



STATE OF
OHIO
BOARD OF PHARMACY

Rules for Stakeholder Feedback – Pain Management Clinic Ownership and Operation Rules

Date Issued: 11/15/2021

The State of Ohio Board of Pharmacy has been approached by owners of pain management clinics that seek to enter into operation agreements with management companies. To ensure the facility complies with Ohio's pain management clinic law, the Board proposes the adoption of new rule 4729:5-11-05.

Comments on the proposed rules will be accepted until close of business on **November 30, 2021**. Please send all comments to the following email address:
RuleComments@pharmacy.ohio.gov.



4729:5-11-05 Ownership and Operation. (NEW)

(A) As used in this rule, "operator" means a person, persons, 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, the following:

- 1) Control over day-to-day operations of a location; or
- 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 (C) of this rule, the holder of a category III terminal distributor of dangerous drugs license with a pain management clinic 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) A category III terminal distributor of dangerous drugs license with a pain management clinic classification may employ an operator so long as the physician owner retains sole control of the licensed location and the physician owner ensures all of the following and have documentation of such, where applicable, is maintained on site.

(1) The owner has ensured the operator has not committed an act that constitutes a misdemeanor or felony in this state, regardless of the jurisdiction in which the act was committed; and

(2) If the pain management clinic employs an operator, documentation the pain management clinic obtains from the proposed operator, in a manner determined by the board, that certifies all the following:

(a) That the operator's owners, officers, directors, or employees have not, within 10 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:

(i) 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;

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

(3) That the operator's owners, officers, directors, or employees have not been the subject of any of the following by an appropriate issuing body of any federal, state, or other jurisdiction, even if subsequently dismissed or resolved without formal discipline:

(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.

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

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

(6) That the operator agrees and acknowledges that the contract with the physician 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.

(D) The applicant or licensee is required to provide to the Board upon request unredacted documents related to the ownership and operation.

(E) The information an owner must review and maintain documentation of as required in this rule includes the following persons employed by an operator: corporate officers, including president, vice president, secretary, treasurer, CEO, CFO or any equivalent position, partner, sole proprietor.