

4729-18-01

Office-Based Opioid Treatment - Definitions.(A) As used in this chapter:

- (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.
- (4) "Patient limit" means the maximum number of individual patients that a prescriber may dispense or prescribe a schedule III, IV, or V controlled substance narcotic for the treatment of opioid dependence or addiction at any one time. A patient counts towards a prescriber's patient limit 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.
- (5) "Terminal distributor of dangerous drugs with an office-based opioid treatment classification" means a facility, clinic, or other location licensed as a category III terminal distributor where a prescriber provides office-based opioid treatment to more than thirty patients at any one time. It does not include 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 (12/05/2016); or

(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.

4729-18-02

Ownership and Responsible Person.

(A) The holder of a category III terminal distributor license with an office-based opioid treatment classification shall 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.

(B) An exemption to paragraph (A) of this rule may be granted by the board upon request of an applicant.

(1) An exemption request shall be included as part of the facility's initial licensure application for a terminal distributor of dangerous drugs license with an office-based opioid treatment classification. The request shall include all information, as deemed necessary by the board, to determine if it is in the public interest to issue a license to a facility that does not meet the requirements of paragraph (A) of this rule. The board reserves the right to request additional information from the applicant and conduct an inspection of the facility pursuant to rule 4729-9-09 of the Administrative Code prior to rendering its decision.

(2) If the board approves an exemption to paragraph (A) of this rule, the facility shall retain the exemption unless there is a change of ownership. Upon any change of ownership, the facility shall submit a new application pursuant to rule 4729-9-08 of the Administrative Code.

(3) An applicant whose request is denied by the board will be provided with a written explanation of the denial and allowed one opportunity to resubmit its request to address the identified concerns. The resubmission of the request shall occur with sixty days of receiving the board's written explanation or the application will be deemed abandoned in accordance with rule 4729-9-01 of the Administrative Code.

(4) In determining whether to grant an exemption request pursuant to paragraph (B)(1) of this rule, the Board shall consider, at a minimum, all the following:

(a) The results of criminal records checks conducted in accordance with rule 4729-18-03 of the Administrative Code;

(b) The results of a pre-inspection authorized in accordance with rule 4729-9-09 of the Administrative Code, including compliance with rule 4729-18-04 of the Administrative Code;

(c) A review of any past disciplinary actions taken against any owner that are based, in whole or in part, on the professional's inappropriate prescribing, personally furnishing, diverting, administering, storing, compounding, supplying or selling a controlled substance or other dangerous drug; and

(d) Commission of an act by any owner that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed.

(C) A location licensed as a terminal distributor of dangerous drugs with an office-based opioid treatment classification shall have a responsible person at all times.

(1) Only a physician who meets the following shall may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with an office-based opioid treatment classification license as defined in section 4729.553 of the Revised Code:

(a) The physician is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery; and

(b) The physician possesses a waiver to prescribe or personally furnish buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) (2/20/2017).

(2) A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the physician will be physically present at the location for at least fifteen hours per week. If the facility is not open more than fifteen hours per week, the minimum amount of on-site supervision shall be at least fifty percent of the total hours the facility is open, as reported to the board by the licensee on the application. Any changes to the licensee's hours of operation shall be reported to the Board, in a manner determined by the Board, within three business days.

(a) The hour requirements of this paragraph do not apply if either:

(i) The responsible person is unable to meet the requirements due to a documented illness or emergency and there is another physician on-site who meets the requirements of paragraph (C)(1) of this rule who can provide on-site supervision in accordance with the requirements described in this paragraph. The physician shall assume all responsibilities for compliance with this rule in the absence of the responsible person.

(ii) The location is closed for a state or federal holiday or other documented reason.

(3) The person to whom the category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification has been issued, the responsible person and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of an office based opioid

treatment facility and prescribing of controlled substances.

(4) Unless otherwise approved by the Board, no responsible person for a location licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification under section 4729.553 of the Revised Code shall:

(a) Have ever been denied a license to prescribe, dispense, personally furnish, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, personally furnishing, diverting, supplying or selling a controlled substance or other dangerous drug.

(b) Have been the subject of any of the following by the drug enforcement administration, the substance abuse and mental health services administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension or revocation of the physician's license, registration or DATA 2000 waiver;

(ii) A disciplinary action that was based, in whole or in part, on the physician's inappropriate prescribing, personally furnishing, diverting, administering, storing, compounding, supplying or selling a controlled substance or other dangerous drug; or

(iii) Surrender of any license or registration in lieu of disciplinary action.

(c) Have been convicted of any of the following:

(i) a felony;

(ii) a misdemeanor related to, or committed in, the practice of medicine;
or

(iii) an act of moral turpitude; or

(iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(5) When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner prescribed by the board.

(6) If applicable, a complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled

substances on hand with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

(7) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs as required in rule 4729-9-11 of the Administrative Code and maintaining all records relating to the distribution dangerous drugs pursuant to rule 4729-9-22 and rule 4729-9-14 of the Administrative Code.

(D) Unless approved by the board, no applicant for a terminal distributor of dangerous drugs with an office based opioid treatment classification shall be licensed as a terminal distributor of dangerous drugs with a pain management clinic classification pursuant to section 4729.552.

(E) A facility licensed as a terminal distributor of dangerous drugs with an office-based opioid treatment classification shall maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list and shall comply with change of ownership requirements in accordance with section 4729-9-08 of the Administrative Code.

4729-18-03

Criminal Records Checks for Office-Based Opioid Treatment Facilities.

- (A) All criminal records checks conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations (FBI) records check.
- (B) Pursuant to section 4729.553 of the Revised Code, a terminal distributor of dangerous drug license with an office-based opioid treatment classification will not be issued until the physician owner(s), or, if incorporated, the physician officers, of the office-based opioid treatment facility submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all required criminal records checks the license process will proceed.
- (C) If an exemption is requested pursuant to paragraph (B) of rule 4729-18-02 of the Administrative Code, a terminal distributor of dangerous drug license with an office-based opioid treatment classification will not be issued until the following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:
- (1) Based upon the terminal distributor's business type:
 - (a) All partners of a partnership;
 - (b) The sole proprietor of a sole proprietorship;
 - (c) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and, if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;
 - (d) The agency director of a government agency.
 - (2) The persons listed in paragraph (C)(1) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to a background check in accordance with this rule.
 - (3) The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all required criminal records checks the license process will proceed.

- (D) If there is a change in any of the persons listed in paragraphs (B) and (C) of this rule, only the new persons shall submit to a criminal records check as part of the change of ownership requirements pursuant to rule 4729-9-08 of the Administrative Code.
- (E) Physician owner(s), physician officers or owners pursuant to paragraph (C) of this rule are required to have all employees submit to a BCI&I and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code or a felony drug abuse offense as defined in section 2925.01 of the Revised Code.
- (1) BCI&I shall send the results of the BCI&I criminal records check directly to the employer or potential employer. BCI&I shall provide a letter regarding the FBI criminal records check to the employer or potential employer stating that there is either no record of any conviction or a letter stating that the request may not meet the criteria.
 - (2) When an employer or potential employer receives a letter stating that the request may not meet the criteria, they may share this information with the employee or potential employee.
 - (3) In order to complete the criminal records check, the employee or potential employee must then complete a "Request for Release-FBI Rapsheet" and send it to BCI&I to request a copy of the FBI criminal record results be sent directly to the employee or potential employee. The employee or potential employee must provide the results to the employer or potential employer. The employee or potential employee must provide the results to the employer or potential employer in the original sealed envelope received from BCI&I.
 - (4) The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

4729-18-04**Compliance.**

(A) A facility licensed as a terminal distributor of dangerous drugs with an office-based opioid treatment classification and all prescribers practicing at that facility shall comply with the following:

- (1) The requirements for conducting office-based opioid treatment pursuant to rule 4731-11-12 of the Ohio Administrative Code;
- (2) Patient limits and all other requirements set forth in 42 CFR Part 8 (9/9/2016);
- (3) Recordkeeping requirements pursuant to rule 4729-9-14 and 4729-9-22 of the Administrative Code;
- (4) Inspection and corrective action requirements pursuant to rule 4729-9-09 of the Administrative Code; and
- (5) All other state and federal laws, regulations, and rules pertaining to the prescribing of controlled substances and the distribution of dangerous drugs.