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)

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 as a Schedule I controlled substance. The Cabinet for Health and Family Services recognizes that tianeptine 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 substance: tianeptine.

(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.

(7 Ky.R. 794; eff. 5-6-1981; Recodified from 901 KAR 1:015, 4-14-1982; 11 Ky.R. 1674; eff. 6-4-1985; 12 Ky.R. 266; eff. 9-10-1985; 1175; eff. 2-4-1986; 13 Ky.R. 1944; eff. 6-9-1987; 15 Ky.R. 863; eff. 11-4-1988; 20 Ky.R. 659; eff. 10-21-1993; 39 Ky.R. 1789; 2032; eff. 5-3-2013; 42 Ky.R. 1972; eff. 3-4-2016; 43 Ky.R. 1068, 1381; eff. 3-3-2017; 44 Ky.R. 143, 531; eff. 9-20-2017; 49 Ky.R. 2171; eff. 10-25-2023.)

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: March 14, 2023

FILED WITH LRC: March 23, 2023 at 8:15 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on June 27, 2023, 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 June 16, 2023, 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 until June 30, 2023. 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 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(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 tianeptine 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 tianeptine as a Schedule I controlled substance via emergency administrative regulation and this identical ordinary regulation. Tianeptine has no accepted medical use in treatment and inclusion on Kentucky's Schedule I list will help reduce the risk to public health. Tianeptine was recently banned by two of Kentucky's border states, Indiana and Ohio.

(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 tianeptine 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 tianeptine as a Schedule I controlled substance.

(3) 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 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. This amendment affects stores that currently sell tianeptine.

(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 is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Tianeptine products should be removed from store shelves and disposed of immediately.

(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 incurred by any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Tianeptine is an atypical tricyclic antidepressant that is not approved by the U.S. Food and Drug Administration (FDA) for medical use. The FDA has warned that many companies are illegally marketing and selling products containing tianeptine to the public with unproven beneficial claims, i.e., dietary supplement, treatment for anxiety, depression, or opioid disorder. Selling products containing tianeptine to consumers based on such false claims is dangerous, especially as it relates to the claim of treating opioid use disorder since reliance on these products may delay appropriate treatment and put consumers at greater risk of overdose and death. Moreover, in a 2022 update, the FDA warned consumers that it has identified cases in which people experienced serious harmful effects from abusing or misusing tianeptine by itself or with other drugs. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death. The FDA also reports that poison control centers cases involving tianeptine exposure increased nationwide from 11 cases between 2000 and 2013 to 151 in 2020 alone. Inclusion on Kentucky's Schedule I list will help reduce the risk to public health by making possession of the drug illegal.

(5) 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.

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

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

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

(8) 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.

(9) 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 NOTE

(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?

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.

(2) Identify each state or 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

(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?

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

(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?

This amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year?

This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years?

This amendment imposes no additional costs on the administrative body during subsequent years.

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

Revenues (+/-):See response above.

Expenditures (+/-):This administrative regulation is anticipated to have minimal fiscal impact to the cabinet.

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation imposes no additional costs on regulated entities.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation imposes no additional costs on regulated entities during subsequent years.

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

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation is not expected to have a major economic impact on the regulated entities.

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. 1308.12 lists controlled substances that have been classified by the DEA as Schedule II drugs. 21 C.F.R. 1308.13 lists controlled substances that have been classified by the DEA as Schedule III drugs. 21 C.F.R. 1308.14 lists controlled substances that have been classified by the DEA as Schedule IV drugs. 21 C.F.R. 1308.15 lists controlled substances that have been classified by the DEA as Schedule V drugs. 21 C.F.R. 1308.35 exempts certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols from scheduling. 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?
This administrative regulation differs from the federal regulation because it designates tianeptine as a Schedule I controlled substance. Tianeptine is not currently controlled under the federal Controlled Substances Act. This administrative regulation differs from the federal regulation because it designates pentazocine, barbital, methylphenobarbital, and phenobarbital as a Schedule III controlled substance in Kentucky. The federal regulation designates these substances as a Schedule IV controlled substance. Designating pentazocine, barbital, methylphenobarbital, and phenobarbital as a Schedule III controlled substance is not a new change to Kentucky's schedules of controlled substances. This administrative regulation differs from the federal regulation because it designates nalbuphine as a Schedule IV controlled substance and gabapentin as a Schedule V controlled substance. The federal regulation does not designate nalbuphine or gabapentin as controlled substances. Designating nalbuphine and gabapentin as a Schedule IV and Schedule V controlled substance respectively is not a new change to Kentucky's schedules of controlled substances.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
The cabinet recognizes that tianeptine has no accepted medical use in treatment and inclusion on Kentucky's Schedule I list will help reduce the risk to public health. The cabinet also recognizes that pentazocine and derivatives of barbituric acid or its salts have significant abuse potential and inclusion as a Schedule III controlled substance in Kentucky will help reduce the risk to public health. The cabinet further recognizes that nalbuphine and gabapentin have significant abuse potential and inclusion in Kentucky's controlled substance schedules will help reduce the risk to public health.