CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Audits and Investigations
(Amendment)

902 KAR 55:015. Schedules of controlled substances.

RELATES TO: KRS 217.005-217.215, 218A.010, 218A.020, 218A.040, 218A.060, 218A.080, 218A.100, 218A.120, 218A.200, 21 C.F.R. 1308.11, 1308.12, 1308.13, 1308.14, 1308.15, 1308.35, 1308.49, 21 U.S.C. 301 – 399f

STATUTORY AUTHORITY: KRS 218A.020(1), (3)

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(1) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations in order to add, delete, or reschedule substances enumerated in KRS Chapter 218A. KRS 218A.020(3) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations to control substances at the state level in the same numerical schedule corresponding to the federal schedule or control a substance in a more restrictive schedule than the federal schedule. This administrative regulation designates Schedule I, II, III, IV, and V drugs. This administrative regulation differs from the federal regulation, 21 C.F.R. 1308.11, because it designates tianeptine and bromazolam as Schedule I controlled substances. The Cabinet for Health and Family Services recognizes that tianeptine and bromazolam have no accepted medical use in treatment and inclusion on Kentucky's Schedule I list will help reduce the risk to public health. This administrative regulation differs from the federal regulation, 21 C.F.R. 1308.14, because it designates pentazocine, barbital, methylphenobarbital, and phenobarbital as a Schedule III controlled substance. The federal regulation designates these substances as a Schedule IV controlled substance. The Cabinet for Health and Family Services recognizes that pentazocine and derivatives of barbituric acid or its salts have significant abuse potential, and inclusion on Kentucky's Schedule III list will help reduce the risk to public health. This administrative regulation further differs from the federal regulation, 21 C.F.R. 1308.14-1308.15, because it designates nalbuphine as a Schedule IV controlled substance and gabapentin as a Schedule V controlled substance. The Cabinet for Health and Family Services recognizes that nalbuphine and gabapentin have significant abuse potential, and inclusion on Kentucky's controlled substances schedules will help reduce the risk to public health.

Section 1. Schedule I Controlled Substances.

(1) Each substance that is scheduled or designated as a Schedule I controlled substance under 21 C.F.R. 1308.11, including a substance temporarily scheduled or designated under 21 C.F.R. 1308.11(h) or 1308.49, shall be scheduled or designated at the state level as a Schedule I controlled substance.

(2) The Cabinet for Health and Family Services designates the following as Schedule I controlled substances:

(a) Tianeptine;

(b) Bromazolam.

(3) The following shall be exempt from control as a Schedule I substance:

(a) Cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols pursuant to the exemption established in 21 C.F.R. 1308.35; and

(b) Any substance or product exempt from the definition of marijuana pursuant to KRS 218A.010(27)(a) – (f).

Section 2. Schedule II Controlled Substances. Each substance that is scheduled or designated as a Schedule II controlled substance under 21 C.F.R. 1308.12 shall be scheduled or designated at the state level as a Schedule II controlled substance.

Section 3. Schedule III Controlled Substances.

(1) Except as provided by subsection (2) of this section, each substance that is scheduled or designated as a Schedule III controlled substance under 21 C.F.R. 1308.13 shall be scheduled or designated at the state level as a Schedule III controlled substance.

(2) The Cabinet for Health and Family Services designates the following as Schedule III controlled substances:

(a) Pentazocine;

(b) Barbital;

(c) Methylphenobarbital; and

(d) Phenobarbital.

(3) This section shall not apply to any material, compound, mixture, or preparation containing any quantity of an anabolic steroid substance, or any isomer, ester, salt, or derivative thereof that is:

(a) Expressly intended for administration through implant to livestock or other nonhuman species; and

(b) Approved by the United States Food and Drug Administration for use as described in this subsection.

Section 4. Schedule IV Controlled Substances.

(1) Except as provided by subsection (2) of this section and Section 3(2) of this administrative regulation, each substance that is scheduled or designated as a Schedule IV controlled substance under 21 C.F.R. 1308.14 shall be scheduled or designated at the state level as a Schedule IV controlled substance.

(2) The Cabinet for Health and Family Services designates the following as a Schedule IV controlled substance: nalbuphine.

Section 5. Schedule V Controlled Substances.

(1) Except as provided by subsection (2) of this section, each substance that is scheduled or designated as a Schedule V controlled substance under 21 C.F.R. 1308.15 shall be scheduled or designated at the state level as a Schedule V controlled substance.

(2) The Cabinet for Health and Family Services designates the following as a Schedule V controlled substance: gabapentin.

Section 6. Dispensing Without Prescription. A controlled substance listed in Schedule V, which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 to 399f, may be dispensed by a pharmacist without a prescription to a purchaser at retail, if:

(1) The medicinal preparation contains, in addition to the controlled substances, some drug or drugs conferring upon it medicinal qualities other than those possessed by the controlled substances alone;

(2) Not more than 240cc (eight (8) ounces) or more than forty-eight (48) dosage units of any controlled substance containing opium is dispensed at retail to the same purchaser in any given forty-eight (48) hour period;

(3) The labeling and packaging is in accordance with the current requirements of KRS 217.005 to 217.215, 21 U.S.C. 301 to 399f, and the United States Pharmacopeia;

(4) The preparation is dispensed or sold in good faith as a medicine and not for the purpose of evading the provisions of KRS Chapter 218A;

(5) The preparation is not displayed in areas open to the public;

(6) The dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist. After the pharmacist has fulfilled his or her

professional and legal responsibilities as set forth in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist;

(7) The purchaser is at least eighteen (18) years of age;

(8) The pharmacist requires every purchaser of a controlled substance under this section not known to the pharmacist to furnish suitable identification, including proof of age if appropriate; and

(9) The dispensing of exempt controlled substances under this administrative regulation is recorded in a bound book that shall be maintained in accordance with the recordkeeping requirements of KRS 218A.200 and contain the:

(a) Name and address of the purchaser;

(b) Name and quantity of controlled substance purchased;

(c) Date of each purchase; and

(d) Name or initials of the pharmacist who dispensed the substance to the purchaser.

COMPILER'S NOTE: 2025 RS HB 6, enacted by the General Assembly on March 27, 2025, altered the information to be provided at the time an administrative regulation is filed. Aside from formatting changes necessary to upload the regulation into the LRC's publication application, this regulation has been published as submitted by the agency.

TRICIA STEWARD, Inspector General
STEVEN J. STACK, MD, MBA, Secretary

APPROVED BY AGENCY: August 18, 2025

FILED WITH LRC: August 18, 2025 at 2:35 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 24, 2025, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by November 17, 2025, five (5) 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 canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. 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 this proposed administrative regulation through November 30, 2025. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

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