

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.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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