



## PROPOSED RULE FOR STAKEHOLDER COMMENT

**Issued 8/28/2020**

Acting under the authority of the Ohio Revised Code Chapter 4729, the State of Ohio Board of Pharmacy proposes the amendment of a rule regarding the ownership and operation of a terminal distributor of dangerous drugs with an office-based opioid treatment classification.

The intent of the rule is to ensure a comprehensive review of non-physician entities operating an OBOT clinic to promote the provision of quality MAT services.

Comments on the proposed rules will be accepted until close of business on **September 25, 2020**. Please send all comments to the following email address:

[ali.simon@pharmacy.ohio.gov](mailto:ali.simon@pharmacy.ohio.gov).



**4729:5-18-02 Ownership and Operation. (AMEND)**

(A) As used in this rule, "operator" means a person or entity that, through contract, informal arrangement, or other written or oral agreement, performs or manages some combination of services at the office-based opioid treatment clinic, including, but not limited to, any of the following:

(1) Control over day-to-day operations of a location;

(2) Participates in staffing decisions such as hiring, termination, promotion, or allocation of staff resources or structure;

(3) Has input into which clients or patients to accept or terminate from the program;

(4) Has input into methods of payments accepted;

(5) Selecting which contractors will provide services to the location and or providing payment to or for the selected contractors; or

(6) Handling payroll services for the location.

(B) Except as provided in paragraph (D) of this rule, the holder of a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification shall be in control of a clinic 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.

(C) Except as provided in paragraph (D) of this rule, the holder of a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification shall not utilize the services of an operator.

(D) A waiver of the requirements in paragraphs (B) and/or (C) of this rule may be granted by the board upon request of an applicant.

(1) A waiver request shall be included as part of the clinic'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 clinic that does not meet the requirement in paragraphs (B) and (C) of this rule. The board reserves the right to request additional information from the applicant and conduct an inspection of the clinic pursuant to rule 4729:5-3-03 of the Administrative Code prior to rendering its decision.

(2) In determining whether to grant a waiver request, the board shall consider, at a minimum, all the following:

(a) The results of criminal records checks conducted in accordance with rule 4729:5-18-03 of the Administrative Code;

(b) The results of an inspection authorized in accordance with rule 4729:5-3-03 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 owner's inappropriate prescribing, personally furnishing, diverting, administering, storing, compounding, supplying or selling a controlled substance or other dangerous drug;

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

(e) If the clinic is requesting to use an operator, documentation the clinic obtains from the proposed operator, in a manner determined by the board, that certifies all the following:

(i) That the operator's owners, officers, directors, or employees have not, within 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 as described in division (K)(3) of section 2913.01 of the Revised Code, regardless of the jurisdiction in which the act was committed;

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

(ii) That the operator's owners, officers, directors, or employees have not been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

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

(iii) That the operator maintains all approvals, licenses, or other qualifications needed to conduct business in this state;

(iv) That the operator will immediately notify the clinic if at any time during the term of the contract any information provided in the operator's certification changes; and

(v) That the operator agrees and acknowledges that the contract is subject to immediate termination if the operator provided any false or misleading information in its certification or if there is a subsequent material change to the certification.

(3) If a waiver is granted, failure to strictly comply with the conditions or restrictions contained in the approved waiver will immediately render the approval void, and the requestor may be subject to discipline or other formal action as if the waiver or variance had never been granted.

(4) If a waiver is granted in accordance with this rule:

(a) The clinic shall retain a physician-owner waiver only until there is a change of ownership at which time a new application shall be submitted pursuant to rule 4729:5-2-03 of the Administrative Code.

(b) The clinic shall retain an operator-waiver only until there is a change of operator, at which time a new waiver request shall be submitted.

(c) If a clinic discontinues use of an operator without employing a new operator, the clinic must notify the Board within ten days in a manner determined by the board.

(E) Certification documents described in paragraph (D)(2)(e) of this rule shall be prepared and signed by an employee of the operator who is directly authorized to sign on behalf of the operator.

(F) Any waiver that is granted pursuant to this rule is limited to the location for which the waiver was requested.

(G) An operator, with approval of the Board, may provide management services to more than one location, but each location seeking to use an operator must request a waiver pursuant to this rule.

(H) An operator granted a waiver under this rule, may not delegate its obligations or contractual duties to any third party, including affiliates or subcontractors, without prior approval from the Board. Any review of a third party assignee must include certifications related to its owners, officers, directors, or employees as set forth in (D)(2)(e).

(G) The clinic shall notify the board, in a manner determined by the board, within ten business days, if it receives notification pursuant to paragraph (D)(2)(e)(iv) of this rule, terminates a contract pursuant to paragraph (D)(2)(e)(v) of this rule, or otherwise discovers that an operator has provided false or misleading information in its certification.