill 319 - 131st General Assembly

(A) As used in this section:

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

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

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

(B)(1) Except as provided in division (B)(2) 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 division (G) of 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 is licensed or certified by the department of mental health and addiction services under Chapter 5119. of the Revised Code.

(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 authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, unless the state board of pharmacy has exempted the holder from this requirement;

(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 all employees of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and ensure that no person is employed who has previously been convicted of, or pleaded guilty to, either of the following:

(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.

(5) 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.