

201 KAR 5:130. Controlled substances.

RELATES TO: KRS 218A.172, 218A.202, 218A.205(3)

STATUTORY AUTHORITY: KRS 218A.205(3)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.205(3) requires the board to promulgate administrative regulations on: prescribing standards for controlled substances; a procedure to temporarily suspend, limit, or restrict a license if unrestricted practice poses a danger to the health, welfare, or safety of patients or the public; a procedure for the expedited review of complaints pertaining to controlled substances; and penalties for convictions of offenses related to controlled substances. This administrative regulation establishes the requirements relating to controlled substances in the practice of optometry.

Section 1. Authorization to Prescribe Controlled Substances. A Kentucky licensed optometrist authorized to prescribe controlled substances for humans shall:

- (1) Have a current and valid DEA number;
- (2) Have submitted to the board a fingerprint-supported criminal record check by the Department of Kentucky State Police and Federal Bureau of Investigation for initial licensure to practice; and
- (3) Register and maintain such registration with Kentucky All Schedule Prescription Electronic Reporting (KASPER).

Section 2. Professional Standards for Prescribing Controlled Substances. (1) A Kentucky licensed optometrist authorized to prescribe controlled substances for humans shall:

- (a) Prescribe controlled substances only for the examination or treatment for a condition of the eye and its appendages;
- (b) Prescribe only Schedule II limited to hydrocodone combination products as defined in KRS 218A.010, Schedule III, IV, or V controlled substances; and
- (c) Prescribe controlled substances for a quantity therapeutically sufficient, up to seventy-two (72) hours.
 - (2) Prior to prescribing any controlled substance, a Kentucky licensed optometrist shall:
 - (a) Examine the patient face-to-face and in-person;
 - (b) Obtain a medical history and conduct a physical examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;
 - (c) Verify the fact that the patient that is prescribed a controlled substance is who the patient claims to be; and
 - (d) Establish a documented diagnosis through the use of accepted medical practices.
 - (3) Prior to prescribing a Schedule II controlled substance, a Kentucky licensed optometrist shall also:
 - (a) Query the electronic monitoring system established in KRS 218A.202 for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;
 - (b) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence;
 - (c) Discuss treatment objectives and further diagnostic examinations required; and
 - (d) Obtain written consent for the treatment.
 - (4) The requirements set forth within subsection (3) of this section shall not apply when:
 - (a) A licensed Kentucky optometrist prescribes or administers a controlled substance imme-

diately prior to, during, or within the fourteen (14) days following an operative or invasive procedure, if the prescribing or administering is medically related to the operative or invasive procedure and the medication usage does not extend beyond the fourteen (14) days;

(b) A licensed Kentucky optometrist prescribes or administers a controlled substance necessary to treat a patient in an emergency situation; or

(c) A licensed Kentucky optometrist prescribes or administers a controlled substance for the following:

1. Administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a practitioner in those hospitals or facilities where no institutional account exists, queries the electronic monitoring system established in KRS 218A.202 for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within the twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

3. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health; or

4. Within seven (7) days of an initial prescribing or dispensing as set forth within this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing or dispensing; and

b. Requires the patient to dispose of any remaining unconsumed medication.

(5) A Kentucky licensed optometrist authorized to prescribe controlled substances for humans shall not:

(a) Dispense any controlled substances;

(b) Write a prescription for a controlled substance that is refillable; and

(c) Prescribe:

1. With the intent or knowledge that a medication will be used, or is likely to be used, for other than a medicinal or an accepted therapeutic purpose; or

2. With the intent to evade any law with respect to sale, use, or disposition of the medication.

Section 3. Professional Standards for Documentation. A Kentucky licensed optometrist authorized to prescribe controlled substances shall keep accurate, readily accessible, and complete medical records which include:

(1) Medical history and eye examination;

(2) Diagnostic, therapeutic, and laboratory results;

(3) Evaluations and consultations;

(4) A written plan stating treatment objectives and further diagnostic examinations required;

(5) Discussion of risk, benefits, and limitations of treatments;

(6) Treatments;

(7) Medications, including date, type, dosage, and quantity prescribed;

(8) Instructions and agreements; and

(9) Written consent for treatment if the patient is prescribed a Schedule II controlled substance.

Section 4. Temporary Suspension, Limit, or Restriction of License. (1) The board may, without benefit of a hearing, temporarily suspend, limit, or restrict the license of an optometrist authorized to prescribe controlled substances if the board finds on the basis of reasonable evidence that the licensee has violated a statute or administrative regulation the board is empowered to enforce, or continued unrestricted practice by the licensee would constitute the substantial likelihood of danger to the health, welfare, or safety of the licensee's patients or of the general public.

(2) The temporary suspension, limit, or restriction of a license shall take effect upon receipt by the licensee of written notice, delivered by certified mail or in person, specifying the statute or administrative regulation violated. At the time the temporary suspension, limit, or restriction order issues, the board shall schedule a disciplinary hearing to be held in accordance with the provisions of KRS Chapter 13B within ten (10) days.

Section 5. Complaints. (1) The board shall consider all written complaints and sufficient anonymous complaints pertaining to the improper, inappropriate, or illegal prescribing of controlled substances. An anonymous complaint shall be considered sufficient if it is accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint is meritorious.

(2) Upon receipt of a complaint pertaining to the improper, inappropriate, or illegal prescribing of controlled substances, the board:

(a) May send a copy of the complaint to the Office of the Attorney General, the Department of the Kentucky State Police, and the Cabinet for Health and Family Services within three (3) business days to the extent otherwise allowed by law;

(b) Shall commence an investigation within seven (7) business days of the complaint;

(c) Shall produce a charging decision within 120 days of the complaint, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation; and

(d) Shall obtain the services of a specialist in the treatment of pain and a specialist in drug addiction to evaluate information received regarding a licensee's prescribing practices related to controlled substances if the board or its staff does not possess such expertise to ascertain if the licensee under investigation is engaging in improper, inappropriate, or illegal practices.

Section 6. Penalties. (1) Pursuant to the provisions of KRS 218A.205 (3):

(a) A licensee or applicant convicted of a felony offense in any state related to a controlled substance after July 20, 2012 shall, at a minimum, have a permanent ban on prescribing any and all controlled substances;

(b) A licensee or applicant who has been convicted of any misdemeanor offense relating to prescribing or dispensing controlled substances in any state shall have his or her authority to prescribe controlled substances suspended for at least three (3) months, and shall be further restricted as determined by the board; and

(c) A licensee or applicant disciplined by a licensing board of another state related to the improper, inappropriate, or illegal prescribing or dispensing of controlled substances shall, at a minimum, have the same disciplinary action imposed by the licensing board of the other state.

(2) A licensee or applicant who is authorized to prescribe controlled substances shall be subject to discipline by the board if:

(a) A licensee who is required to register for an account with KASPER fails to do so or does not maintain continuous registration; or

(b) A licensee or applicant fails to report to the board, within thirty (30) days of the action:

1. Any conviction involving controlled substances; or

2. Disciplinary action taken by another licensure board involving controlled substances.

(3) For purposes of this section, a conviction of a misdemeanor or felony offense relating to a controlled substance means any conviction or plea to a criminal charge, regardless of adjudication or the title of the offense named in the plea or judgment of conviction, that is determined from all available facts to have been based upon or resulted from, in whole or part, an allegation of conduct involving the improper, inappropriate, or illegal prescribing, dispensing, distribution, possession, or use of a controlled substance.

(4) Any violation of the professional standards established in this administrative regulation shall constitute a violation of KRS 218A.205, which may result in the imposition of disciplinary sanctions by the board pursuant to KRS 320.310.

(5) Pursuant to the provisions of KRS 218A.205(3)(g), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent. (39 Ky.R. 656; eff. 2-1-2013; 44 Ky.R. 2549; eff. 8-31-2018.)