CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Audits and Investigations

(Amended After Comments)

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 and bromazolam as [~~a~~]Schedule I controlled substances[~~substance~~]. The Cabinet for Health and Family Services recognizes that tianeptine and bromazolam have[~~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; **and**

(c) 7-hydroxymitragynine (7-OH) concentrated at a level above 400 parts per million on a dry weight basis. This designation does not apply to mitragynine.

(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.

902 KAR 55:015

REVIEWED:

1/6/2026
Date

Signed by:
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Tricia Steward, Inspector General
Office of Inspector General

APPROVED:

1/6/2026
Date

Signed by:
A0C077BED9A2471...
Steven J. Stack, MD, MBA, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

902 KAR 55:015: Schedules of controlled substances.
Agency Contact: Valerie Moore
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Contact Person: Krista Quarles
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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. The amended after comments version adds 7-hydroxymitragynine to the list of Schedule I controlled substances. This additional language makes it clear that this scheduling does not apply to mitragynine.

(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. The scheduling of 7-hydroxymitragynine is necessary as this substance has no known medical uses and

is considered a substance of great concern by the federal Food and Drug Administration and the Drug Enforcement Agency.

(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 and 7-hydroxymitragynine 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 and 7-hydroxymitragynine 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. Businesses selling 7-hydroxymitragynine products that exceed 400 parts per million on a dry weight basis will need to remove these products from their shelves and return the products to the distributor.

(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.

Retailers will still be able to offer kratom products and products that contain lower levels of 7-hydroxymitragynine.

(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

902 KAR 55:015: Schedules of controlled substances.
Agency Contact: Valerie Moore
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Contact Person: Krista Quarles
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(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. The amended after comments version does not impact the fiscal impact statement.

(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, 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 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 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

Administrative Regulation: 902 KAR 55:015
Agency Contact: Valerie Moore
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Contact Person: Krista Quarles
Phone Number: (502) 564-7476
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(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.

STATEMENT OF CONSIDERATION
RELATING TO 902 KAR 55:015
Cabinet for Health and Family Services
Office of Inspector General and Department for Public Health

Amended after Comments

(1) A public hearing on 902 KAR 55:015 was held virtually on November 24, 2025, at 9 a.m. via Cabinet for Health and Family Services' Zoom meeting platform. In addition to those who attended the public hearing, written comments were received during the public comment period.

(2) The following individuals provided comments via the public comment process:

Name and Title	Agency/Organization/Entity/Other
David Bales	
Austin R. Brinkley, Attorney	Frost Brown Todd, LLP, representing Holistic Alternative Recovery Trust, Inc.
Julie Brooks Policy Specialist	Department for Public Health Cabinet for Health and Family Services
Mary Hentz	
Brad S. Keeton, Attorney	Frost Brown Todd, LLP, representing Holistic Alternative Recovery Trust, Inc.
Zachary S. Rice, Attorney	Frost Brown Todd, LLP, representing Holistic Alternative Recovery Trust, Inc.

(3) The following individual from the promulgating administrative body responded to the written comments:

Name and Title	Agency/Organization/Entity/Other
Julie Brooks Policy Specialist	Department for Public Health Cabinet for Health and Family Services
Valerie Moore Policy Specialist	Office of Inspector General Cabinet for Health and Family Services

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Scheduling of 7-hydroxymitragynine (7-OH)

(a) Comment: Julie Brooks, Policy Specialist, Department for Public Health, Cabinet for Health and Family Services, commented: "For consistency the department proposes the scheduling of 7-hydroxymitragynine (7-OH) at 400 parts per million or above on a dry weight basis be added to the ordinary version of 902 KAR 55:015. The language for this scheduling will mirror the language added through an agency amendment to the emergency version of this administrative regulation that was approved by the Administrative Regulation Review Subcommittee on November 10, 2025. This designation will not apply to mitragynine."

(a) Comment: Mary Hentz commented: "I'm writing here today to strongly oppose the emergency scheduling of 7-Hydroxymitragynine. There is no verified evidence of deaths or public health harm from 7-OH, and there's no emergency justification to skip public input. 7-OH is a natural alkaloid found in kratom — not a synthetic drug. Many people rely on it safely to manage pain, recovery, or mental health when other options have failed. This is a harm reduction product that has absolutely contributed to the decrease in overdose related deaths, and scheduling it would cause those numbers to rise again. Please delay or stop this action until proper scientific review and public input can be done."

(a) Comment: David Bales commented: "I am writing to express how deeply concerned I am about the recent classification of 7-OH as a Schedule I substance in Kentucky, and how that decision will impact someone like me who relies on it for pain relief. While I understand the state's efforts to protect people from harmful substances, this move leaves me in an impossible position. For years I have endured chronic pain that no standard treatments have alleviated. 7-OH has been the only thing that allowed me to function and take care of my son. With the new ban, I am facing a future where I no longer have access to the only effective option I've found. I fear the consequences of losing it will be devastating — not because I want to misuse anything, but because I am simply trying to survive my pain and remain functional. I'm asking you to please consider providing relief, exemptions, or alternate pathways for patients in my situation. There must be a way to regulate

powerful compounds for public safety while also considering the needs of people who genuinely have no other options. Thank you for your time and understanding."

(a) Comment: Austin R. Brinkley, Brad S. Keeton, and Zachary S. Rice, attorneys with Frost Brown Todd, LLP, representing Holistic Alternative Recovery Trust, Inc. (HART), commented: "7-Hydroxymitragynine, also known as 7-OH, is a naturally occurring alkaloid in the *Mitragyna speciosa* tree, a member of the coffee family. Unlike opioids and illicitly manufactured fentanyl, 7-OH has never been confirmed as the sole cause of any fatal overdoses.

"The safety profile of 7-OH is not merely benign; it is beneficial. Thousands of individuals have used 7-OH for pain relief, to manage opioid withdrawal, and for other health conditions. Further, kratom powder has been widely available in this country for almost two decades. As discussed below, in 2018, the U.S. Food and Drug Administration expressly rejected efforts to regulate kratom and 7-OH.

"In 2024, Kentucky enacted the Kratom Consumer Protection Act (KCPA), codified as KRS 217.2201 through 217.2209. The KCPA authorizes the sale of kratom and kratom products (which by definition includes 7-OH) subject to regulation by the Kentucky Department for Public Health (KDPH). Notably, the KCPA regulates the sale of kratom and kratom-derived products in Kentucky but does not provide for civil or criminal penalties for the use or possession of such products.

"KRS 218A.040-120 classifies controlled substances into schedules, numbered I-V. These schedules regulate the manufacture, distributions, preparation, and dispensing of the substances listed therein. Schedule I is the most restrictive, banning all authorized uses and possession of the classified substance.

"KRS 218A.020(1)(a)-(h) provides the criteria that the Cabinet must consider before scheduling a substance. For example, the Cabinet must consider:

- The actual or relative potential for abuse;
- The scientific evidence of its pharmacological effect, if known;
- The state of current scientific knowledge regarding the substance;
- The history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- The risk to the public health;
- The potential of the substance to produce psychic or physiological dependence liability; and
- Whether the substance is an immediate precursor of a substance already controlled under this chapter.

"On the contrary, available epidemiological data and real-world usage patterns suggest that 7-OH has been widely used as a harm reduction tool by individuals with substance use disorder that reduces use of illicit street-based drugs such as fentanyl or heroin, manages withdrawal symptoms, and effectively addresses chronic pain. The absence of overdose deaths attributable solely to 7-OH undermines any claim that the substance presents a substantial likelihood of harm under the statutory definition.

"The Certification and Emergency Statement issued to purportedly meet the requisite statutory findings in support of the emergency faction falls woefully short of demonstrating that 7-OH presents an imminent hazard to the safety of the community. The Emergency Rule fails to provide any basis whatsoever for designating 7-OH as a Schedule I substance, much less documentary evidence that would put the public on notice of such danger. Although there are outdated and hyperbolic newspaper articles and social media posts, these do not meet the requirements as set out in KRS 13A.190(1)(a), and as such cannot be used as the basis for adding 7-OH to the Emergency Rule.

"In addition to the absence of verified deaths or confirmed addiction syndromes, 7-OH stands apart from opiates and other illicit drugs in its actual impact on behavior, functioning, and community well-being. Unlike people who use opiates, no data demonstrates that those who consume 7-OH are engaging in behaviors commonly associated with substance use disorder or addiction, such as engaging in hazardous use, neglecting their major societal roles to use drugs, or engaging in criminal activity. To the contrary, many users report that 7-OH has allowed them to maintain employment, restore relationships, and function as productive members of society. Survey data of current 7-OH users nationwide confirms these beneficial effects.

"In assessing KRS 218A.020(1)(a)'s criteria that the substance have a potential for abuse, the Cabinet must consider whether its use reflects characteristics of addiction or substance abuse as medically and legally recognized. The accepted clinical standard for determining addiction is set forth in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5"), which defines substance use disorder based on eleven criteria, including impaired control, compulsive use despite harm, social dysfunction, abandonment of responsibilities, withdrawal, tolerance, repeated attempts to quit, cravings, engagement in hazardous use (e.g., injecting, etc.), and having social/interpersonal problems related to use. These criteria are designed to distinguish harmful, addictive conduct from functional or therapeutic use.

"By these metrics, 7-OH does not meet the DSM-5 indicators of abuse. Users are not exhibiting patterns of family estrangement, workplace failure, or compulsive self-harm; rather, the evidence shows the opposite: stable employment, restored family relationships, avoidance of illicit drugs, and overall improvement in physical and social functioning. Physiological dependence alone, without associated harm or dysfunction, does not satisfy the DSM-5 standard for a substance use disorder. The Cabinet's failure to apply any recognized medical or diagnostic criteria, including the DSM-5, in declaring that 7-OH presents a "potential for abuse" renders its emergency scheduling determination arbitrary, unsupported, and contrary to the legislature's directive that scheduling decisions be grounded in science, not speculation".

(b) Response: Following Governor Beshear's announcement on November 5, 2025, of the intent to classify 7-hydroxymitragynine (7-OH) as a Schedule I narcotic, the Cabinet for Health and Family Services received a number of public comments regarding the anecdotal benefits of kratom and 7-OH, even contributing

the rise in 7-OH consumption with the decline in overdose rates. However, while kratom is legal at the federal level, the federal Food and Drug Administration notes that kratom and 7-OH have not been approved for medical use, as a dietary supplement, or as a food additive in conventional food. The Drug Enforcement Administration has listed kratom as a drug of concern due to the risk of serious adverse events. In June 2025, the Kentucky Department for Public Health and the Kentucky Office of Drug Control Policy issued a joint statement warning the public about the dangers of consuming products that contain 7-OH and kratom. This notice listed the potential for severe adverse reactions including liver toxicity, seizures, and addiction. Furthermore, this notice acknowledges that there are no guarantees that the products contain the ingredients listed on the label or that the ingredients are present in the correct concentrations.

According to an April 2025 report on state laws regarding kratom by the Legislative Analysis and Public Policy Association, six (6) states had enacted legislation to classify kratom and its ingredients as Schedule I drugs. Louisiana followed suit in June 2025, and in August 2025, Florida also enacted legislation to add 7-hydroxymitragynine at a concentration of 400 parts per million on a dry weight basis to the states list of Schedule I drugs. The proposed regulatory language to schedule 7-hydroxymitragynine in Kentucky is not a complete ban on kratom and 7-OH products. Products that contain kratom and lower doses of 7-OH are still legal to sell and possess if the product meets the statutory requirements in Kentucky Revised Statute (KRS) 217.2201-217.2203.

The cabinet is amending this administrative regulation in response to some of these comments.

(2) Subject: Rule making procedure

(a) Comment: Austin R. Brinkley, Brad S. Keeton, and Zachary S. Rice, attorneys with Frost Brown Todd, LLP, representing Holistic Alternative Recovery Trust, Inc. (HART), commented: "The emergency scheduling of 7-OH is an unsupported policy error with real human consequences. It is also improper and an unprecedented use of the limited emergency scheduling authority set forth in KRS 218A.020 and KRS 13B.125.

"By scheduling 7-OH on an emergency basis, the Cabinet has improperly expanded its restricted rulemaking authority set out in KRS 218A.020 and KRS 13B.125, which limits scheduling to substances that "[m]eet an imminent threat to public health, safety, welfare, or the environment." The intention of the statute is to allow administrative agencies to take action in emergencies on a temporary basis when there is sufficient scientific and documentary data to show an imminent threat to the public. However, the Cabinet provided no evidence that 7-OH poses an imminent threat to public safety sufficient to justify invoking its limited emergency rulemaking authority to classify 7-OH as a Schedule I substance, much less enacting a consistent final rule.

"HART challenges the validity of the Rule on the grounds that: (1) the Cabinet's adoption of the Emergency Rule failed to comply with the rulemaking requirements of KRS 218A.020, §13B.125, and 13A.190(1)(a); (2) the rulemaking process had the violated due process rights of the consumers, manufacturers, importers, distributors, and retailers by failing to provide notice of the hearing according to KRS 13B.125; (3) the Rule enlarges and exceeds the Cabinet's rulemaking authority; (4) the Rule contravenes the statutory language of the Kratom Consumer Protection Act and the intent of the Kentucky legislature; and (5) the Rule is arbitrary and capricious.

"The Emergency Rule fails to contain any statement of emergency justifying the reclassification of 7-OH products.

"The Rule is invalid because it violates the applicable rulemaking procedures, was not adopted under a procedure which was fair under the circumstances, exceeds the Cabinet's rulemaking authority and otherwise constitutes an invalid exercise of delegated legislative authority".

(b) Response: In accordance with Kentucky Revised Statute (KRS) 13A.190(3)(c)2., the Cabinet for Health and Family Services (CHFS) filed an agency amendment to emergency administrative regulation 902 KAR 55:015E to immediately list products that contain 7-hydroxymyitragynine (7-OH) at a rate of 400 parts per million or above as a schedule I drug. The agency amendment was submitted timely to the co-chairs of the Administrative Regulation Review Subcommittee (ARRS). Notice of the proposed agency amendment, including a statement of justification, was posted publicly under the ARRS meeting materials for the November 2025 meeting on the Legislative Research Commission website. In addition, a notice of the proposed amendment was forwarded to all those who receive RegWatch Notification from the CHFS Office of Inspector General on November 5, 2025. A discussion of the proposed agency amendment was held during the November 10, 2025, meeting of ARRS. At this time, members of the public were provided an opportunity to make a public comment on the proposed agency amendment. KRS 13A.030(2)(a)1. and 6. authorizes the members of ARRS to determine an administrative regulation is deficient if it has been wrongfully promulgated and is in excess of the administrative body's authority. No finding of deficiency on the proposed agency amendment was suggested or discussed during the November meeting.

During the 2025 legislative session, the House of Representatives adopted House Resolution 88 by voice vote. This resolution directed the Kentucky Department for Public Health in conjunction with the Kentucky Office of Drug Control Policy to issue a public statement regarding the potential harm of consuming 7-hydroxymitragynine products. This resolution acknowledges that 7-hydroxymitragynine is a naturally occurring alkaloid in kratom; however, "food chemists have developed techniques to synthesize 7-hydroxymitragynin from mitragynine allowing the artificial increase in the levels of 7-hydroxymitragynine in kratom products" and "there are companies marking products labeled as kratom that may primarily contain the more potent synthetic product called 7-hydroxymitragynine". The cabinet believes that the scheduling of 7-

hydroxymitragynine at 400 parts per million or above does comport to the intent of the Kratom Consumer Protection Act (KRS 217.2201-217.2209) and the Kentucky Legislature. More specifically, KRS 217.2202(2)(d) prohibits the manufacture, distribution, or sell of any kratom product that "contains any synthetic alkaloid, including synthetic mitragynine, synthetic 7-hydroxymitragynin, or any other synthetically derived compound".

The citation to KRS 13B.125 as evidence that the cabinet has violated the due process rights of manufacturers, retailers, and consumers is a misinterpretation of the administrative hearing proceedings covered under KRS Chapter 13B. The provisions of KRS Chapter 13B are specific to the administrative hearing rights of a named individual. KRS 13B.020(2)(b) specifically exempts "public hearings required in KRS Chapter 13A for the promulgation of administrative regulations" from the administrative hearings under KRS Chapter 13B. The cabinet has not issued any administrative order to a named manufacturer or retailer of 7-hydroxymitragynine.

The cabinet is not amending this administrative regulation in response to these comments.

Summary of Statement of Consideration
and
Action Taken by Promulgating Administrative Body

A public hearing on 902 KAR 55:015 was held virtually on November 24, 2025, at 9 a.m. via Cabinet for Health and Family Services' Zoom meeting platform. The Office of Inspector General and the Department for Public Health responded to the comments and amends the administrative regulation as follows:

Page 2
Section 1(2)
Lines 21-23

After "(b) bromazolam",
Insert the following:

;and
(c) 7-hydroxymitragynine (7-OH) concentrated at a level above 400 parts per million on a dry weight basis. This designation does not apply to mitragynine