

201 KAR 20:063. Restrictions on use of amphetamine-like anorectic controlled substances.

RELATES TO: KRS 314.011, 314.042, 314.091, 314.195

STATUTORY AUTHORITY: KRS 314.131

NECESSITY, FUNCTION, AND CONFORMITY: KRS 314.131 authorizes the board to promulgate administrative regulations necessary to enable it to carry into effect the provisions of KRS Chapter 314 and to regulate the conduct of licensees. This administrative regulation establishes the requirements governing the use of amphetamine-like anorectic controlled substances.

Section 1. Definitions. (1) "Board" is defined in KRS 314.011(1).

(2) "Body mass index" means the weight of the patient in kilograms divided by the height in meters, squared.

(3) "Schedule III or IV amphetamine-like controlled substance" means a drug classified as a stimulant pursuant to:

- (a) 902 KAR 55:025, Section 2; or
- (b) 902 KAR 55:030, Section 1.

Section 2. Prior to prescribing, ordering, or administering a Schedule III or IV amphetamine-like controlled substance, an advanced practice registered nurse (APRN) shall:

(1) Meet the requirements for the Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances (CAPA-CS) as required by KRS 314.042 and 201 KAR 20:057; and

(2) Take into account the:

- (a) Drug's potential for abuse;
- (b) Possibility that a drug may lead to dependence;
- (c) Possibility a patient will obtain the drug for a nontherapeutic use;
- (d) Possibility a patient will distribute it to others; and
- (e) Potential illicit market for the drug.

Section 3. Treatment of Obesity with a Schedule III or IV Amphetamine-like Controlled Substance. (1) Prior to prescribing, ordering, or administering a Schedule III or IV amphetamine-like controlled substance to treat obesity in a patient sixteen (16) years of age or older, the APRN shall:

(a) Establish an APRN/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 APRN shall obtain and review a KASPER report for the twelve (12) month period immediately preceding the patient encounter, before prescribing 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, an APRN shall:

(a) Maintain an APRN/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 APRN continues the use of a substance beyond three (3) months, the APRN shall obtain and review a current KASPER report.

(3) An APRN 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 prescriber without the prescriber'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 APRN for Schedule III or IV amphetamine-like 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 APRN 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 APRN'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 4. Waiver. (1) For a legitimate medical purpose, such as a change in the Federal Food and Drug Administration's (FDA's) approval or an off-label use of a Schedule III or IV amphetamine-like controlled substance, an APRN may apply in writing for a written waiver of any requirement in this administrative regulation.

(2) An off-label use shall occur when a Schedule III or IV amphetamine-like controlled substance is used in a manner not specified in the FDA's approved packaging label or insert.

(3) The board may issue a waiver with terms and conditions as agreed upon by the board and the APRN.

Section 5. Failure to comply with the requirements of this administrative regulation and the scope and standards of practice in 201 KAR 20:057 shall constitute actions inconsistent with the practice of nursing pursuant to KRS 314.091(1). (41 Ky.R. 2692; Am. 42 Ky.R. 275; eff. 9-4-2015.)