Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Steven Stack, MD
SECRETARY

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November 3, 2025

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 902 KAR 55:015E. Schedules of controlled substances.

Dear Co-Chairs West and Lewis,

After consideration of the issues raised by 902 KAR 55:015E, the Department for Public Health in collaboration with the Office of Inspector General proposes the attached agency amendment to this emergency administrative regulation. The amendment adds 7-hydroxymitragynine, commonly known as 7-OH, concentrated at a level above 400 parts per million on a dry weight basis as a scheduled I controlled substance. 7-OH is present in low concentrations in natural kratom and synthetic version of 7-OH are often much more potent than the naturally occurring compound and significantly increases the risk of overdose, severe health issues and even death.

The fiscal impact statement for the administrative regulation remains the same.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at (502) 229-3377.

Sincerely,

Stacy Carey

Stacy Carey
Executive Staff Advisor
Office of Legislative and Regulatory Affairs

Agency Amendment
(ARRS – November 2025)

Cabinet for Health and Family Services
Department for Public Health
Division of Public Health Protection and Safety

902 KAR 55:015E. Schedules of controlled substances.

Page 2
Section 1(2)
Lines 20-21

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

<u>; and</u>

<u>(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.</u>

FISCAL IMPACT STATEMENT

Administrative Regulation: 902 KAR 55:015E
Agency Contact: Valerie Moore
Phone Number: (502) 226-0196
Email: valeriek.moore@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(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 agency amendment does not impact the fiscal impact statement filed with the regulation on 8/18/2025.

(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.