

201 KAR 9:250. Registration and oversight of pain management facilities.

RELATES TO: KRS 218A.175, 311.530-311.620, 311.990

STATUTORY AUTHORITY: KRS 311.565(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. This administrative regulation establishes the requirements for registration and oversight for pain management facilities.

Section 1. Definitions. (1) "Board" is defined by KRS 311.550(1).

(2) "In good standing" means an active license to practice medicine or osteopathy that is not currently subject to any final order imposing any disciplinary sanction authorized by KRS 311.595, agreed order, or letter of agreement issued by or entered into with the board.

(3) "Pain management facility" is defined by KRS 218A.175(1), and each separate operating location of a physician's practice that meets the criteria established by this definition shall be considered a separate pain management facility.

(4) "Practitioner" means a licensed or certified health care practitioner who is legally authorized to prescribe or dispense controlled substances.

Section 2. Ownership or Investment Interest. (1)(a) A physician who has an ownership or investment interest in a pain management facility during any period when the physician is not licensed to practice medicine or osteopathy within the Commonwealth of Kentucky shall be deemed to be:

1. In violation of KRS 311.595(12); and

2. Practicing medicine without a license and subject to criminal sanctions.

(b) If the board determines that a physician has maintained an ownership or investment interest in a pain management facility during a period when that physician was not licensed to practice medicine or osteopathy within the Commonwealth of Kentucky, it may deny an application for licensing filed by that physician or may take appropriate disciplinary action against a license previously issued to the physician.

(2) A physician who maintains an ownership or investment interest in a pain management facility during any period when the physician's Kentucky license is not in good standing shall be in violation of KRS 311.595(12) and subject to disciplinary action by the Board.

Section 3. Registration; Amended Registration; Fee; New Facility Registration. (1) On or before September 1, 2012 and September 1 of each succeeding year, every pain management facility operating as the private office or clinic of a physician within the Commonwealth of Kentucky shall register with the board, providing the following specific information in writing:

(a) The name, business address, profession, current professional licensing status, and nature and extent of ownership or investment interest of each person who has or maintains an ownership or investment interest in the pain management facility;

(b) The names and addresses of every pain management facility in which the person has an ownership or investment interest;

(c) The hours of operation of every pain management facility in which the person has an ownership or investment interest;

(d) The names and professional status of each employee at each practice location owned and operated by that pain management facility;

(e) The name, professional license number, and practice address of the qualified physician owner or owner's physician designee who will be physically present practicing medicine in the

pain management facility for at least fifty (50) percent of the time patients are present at the facility. The facility shall also state its plan for ensuring that the designated physician owner or owner's physician designee will be physically present practicing medicine in the facility and, if the facility owns and operates multiple practice locations, the plan to ensure that a physician owner or owner's physician designee is physically present practicing medicine in each practice location for at least fifty (50) percent of the time that patients are seen at each pain management facility;

(f) For each owner's physician designee who will fulfill the oversight responsibility, an attestation that the physician designee is employed by the owner and the plan for owner supervision of the physician designee; and

(g) An attestation by the physician owner that the owner or owner's physician designee:

1. Meets one (1) of the requirements established in KRS 218A.175(3) and specifying each qualification met by the physician owner or owner's physician designee; or

2. Was an owner of that specific pain management facility prior to and continuing through July 20, 2012 and meets one (1) of the following qualifications:

a. Successfully completed a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS); or

b.(i) Registered the ownership or investment interest in that pain management facility with this board on or before September 1, 2012;

(ii) Was eligible for and provided the board with written verification that the licensee registered to complete the certification examination offered by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians in April 2013; and

(iii) Became certified by the American Board of Pain Medicine or by the American Board of Interventional Pain Physicians by September 1, 2013.

(2) If the physician failed the certification examination or failed to become certified by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians by September 1, 2013, the physician shall meet one (1) of the requirements established in KRS 218A.175(3), to continue to be qualified to provide the on-site supervision required by Section 5 of this administrative regulation.

(3) At the time of filing of the registration required by subsection (1) of this section, each pain management facility operating as the private office or clinic of a physician shall pay an annual fee of \$500 for each pain management facility to the board to defray the costs of registration and enforcement of this administrative regulation.

(4) If, during the effective period of the annual registration, a new or different physician obtains an ownership or investment interest in the pain management facility, or there is a change in the physician owner or physician designee who will practice on-site at least fifty (50) percent of the time the facility is open to patients, the facility shall file an amended registration with the board identifying these physicians and providing the information required by subsection (1) of this section about the new or different physicians, within fourteen (14) calendar days of that change.

(5) Failure to file the required registration or to pay the annual fee on or before September 1 of each year shall constitute a violation of KRS 311.595(12) and shall serve as a basis for discipline by the board against the license of any physician who has an ownership or investment interest in the facility that failed to file the required registration.

(6) If a new pain management facility operating as the private office or clinic of a physician comes into existence after September 1 of a calendar year but before September 1 of the fol-

lowing calendar year, that new pain management facility shall register with the board within fourteen (14) calendar days of its legal formation, and shall meet each of the registration requirements of this section.

Section 4. Identification and Qualifications of Prescribers Employed by the Facility; Notification of Changes. (1) As part of its initial or annual registration, the facility shall identify each practitioner, who is employed by the facility in any capacity, who will be prescribing or dispensing controlled substances to patients of the facility.

(2) Each licensed physician who will prescribe or dispense controlled substances to patients of the facility as part of the employment arrangement with the facility shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout the employment agreement with the facility. This continuing medical education requirement shall satisfy the requirement of 201 KAR 9:310.

(3) A licensed physician shall not prescribe or dispense controlled substances to patients of the facility if the physician has:

(a) Had an application for a license or certificate to prescribe, dispense, or administer controlled substances denied in any jurisdiction or by any governmental agency;

(b) Had a Drug Enforcement Administration permit to prescribe, dispense, or administer controlled substances revoked;

(c) Had the professional ability or authority to prescribe or dispense controlled substances revoked, restricted, or limited in any manner by a licensing authority of any state, except as provided by subsection (4) of this section; or

(d) Been convicted of or entered a plea of guilt, nolo contendere, or Alford plea, regardless of adjudication, to any felony or misdemeanor relating to controlled substances, in any state or federal court.

(4) The prohibition established in subsection (3)(c) of this section shall not apply if:

(a)1. The conduct requiring the revocation, restriction, or limitation was directly related to the physician's impairment as a result of controlled substance abuse or dependence;

2. The order imposing the revocation, restriction, or limitation is no longer in effect;

3. The physician has achieved a level of recovery which provides the licensing authority sufficient assurance that the physician will not likely engage in similar conduct while practicing at the pain management facility; and

4. The board or its panel has specifically approved the physician to practice in that specific pain management facility; or

(b) The physician has entered into an agreed order with terms and conditions requiring only remedial education and monitoring.

(5) The facility shall notify the board in writing within fourteen (14) days of each change in physician staffing of the facility.

Section 5. On-site Supervision. (1) If the physician owner or qualified designee is not present in each practice location of a pain management facility for at least fifty (50) percent of the time that patients are present at the practice location for any given calendar week as required by KRS 218A.175(3), the facility shall immediately notify the board of that fact in writing and include the reasons.

(2) Any violation of KRS 218A.175(3) or this section shall constitute a violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(3) and (4) by the physician owner and, if applicable, the qualified designee who was responsible for being present at the practice location during that period.

Section 6. Record-Keeping; Inspection. (1) Each pain management facility shall document on a weekly basis that a physician owner or an owner's physician designee who is employed by and under the direct supervision of the owner was physically present practicing medicine in the facility for at least fifty (50) percent of the time that patients were present in the facility during that week. This documentation shall include:

(a) The name, practice address, and phone number of the physician owner or physician designee who fulfilled this oversight function for that specific week;

(b) The practice address of each practice location owned and operated by that pain management facility;

(c) The days and hours each practice location of the pain management facility was open to patients during that specific week; and

(d) The days and hours the physician owner or physician designee was present in each practice location for the pain management facility for that specific week.

(2) Each pain management facility shall maintain appropriate records of the patients receiving treatment at that facility so that the board may determine the identity and number of patients treated during any given time period.

(3) The pain management facility shall maintain the weekly reports required by subsection (1) of this section and any daily sign-in sheets maintained by the practice on site in a readily accessible location for a minimum period of six (6) years.

(4) Upon request by an employee or agent of the board, the pain management facility shall permit the board employee or agent to inspect and copy the weekly reports and daily sign-in sheets maintained on site.

(5) For the purpose of enforcing the provisions of this administrative regulation, an agent of the board shall have the power and authority to:

(a) Enter upon professional premises during periods when those premises are otherwise open to patients or the public;

(b) Obtain evidence, including psychiatric or nonpsychiatric patient records, by consent or pursuant to a subpoena or search warrant;

(c) Interview all persons including owners, employees, or patients; and

(d) Require the production of books, papers, documents, or other documentary evidence either by consent or pursuant to a subpoena or search warrant.

Section 7. Proof of Operation of a Pain Management Facility. (1) The board may establish sufficient proof that a clinic, practice, or facility is a pain management facility subject to the provisions of this administrative regulation by establishing that:

(a) The facility has filed a registration with the board as a pain management facility; or

(b) 1. For any selected thirty (30) day period, the majority of patients receiving medical treatment from the clinic, practice, or facility received controlled substances or a prescription for controlled substances during that period; and

2. One (1) of the following additional conditions was present during that thirty (30) day period as required by KRS 218A.175(1)(a):

a. A primary component of the practice was the treatment of pain; or

b. The facility advertised in any medium for any type of pain management services.

(2) The board may establish sufficient proof that the majority of patients treated in the facility for any specified thirty (30) day period received controlled substances or a prescription for controlled substances on their visit by comparing the names on the sign-in sheet to the KASPER report for that thirty (30) day period.

Section 8. Violations; Enforcement; Emergency Action. (1) Any violation of the requirements of this administrative regulation shall constitute a violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(4) and may constitute a violation of KRS 311.595(9), as illustrated by KRS 311.597(3) given the circumstances.

(2) In order to lawfully prescribe or dispense controlled substances within the Commonwealth of Kentucky while practicing at a pain management facility, a licensee shall practice in a lawful pain management facility.

(3) A pain management facility shall be considered an unlawful pain management facility if it:

(a) Permits an unqualified person to gain or maintain an ownership or investment interest in the pain management facility; or

(b) Fails to ensure that a qualified physician owner or physician designee is physically present practicing medicine in the facility for at least fifty (50) percent of the time that patients are present in the facility.

(4) Prescribing or dispensing controlled substances within the Commonwealth of Kentucky while employed by or practicing in an unlawful pain management facility within the Commonwealth of Kentucky shall constitute a violation of KRS 311.595(9) and (12) which constitutes an immediate danger to the public health, safety, or welfare of the public, for the purposes of KRS 311.592 and 13B.125.

(5) If the board receives proof that a licensed physician is prescribing or dispensing a controlled substance while employed by or practicing in an unlawful pain management facility within the Commonwealth of Kentucky, the appropriate inquiry panel or its chair shall promptly issue an emergency order restricting that licensee from prescribing or dispensing a controlled substance within the Commonwealth of Kentucky until the licensee has provided sufficient proof that the licensee is no longer employed by or practicing in an unlawful pain management facility.

(6) An emergency order restricting a licensee from prescribing or dispensing a controlled substance within the Commonwealth of Kentucky issued pursuant to subsection (5) of this section shall remain valid and in effect until the board has received sufficient proof that the licensee is no longer employed by or practicing in an unlawful pain management facility. Upon receipt of that proof, the panel or its chair shall immediately issue an order terminating the emergency order issued pursuant to subsection (5) of this section.

(7) If a licensee who is affected by an emergency order issued pursuant to subsection (5) of this section requests an emergency hearing pursuant to KRS 13B.125(3), the hearing officer conducting the emergency hearing shall affirm the emergency order if presented with substantial evidence that the licensee was prescribing or dispensing controlled substances within an unlawful pain management facility.

(8) If a licensee prescribes or dispenses a controlled substance within the Commonwealth of Kentucky during any period when the licensee is employed by or practicing in an unlawful facility, each instance of prescribing or dispensing shall constitute a separate violation of KRS 311.595(12) and (9), as illustrated by KRS 311.597(1)(b), and shall serve as the basis for disciplinary sanctions pursuant to KRS 311.595.

Section 9. Periodic KASPER Reviews. (1) The board shall have the authority pursuant to KRS 218A.202 and 218A.240 to obtain KASPER reports and analyses for each practitioner practicing in a pain management facility.

(2) At least once each year, the board shall obtain a KASPER review and analysis for each physician who has or maintains an ownership or investment interest in, or is employed by, or practices in, a pain management facility to determine whether improper, inappropriate, or ille-

gal prescribing is occurring. If the board determines that there is evidence to indicate that improper, inappropriate, or illegal prescribing is occurring, it shall initiate an investigation of that physician and notify the appropriate agencies of its investigation. (39 Ky.R. 667; 1173; 1664; eff. 3-4-2013; 42 Ky.R. 2807; 43 Ky.R. 192; eff. 8-17-2016.)