

201 KAR 9:016. Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances.

RELATES TO: KRS 311.550, 311.595(9), 311.597, 311.842, 311.850(1)(s)

STATUTORY AUTHORITY: KRS 311.565(1), 311.842(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of licensees. KRS 311.595(9) and 311.597 authorize disciplinary action against physicians for specified offenses. KRS 311.842(1) requires the board to promulgate administrative regulations establishing prescribing and administering standards for physician assistants. This administrative regulation establishes the requirements governing the use of amphetamine and amphetamine-like anorectic controlled substances.

Section 1. Definitions.

- (1) "Board" is defined by KRS 311.550(1).
- (2) "Body mass index" means the weight of the patient in kilograms divided by the height in meters, squared.
- (3) "Licensee" means a person licensed to practice medicine or osteopathy or to practice as a physician assistant in the Commonwealth of Kentucky and authorized to prescribe, dispense, or administer controlled substances unless otherwise exempted by law.
- (4) "Schedule II amphetamine or amphetamine-like controlled substance" means:
 - (a) Amphetamine, its salts, optical isomers, and salts of optical isomers; or
 - (b) Methylphenidate.
- (5) "Schedule III or IV amphetamine-like controlled substance" means a drug classified as a stimulant pursuant to 902 KAR 55:015, Section 3 or 4.

Section 2. Prior to prescribing, ordering, dispensing, administering, selling, supplying, or giving an amphetamine or amphetamine-like controlled substance, a licensee shall take into account the:

- (1) Drug's potential for abuse;
- (2) Possibility that a drug may lead to dependence;
- (3) Possibility a patient will obtain the drug for a nontherapeutic use;
- (4) Possibility a patient will distribute it to others; and
- (5) Potential illicit market for the drug.

Section 3. Schedule II Amphetamine or Amphetamine-like Controlled Substances.

- (1) The patient's record shall denote the diagnosis that justifies treatment with a Schedule II amphetamine or amphetamine-like controlled substance.
- (2) A Schedule II amphetamine or amphetamine-like controlled substance shall be used to treat only:
 - (a) Narcolepsy;
 - (b) Attention deficit/hyperactive disorder;
 - (c) Resistant depressive disorder in combination with other antidepressant medications, or if alternative antidepressants and other therapeutic modalities are contraindicated;
 - (d) Drug-induced brain dysfunction;
 - (e) A diagnosis for which the clinical use of the Schedule II amphetamine or amphetamine-like controlled substance is investigational and the investigative protocol has been submitted, reviewed, and approved by the board prior to the clinical use of the drug; or
 - (f) An adult patient with a moderate to severe binge-eating disorder, if diagnosed according to criteria set forth in the Diagnostic and Statistical Manual of Mental Disorders at the time of diagnosis.

(3) A Schedule II amphetamine or amphetamine-like controlled substance shall not be utilized to treat obesity.

Section 4. Treatment of Obesity with a Schedule III or IV Amphetamine-like Controlled Substance.

(1) Prior to prescribing, administering, dispensing, ordering, selling, supplying, or giving a Schedule III or IV amphetamine-like controlled substance to treat obesity in a patient sixteen (16) years of age or older, the licensee shall:

- (a) Establish a licensee /patient relationship;
- (b) Determine that the patient is obese or overweight with medical risk factors and is a proper candidate for weight reduction treatment;
- (c) Determine and record the extent of prior anorectics or other controlled substances used by the patient. The prescribing licensee shall obtain and review a KASPER report for the twelve (12) month period immediately preceding the patient encounter, before prescribing or dispensing controlled substances to the patient;
- (d) Determine that the patient has either:
 - 1. A body mass index of twenty-seven (27) or more, unless the body mass index is twenty-five (25) to twenty-seven (27) and the patient has a co-morbidity such as a cardiovascular disease, diabetes mellitus, dyslipidemia, hypertension, or sleep apnea;
 - 2. Body fat greater than or equal to thirty (30) percent in females or greater than or equal to twenty-five (25) percent in males;
 - 3. Current body weight greater than or equal to 120 percent of a well-documented, long-standing, healthy weight that the patient maintained after age eighteen (18);
 - 4. A waist-hip ratio or waist circumference at a level indicating that the individual is known to be at increased cardiovascular or co-morbidity risk because of abdominal visceral fat; or
 - 5. Presence of a co-morbid condition or conditions aggravated by the patient's excessive adiposity; and
- (e) Provide the patient with carefully prescribed diet, together with counseling on exercise, behavior modification, and other appropriate supportive and collateral therapies.

(2) During treatment for obesity, a licensee shall:

- (a) Maintain a licensee /patient relationship throughout the treatment process;
- (b) Maintain an adequate patient record in accordance with subsection (4) of this section; and
- (c) Justify in the patient record the use of any Schedule III or IV amphetamine-like controlled substance beyond three (3) months. Before the licensee continues the use of a substance beyond three (3) months, the licensee shall obtain and review a current KASPER report.

(3) A licensee shall terminate the use of Schedule III or IV amphetamine-like controlled substances if:

- (a) The patient does not demonstrate weight loss and does not attempt to comply with exercise and dietary changes;
- (b) The body mass index of the patient without a co-morbid condition is less than twenty-seven (27) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;
- (c) The body mass index of the patient with a co-morbid condition is less than twenty-five (25) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;
- (d) The patient has regained the weight lost, using sympathomimetics as part of a complete program and reuse of the medication does not produce loss of the weight gain

- to help maintain a minimum of five (5) percent weight loss; or
- (e) The patient has obtained a Schedule III or IV amphetamine-like controlled substance from another provider without the licensee's knowledge and consent.
- (4) The board shall consider the following factors in reviewing the adequacy of a patient record:
- (a) Medical history, including:
 - 1. Illnesses, with particular emphasis on cardiovascular diseases;
 - 2. Surgery;
 - 3. Lifestyle;
 - 4. Medications, including controlled substances;
 - 5. Eating habits;
 - 6. Exercise;
 - 7. Weight gain or loss;
 - 8. Prior efforts at weight control or reduction;
 - 9. Prior treatment compliance;
 - 10. Menstruation or pregnancy; and
 - 11. Psychiatric history with particular reference to depression, paranoia, psychosis, or chemical dependency;
 - (b) Social history;
 - (c) Family history;
 - (d) Complete physical examination;
 - (e) Evaluation of laboratory tests including:
 - 1. CBC;
 - 2. Fasting blood sugar;
 - 3. Thyroid panel or TSH;
 - 4. Lipid profile;
 - 5. Serum potassium;
 - 6. Liver function test; and
 - 7. Renal function test;
 - (f) An informed consent signed by the patient that cites the limitations and risk of anorectic treatment including potential dependency or psychiatric illness;
 - (g)
 - 1. A signed agreement that the patient has voluntarily agreed to:
 - a. Have one (1) prescribing licensee for controlled substances;
 - b. Use one (1) pharmacy to fill prescriptions for controlled substances;
 - c. Not have early refills on the prescriptions for controlled substances; and
 - d. Provide full disclosure of other medications taken; or
 - 2. Documentation that:
 - a. The licensee requested the patient sign an agreement meeting the requirements of subparagraph 1 of this paragraph;
 - b. The patient declined to sign the agreement; and
 - c. Indicates the licensee's clinical reasons for prescribing, or continuing to prescribe, a Schedule III or IV amphetamine-like controlled substance to the patient, in light of the patient's refusal to sign the agreement; and
 - (h) A record of each office visit, including:
 - 1. The patient's weight;
 - 2. The patient's blood pressure;
 - 3. The patient's pulse;
 - 4. The presence or absence of medication side effects or complications;
 - 5. The doses of medications prescribed;
 - 6. The patient's body mass index; and
 - 7. Evaluation of the patient's compliance with the total treatment regimen.

Section 5. Waiver. For a legitimate medical purpose, a licensee may apply in writing for a written waiver of any requirement in this administrative regulation. The board may issue a waiver with terms and conditions it deems appropriate.

Section 6. Failure to comply with the requirements of this administrative regulation shall constitute dishonorable, unethical, or unprofessional conduct by a licensee which is apt to deceive, defraud, or harm the public under:

(1) KRS 311.595(9) and 311.597; or

(2) KRS 311.850(1)(s).

(10 Ky.R. 69; eff. 12-2-1983; Am. 13 Ky.R. 1087; eff. 1-13-1987; 15 Ky.R. 1285; 1645; eff. 12-13-1988; 16 Ky.R. 1223; eff. 2-3-1990; 28 Ky.R. 443; 1794; eff. 2-7-2002; 40 Ky.R. 108; 785; eff. 10-16-2013; 42 Ky.R. 2796; eff. 7-20-2016; 47 Ky.R. 364, 941; eff. 11-196-2020.)