201 KAR 8:540. Dental practices and prescription writing.

RELATES TO: KRS 218A.205(3), 313.060, 313.085, 422.317, 42 U.S.C. 300ee-2 note STATUTORY AUTHORITY: KRS 218A.205(3), 313.060(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 313.060(1) requires the board to promulgate administrative regulations relating to dental practices that shall include minimal requirements for documentation and Centers for Disease Control and Prevention compliance. 42 U.S.C. 300ee-2 note requires each state to institute the guidelines issued by the United States Centers for Disease Control and Prevention or guidelines that are equivalent to those promulgated by the Centers for Disease Control and Prevention concerning recommendations for preventing the transmission of the human immunodeficiency virus and the hepatitis B virus during exposure-prone invasive procedures. KRS 218A.205(3)(a) and (b) require the board, in consultation with the Kentucky Office of Drug Control Policy, to establish mandatory prescribing and dispensing standards related to controlled substances. This administrative regulation establishes requirements for preventing the transmission of the human immunodeficiency virus and the hepatitis B virus during exposure-prone invasive procedures and includes minimal requirements for documentation and Centers for Disease Control and Prevention compliance. This administrative regulation also establishes mandatory prescribing and dispensing standards related to controlled substances.

Section 1. Applicability. A dentist who is authorized to prescribe, dispense or administer a controlled substance shall comply with the standards of acceptable and prevailing dental practice for prescribing, dispensing or administering a controlled substance established in this administrative regulation.

Section 2. Professional Standards for Documentation of Dental Patients.

- (1) Each patient's dental records shall be kept by the dentist for a minimum of:
 - (a) Seven (7) years from the date of the patient's last treatment;
 - (b) Seven (7) years after the patient's eighteenth birthday, if the patient was seen as a minor; or
 - (c) Two (2) years following the patient's death.
- (2) Each dentist shall comply with KRS 422.317 regarding the release of patient records.
- (3) The dentist shall keep accurate, readily accessible, and complete records which include:
 - (a) The patient's name;
 - (b) The patient's date of birth;
 - (c) The patient's medical history and documentation of the physical exam of the oral and perioral tissues;
 - (d) The date of treatment;
 - (e) The areas to be treated;
 - (f) The material used in treatment;
 - (g) Local or general anesthetic used, route of administration, and the amount;
 - (h) Sedation medications used, the amount, monitoring techniques, and the names of qualified personnel that monitor the patient;
 - (i) Diagnostic, therapeutic, and laboratory results, if any;
 - (j) The findings and recommendations of the dentist and a description of each evaluation or consultation, if any;
 - (k) Treatment objectives;
 - (1) Any and all treatments performed and provided;
 - (m) All medications, including date, type, dosage, and quantity prescribed or dispensed; and
 - (n) Any post treatment instructions.

(4) Prior to prescribing or administering a Schedule II or III controlled substance, the dentist shall obtain the signature of the patient or a legal guardian on a consent form authorizing the treatment plan, including the use of controlled substances.

Section 3. Prescribing and Administration of Controlled Substances.

- (1) In accordance with KRS 313.035, a dentist may prescribe, dispense, and administer any non-controlled drug necessary within the scope of the dentist's practice if the dentist is licensed pursuant to KRS Chapter 313.
- (2) In accordance with KRS 313.035, a dentist may administer and prescribe controlled substances necessary within the scope of the dentist's practice if the dentist:
 - (a) Has obtained a registration from the Drug Enforcement Administration; and
 - (b) Has enrolled with and utilizes the Kentucky All Schedule Prescription Electronic Reporting System as required by KRS 218A.202.
- (3) A dentist shall not compound any scheduled drugs or dispense controlled substances for use by the patient outside the office setting.
- (4) A dentist shall obtain and document all relevant information in a patient's medical and dental records in a legible manner and in sufficient detail to enable the board to determine whether the dentist is conforming to professional standards.
- (5) Prior to the initial prescribing or administration of a Schedule II or III controlled substance, each dentist shall:
 - (a) Obtain and review a KASPER report 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) Document relevant information in the patient's record;
 - (c) Consider the available information to determine if it is medically appropriate and safe to administer or prescribe a controlled substance;
 - (d) Obtain a complete medical history and conduct a physical examination of the oral or maxillofacial area of the patient and document the information in the patient's medical record;
 - (e) Make a written treatment plan stating the objectives of the treatment and further diagnostic examinations required;
 - (f) 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; and
 - (g) Obtain written consent for the treatment.
- (6) Pursuant to KRS 218A.172, the requirements set forth within this section shall not apply when prescribing or administering a controlled substance:
 - (a) As part of the patient's hospice or end of life treatment;
 - (b) To a patient admitted to a licensed hospital as an inpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital.
 - (c) For the treatment of pain associated with cancer or with the treatment of cancer;
 - (d) As necessary to treat a patient in an emergency situation; or
 - (e) To a patient admitted to a long-term care facility.
- (7) A dentist shall not issue a prescription for more than a three (3) day supply of a Schedule II or III controlled substance to treat pain as an acute medical condition unless the following conditions have been met:
 - (a) The dentist, in his or her professional judgment, believes that more than a three (3) day supply of a Schedule II or III controlled substance is medically necessary to treat the patient's pain as an acute medical condition;

- (b) The dentist has documented in the patient's dental record the acute medical condition and lack of alternative treatment options which justifies deviation from the three (3) day supply limit established in this subsection; and
- (c) The patient and the dentist have attested by signature in the patient's dental record that alternative pain relief methods using non-opioid medications were explained to the patient and that the patient understands the risk of dependency when prescribed more than a three (3) day supply of a Schedule II or III controlled substance. This may occur:
 - 1. During, and in addition to, the patient's original consultation and consent process as described in subsection (5) of this section; or
 - 2. As part of a follow-up consultation after the initial three (3) day supply has been prescribed.
- (d) A dentist licensed in Kentucky shall not act to avoid the three (3) day supply limit established in subsection (4) of this section by prescribing or administering a Schedule II or III controlled substance to a patient on consecutive or multiple occasions.
- (8) A dentist may provide one (1) refill within thirty (30) days of the initial prescription for the same controlled substance for the same amount or less or prescribe a lower schedule drug for the same amount without a clinical reevaluation of the patient by the dentist.
- (9) A patient who requires additional prescriptions for a controlled substance shall be clinically reevaluated by the dentist, and the provisions of this section for the prescription of controlled substances shall be followed. If the course of treatment extends beyond three (3) months, the dentist shall obtain and review a new KASPER report. The dentist shall provide any new information about the treatment and modify or terminate treatment as appropriate.
- (10) Any violation of this section shall be considered a violation of KRS 218A.205(3), KRS 313.060, and KRS 313.085, and shall constitute a legal basis for disciplinary action pursuant to KRS 313.035.

Section 4. Penalties and Investigations.

- (1) A licensee convicted of a felony offense related to a controlled substance shall, at a minimum, be banned from prescribing or dispensing a controlled substance.
- (2) A licensee convicted of a misdemeanor offense relating to the prescribing of a controlled substance shall, at a minimum, have a five (5) year ban from prescribing or dispensing a controlled substance.
- (3) A licensee disciplined by a licensing board of another state relating to the improper, inappropriate, or illegal prescribing or dispensing of controlled substances shall, at a minimum, have the same disciplinary action imposed by this state or the disciplinary action prescribed in subsection (1) or (2) of this section, whichever is greater.
- (4) A licensee who is disciplined in another state or territory for an act or omission which would constitute a violation of Section 4 of this administrative regulation and fails to notify the board in writing of the disciplinary action within thirty (30) days of the finalization of the action shall be subject to a fine of \$1,000 for each failure to report.
- (5) If a licensee has been convicted of or has entered a plea of guilt, an Alford plea, or a plea for nolo contendere to any felony offense relating to a controlled substance; has successfully participated in and completed a diversion program; and whose case has been dismissed and the record of that offense expunged; the board may, in its discretion, reinstate the licensee's prescribing and dispensing privileges contingent upon the licensee entering into an agreed order with terms and conditions deemed necessary by the board to implement a minimum five (5) year period of probation.
- (6) The board may privately admonish a licensee who fails to register for an account with the Kentucky All Schedule Prescription Electronic Reporting System or who fails to meet

the requirements of this administrative regulation. If a licensee is privately admonished by the board under this subsection, the licensee shall be given no more than thirty (30) days to become compliant after which time the dentist may be fined up to \$10,000 for failure to be registered with KASPER. A licensee who fails to utilize KASPER prior to prescribing a controlled substance may be fined up to \$250 per incident by the board.

- (7) The Law Enforcement Committee of the Board shall produce a charging decision on the complaint within 120 days of the receipt of the complaint, unless:
 - (a) An investigation pertaining to the prescribing or dispensing of a controlled substance make it impossible to timely present the grievance to the designated review committee, person, or Law Enforcement Committee; or
 - (b) The board holds a complaint pertaining to the prescribing or dispensing of a controlled substance in abeyance to permit a law enforcement agency, upon the agency's request, to perform or complete an investigation.
 - (c) If a charging decision is not produced within 120 days of the date of receipt of the complaint under this subsection, the investigative report shall plainly state the circumstances pursuant to paragraphs (a) and (b) of this subsection that prevented the timely production of the charging decision.

Section 5. Infection Control Compliance.

- (1) Each licensed dentist in the Commonwealth of Kentucky shall:
 - (a) Adhere to the standard precautions outlined in the Guidelines for Infection Control in Dental Health-Care Settings published by the Centers for Disease Control and Prevention; and
 - (b) Ensure that any person under the direction, control, supervision, or employment of a licensee whose activities involve contact with patients, teeth, blood, body fluids, saliva, instruments, equipment, appliances, or intra-oral devices adheres with those same standard precautions.
- (2) The board or its designee shall perform an infection control inspection of a dental practice or office utilizing the Infection Control Inspection Checklist, if the board and its staff become aware of a violation, or a reliable allegation of a violation, of the Guidelines for Infection Control in Dental Health-Care Settings which may pose imminent public risk.

(3)

- (a) Any dentist who is found deficient upon an initial infection control inspection shall have thirty (30) days to be in compliance with the guidelines and submit a written plan of correction to the board.
- (b) The dentist may receive a second inspection after the thirty (30) days have passed and may be required to pay reasonable expenses to the board or its designee to conduct the inspection, not to exceed the amount of the fine required for failure of a second inspection pursuant to this chapter.
- (c) If the dentist fails the second inspection, he or she shall be immediately temporarily suspended pursuant to KRS 313.085 until proof of compliance is provided to the board and the dentist pays the fine as prescribed in this chapter.
- (4) Any licensed dentist, licensed dental hygienist, or dental assistant who performs invasive procedures may seek counsel from the board if he or she tests seropositive for the human immunodeficiency virus or the hepatitis B virus.
- (5) Upon the request of a licensee or registrant, the executive director of the board or designee shall convene a confidential expert review panel to offer counsel regarding under what circumstances, if any, the individual may continue to perform invasive procedures.

Section 6. Termination of a Patient-Doctor Relationship. In order for a licensed dentist to terminate the patient-doctor relationship, the dentist shall:

- (1) Provide written notice to the patient of the termination;
- (2) Provide emergency treatment for the patient for thirty (30) days from the date of termination; and
- (3) Retain a copy of the letter of termination in the patient records.

Section 7. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Guidelines for Infection Control in Dental Health-Care Settings", December 2003, or the latest version issued by the Centers for Disease Control on Infection Control in Dental Health Care Setting; and
 - (b) "Infection Control Inspection Checklist", July 2010.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at http://dentistry.ky.gov.
- (37 Ky.R. 624; 1629; eff. 2-4-2011; 39 Ky.R. 519; 1381; eff. 2-1-2013; 46 Ky.R. 80, 1177, 1410; eff. 11-18-2019.)