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~~[, 801-971]~~

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 ~~[a]~~Schedule I controlled substances~~[substance]~~. The Cabinet for Health and Family Services recognizes that tianeptine and bromazolamhave~~[has]~~ 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~~[a]~~ Schedule I controlled substances~~[substance]~~:~~[tianeptine.]~~

(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.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

Subject Headings:Controlled substance

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation designates Kentucky's schedules of controlled substances.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to comply with KRS 218A.020.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation conforms to the content of KRS 218A.020(3), which 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.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation assists in the effective administration of the statutes by designating Kentucky's schedules of controlled substances.

(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 designates bromazolam as a Schedule I controlled substance.

(b) The necessity of the amendment to this administrative regulation:
This amendment is in response to a recent request from Van Ingram, Executive Director, Office of Drug Control Policy. Mr. Ingram requested that the cabinet designate bromazolam as a Schedule I controlled substance via emergency administrative regulation. Bromazolam has no accepted medical use in treatment and inclusion on Kentucky's Schedule I list will help reduce the risk to public health. Bromazolam was recently banned by two of Kentucky's border states, Virginia and West Virginia. Bromazolam is not approved for use by humans or animals by the FDA.

(c) How the amendment conforms to the content of the authorizing statutes:
In accordance with KRS 218A.020(5), the Office of Drug Control Policy may request the cabinet to schedule any substance that meets the criteria to be scheduled under KRS Chapter 218A. This amendment conforms to the content of KRS 218A.040 by designating bromazolam as a Schedule I controlled substance.

(d) How the amendment will assist in the effective administration of the statutes:
This amendment assists in the effective administration of KRS 218A.040 by designating bromazolam as a Schedule I controlled substance.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This administrative regulation affects Kentucky's pharmacists and prescribing practitioners. State and local law enforcement agencies would also be impacted.

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

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:

Bromazolam is not currently prescribed. Pharmacists and doctors should be advised that this drug will now be considered a Schedule I drug. Law enforcement, both local and state, should be advised that possession of this drug without a prescription is subject to laws currently in place regarding possession or sale of an illicit substance.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

No costs will be incurred by any entity identified in question (4).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

Bromazolam is not currently a prescription medication in the U.S. It is currently only purchased illegally and is not approved for use in humans or animals by the U.S. Food and Drug Administration (FDA). Bromazolam is a triazolobenzodiazepine, a type of benzodiazepine, that was first synthesized in 1976 but never marketed. It is known as a "designer drug" and has been identified in the illicit drug market. When benzodiazepines like bromazolam are sometimes prescribed for anxiety, insomnia, and other conditions, they can also lead to dependence and have potential side effects. Studies, like those using drug discrimination tests with rats, have shown bromazolam to have a high potential for substitution and abuse, similar to other benzodiazepines. Inclusion on Kentucky's Schedule I list will help reduce the risk to public health by making possession of the drug illegal.

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

(a) Initially:

There are no additional costs to the Office of Inspector General for implementation of this amendment.

(b) On a continuing basis:

There are no additional costs to the Office of Inspector General for implementation of this amendment on a continuing basis.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

The source of funding to be used for the implementation and enforcement of this administrative regulation is from general funds.

(8) 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 increase in fees or funding is necessary to implement this amendment.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This amendment does not establish or increase any fees.

(10) TIERING: Is tiering applied?

Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 218A.020, 21 C.F.R. 1308.11, 1308.12, 1308.13, 1308.14, 1308.15, 1308.35, 1308.49.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and Kentucky's pharmacists and prescribing practitioners who rely on state and federal regulations for information regarding scheduled drugs as well as state and local law enforcement agencies and the Department of Corrections.

(a) Estimate the following for the first year:

Expenditures:This amendment will not generate additional revenue for state or local government.

Revenues:This amendment will not generate additional revenue for state or local government.

Cost Savings:This amendment will not generate any cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

(b) How will expenditures, revenue, or cost savings differ in subsequent years? This amendment will not generate additional expenditures, revenue or cost savings for state or local government during subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

This amendment should have no effect on local entities.

(a) Estimate the following for the first year:

Expenditures:No additional expenditures are expected from this amendment.

Revenues:No additional revenues are expected as a result of this amendment.

Cost Savings:No additional cost savings is expected as a result of this amendment.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

No additional budgetary impact is expected as a result of this amendment in subsequent years.

(4) Identify additional regulated entities not listed in questions (2) or (3):

(4) Identify additional regulated entities not identified in questions (2) or (3): All affected entities are listed in questions (2) and (3).

(a) Estimate the following for the first year:

Expenditures:No additional expenditures are expected from this amendment.

Revenues:No additional revenues are expected as a result of this amendment.

Cost Savings:No additional cost savings is expected as a result of this amendment.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

No additional budgetary impact is expected as a result of this amendment in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
There is no anticipated fiscal impact as a result of the amendment to this regulation.

(b) Methodology and resources used to determine the fiscal impact:
No money spent; no money gained equals no fiscal impact.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)
(a) Whether this administrative regulation will have an overall negative or adverse economic impact to the entities identified in questions (2) – (4). ($500,000 or more, in aggregate) This administrative regulation is not expected to have a major economic impact on the regulated entities.

(b) The methodology and resources used to reach this conclusion:
No money spent; no money gained equals no fiscal impact.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
21 C.F.R. 1308.11, 1308.12, 1308.13, 1308.14, 1308.15, 1308.35, 1308.49.

(2) State compliance standards.
KRS 218A.020.

(3) Minimum or uniform standards contained in the federal mandate.
21 C.F.R. 1308.11 lists controlled substances that have been classified by the DEA as Schedule I drugs. 21 C.F.R. 1308. Bromazolam is a triazolobendiazepine, a type of benzodiazepine. 21 C.F.R. 1308.49 allows the DEA to place a substance into Schedule I on a temporary basis if such action is necessary to avoid an imminent hazard to the public safety.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
Yes, the federal government has not scheduled this drug; however, the federal government has sent out warnings and is leaving the decision up to states to control. This administrative regulation differs from the federal regulation because it designates bromazolam as a Schedule I controlled substance. Bromazolam is not currently controlled under the federal Controlled Substances Act. Bromazolam is not a prescription medication and is not approved by the FDA for use in humans or animals. This administrative regulation differs from the federal regulation because it designates bromazolam is not yet regulated by the federal government, although it is not approved for any use by the FDA

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
The cabinet recognizes that bramazolam has no accepted medical use in treatment and inclusion on Kentucky's Schedule I list will help reduce the risk to public health.