

GENERAL GOVERNMENT CABINET
Kentucky Board of Dentistry
(Amendment)

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: ~~[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 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. ~~[Definitions. (1) "Invasive procedure" means a procedure that penetrates hard or soft tissue.~~

~~—(2) "Oral surgery" means any manipulation or cutting of hard or soft tissues of the oral or maxillofacial area and associated procedures, by any means, as defined by the American Dental Association, utilized by a dentist licensed by 201 KAR Chapter 8 and within the dentist's scope of training and practice.]~~

Section 2. Professional ~~[Minimum Documentation]~~ Standards for Documentation of ~~[all]~~ 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 ~~[(18)]~~ 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 pe-

rioral tissues;

(d) The date of treatment;

(e) The ~~[tooth number, surfaces, or]~~ areas to be treated;

(f) The material used in treatment;

(g) Local or general anesthetic used, route of administration~~[the type]~~, and the amount;

(h) Sedation~~[Sleep or sedation dentistry]~~ medications used, the ~~[type, and 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;

(l) Any and all treatments performed and provided;

(m) All medications, including date, type, dosage, and quantity prescribed or dispensed; and

(n)~~(m)~~ Any post treatment instructions.

(4) Prior to prescribing or administering a Schedule II 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~~[Prescription Writing Privileges]~~. (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~~[:~~ ~~—(a) Is~~ is licensed pursuant to KRS Chapter 313.~~[201 KAR 8:532;]~~

(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)~~(b)~~ Has obtained a registration~~[license]~~ from the Drug Enforcement Administration; and

(b)~~(c)~~ Has enrolled with and utilizes the Kentucky All Schedule Prescription Electronic Reporting System as required by KRS 218A.202.

(3)~~(2)~~ A dentist shall not compound any scheduled drugs or dispense ~~[any Schedule I, Schedule II, or Schedule III]~~ controlled substances ~~[containing Hydrocodone]~~ 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)~~Section 4. Prescribing of Controlled Substances by Dentist.~~ ~~(1)~~ Prior to the initial prescribing or administration of a Schedule II~~[any]~~ controlled substance, each dentist shall:

(a) Obtain~~[Except as provided in subsection (2) of this section,]~~ and review a KASPER report for~~[all available data on the patient;]~~ 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 is associated with cancer or with the treatment of cancer; or

(d) As necessary to treat a patient in an emergency situation.

(7) A dentist shall not issue a prescription for more than a three (3) day supply of a Schedule II 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 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 controlled substance.

(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 controlled substance to a patient on consecutive or multiple occasions. ~~(2) A dentist shall not be required to obtain and review a KASPER report if:~~

~~—(a)1. The dentist prescribes a Schedule III controlled substance or one (1) of the Schedule IV controlled substances listed in subsection (3) of this section after the performance of oral surgery; and~~

~~—2. No more than a seventy-two (72) hour supply of the controlled substance is prescribed;~~

~~—(b) The dentist prescribes or dispenses a Schedule IV or V controlled substance not listed in subsection (3) of this section; or~~

~~—(c)1. The dentist prescribes pre-appointment medication for the treatment of procedure anxiety; and~~

~~—2. The prescription is limited to a two (2) day supply and has no refills.~~

~~—(3) A dentist shall obtain and review a KASPER report before initially prescribing any of the following Schedule IV controlled substances:~~

~~—(a) Ambien;~~

~~—(b) Anorexics;~~

~~—(c) Ativan;~~

~~—(d) Klonopin;~~

~~—(e) Librium;~~

~~—(f) Nubain;~~

~~—(g) Oxazepam;~~

~~—(h) Phentermine;~~

~~—(i) Soma;~~

~~—(j) Stadol;~~

~~—(k) Stadol NS;~~

~~—(l) Tramadol;~~

~~—(m) Versed; and~~

~~—(n) Xanax.]~~

~~(8)[(4)]~~ 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)[(5)]~~ 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[5]. Penalties and Investigations. (1) A licensee convicted of a felony offense related to ~~[prescribing and dispensing of]~~ a controlled substance shall, at a minimum, be ~~[permanently]~~ 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~~[who holds a Kentucky license]~~ 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~~[Section 4 of]~~ this administrative regulation. If a licensee is privately admonished by the board under this subsection, the licensee shall~~[receive a private admonishment from the board and]~~ be given no more than thirty (30) days to become compliant after which time the dentist may~~[shall]~~ be fined up to~~[a minimum of \$500 to a maximum of]~~ \$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)[(6)]~~ 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:~~[an extension for a definite period of time is requested by a law enforcement agency due to an ongoing criminal investigation.]~~

(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[6]. 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~~[201 KAR 8:520]~~.

(4) Any licensed dentist, licensed dental hygienist,~~registered dental assistant,~~ or dental assistant ~~[in training for registration]~~ 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[7]. 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[8]. 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>.

JEFF ALLEN, Executive Director

APPROVED BY AGENCY: June 14, 2019

FILED WITH LRC: June 14, 2019 at noon

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this Amendment shall be held on July 25 at 9:00 a.m. Eastern Time at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed Amendment. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed Amendment. Written comments shall be accepted through July 31, 2019. Send written notification of intent to be heard at the public hearing, or written comments on the proposed Amendment to the contact person below.

CONTACT PERSON: Jeff Allen, Executive Director, Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, phone (502) 429-7280, fax (502) 429-7282, email jeffrey.allen@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeff Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for dental prescribing, administration, and dispensing of substances.

(b) The necessity of this administrative regulation: KRS 313.060 requires the board to promulgate administrative regulations relating to dental practices which shall include conscious sedation of patients and compliance with federal controlled substances regulations.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes requirements for dental prescribing, administration, and dispensing of substances in compliance with federal controlled substances regulations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes requirements for dental prescribing, administration, and dispensing of substances in compliance with state controlled substances law.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment updates the requirements for dental prescribing, administration, and dispensing of substances.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary in order to bring the administrative regulation up-to-date with the current legal and regulatory requirements and best practices for dental prescribing, administration, and dispensing.

ing of substances.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment updates the requirements for dental prescribing, administration, and dispensing of substances in compliance with federal controlled substances regulations.

(d) How the amendment will assist in the effective administration of the statutes: The amendment ensures that the requirements for dental prescribing, administration, and dispensing of substances are up-to-date in compliance with state controlled substances law.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will primarily affect the approximately three thousand prescribing dentists licensed in Kentucky. Patients who receive prescriptions from a Kentucky licensed dentist may also be affected.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it an amendment, including:

(a) List the actions that each of the related entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Each entity will be required to prescribe substances and document their prescriptions in accordance with applicable law and administrative regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No costs will be accrued as a result of the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The amendment will result in a healthier patient population and the avoidance of potentially costly violations of applicable law and administrative regulations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No cost.

(b) On a continuing basis: No cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation? Not applicable.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No.

(9) TIERING: Is tiering applied? No; this amendment impacts all similarly situated practitioners equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? None.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.205(3), 313.060(1).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? No cost.

(d) How much will it cost to administer this program for subsequent years? No cost.

Note: If specific dollar amounts cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None.

Expenditures (+/-): None.

Other explanation: Not applicable.