

**CABINET FOR HEALTH AND FAMILY SERVICES**  
**Department for Public Health**  
**Division of Public Health Protection and Safety**  
**(Amended After Comments)**

**902 KAR 45:012. Hemp-derived cannabinoid product retail and food service establishment requirements.**

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 217.992, 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the requirements for retail sale of hemp-derived cannabinoid products, including the permit fee, and methods for use of hemp-derived cannabinoid as an additive to food products. Retail establishments registered with the department prior to **December 31, 2024**~~{the effective date of this administrative regulation}~~ shall be exempted from the permit fee requirement until the annual renewal date. In accordance with 2023 Ky. Act ch 78, in order to limit the ability of minor children accessing adult-use hemp-derived cannabinoid use products, this administrative regulation prohibits the sale of adult-use products within 1,000 feet of an elementary, middle, or high school. Retail establishments registered with the department prior to **December 31, 2024 online at <https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM>**~~{the effective date of this administrative regulation}~~ shall be exempted from this location requirement.

Section 1. Retail Establishment and Food Service Establishment Registration.

(1)

(a) Only approved cannabinoid products or class of products in accordance with 902 KAR 45:021 may be sold in retail and food service establishments. All other cannabinoid products or class of products shall be prohibited.

(b) ~~All {Adult-use}~~ cannabinoid products or class of products shall be registered in accordance with 902 KAR 45:021, Section 1(4).

(c) A retailer ~~or distributor~~ shall ensure that all cannabinoid products sold are properly registered with the department.

(d) A retailer may register a product in lieu of the processor or manufacturer.

(2) Retail establishments and food service establishments offering adult-use cannabinoid products shall be permitted by the cabinet in accordance with this administrative regulation.

(3) The permit shall be:

(a) ~~{Completed online at <https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM>}~~

~~{(b)}~~ Nontransferable in regard to person or address;

- (b) ~~(c)~~ Renewed annually; and
- (c) ~~(d)~~ Include a \$2,000 annual permit fee.
- (4) All retail establishments registered with the department prior to **December 31, 2024**~~April 27, 2024~~, shall have the fee required by subsection (3)(d) of this section waived until the date of the next annual renewal.
- (5) A retailer shall ensure all locations are permitted by the cabinet.
- (6) Retail establishments and food service establishments, **not permitted by the cabinet**, offering adult-use cannabinoid products at a temporary event or festival shall:
  - (a) Register with the cabinet at <https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM>; and
  - (b) Include a \$250 temporary event registration fee.
- (7) Retail establishments offering adult-use cannabinoid products shall not be located within 1,000 feet of an elementary, middle, or high school. Retail establishments registered with the department prior to **December 31, 2024**~~April 27, 2024~~, shall be exempted from the location requirements.
- (8) **An in-state** ~~A~~ business that distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21) years of age, unless the person employed is at least eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.

## Section 2. Retail Sale of Cannabinoid Products.

- (1) All cannabinoid products sold in a retail establishment shall:
  - (a) Be from an approved source;
  - (b) Be packaged and labeled in accordance with 902 KAR 45:021, Section 3; and
  - (c) Have a valid certificate of analysis available upon request.
- (2) Cannabinoid retailers shall maintain records of wholesale cannabinoid product purchase, including the name and address of the cannabinoid processor or manufacturer, and the wholesaler or distributor.
- (3) The following hemp-derived products shall not be marketed, sold, or distributed **direct to the consumer in a retail setting**~~to any person in the commonwealth~~:
  - (a) Whole hemp buds;
  - (b) Ground hemp floral material;
  - (c) Ground hemp leaf material; and
  - (d) Any hemp product with a **total** ~~delta-9~~ THC concentration in excess of zero and three-tenths (0.3) percent.
- (4) All adult-use cannabinoid products shall:
  - (a) Be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21); and
  - (b) Not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21).
- (5)
  - (a) Any person who sells adult-use cannabinoid products at retail shall require proof of age of the buyer to verify the buyer is age twenty-one (21) years or older; and
  - (b) May deliver or ship adult-use cannabinoid products to consumers over twenty-one (21) years of age in packages clearly marked "Adult-use only".
- (6) All persons located in another state or country who deliver, ship, or cause to be delivered or shipped cannabinoid products directly to any Kentucky consumer shall **be registered in accordance with 902 KAR 45:021**~~hold a valid hemp cannabinoid wholesaler or distributor permit issued by the Commonwealth~~.

## Section 3. Ingestible Cannabinoid Products at Food Service Establishments.

- (1) Only registered, pre-packaged adult-use ingestible cannabinoid products may be offered as ready-to-consume or for direct consumption at food service establishments.

- (2) Adult-use cannabinoids shall not be added to an ingestible food product at a food service establishment.
- (3) Non-intoxicating cannabinoids may be added to an ingestible product prior to retail sale at a food service establishment.
- (4) The non-intoxicating cannabinoid shall be obtained from an approved source.
- (5) The food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.
- (6) A food service establishment offering non-intoxicating cannabinoid products in a finished food product shall provide to consumers upon request:
  - (a) The common name of the product; and
  - (b) The manufacturer or distributor of the product.
- (7) A food service establishment shall notify the cabinet within twenty-four (24) hours of becoming aware or within twenty-four (24) hours of when the food service establishment should have been aware of any serious adverse event to a hemp-derived cannabinoid product sold by the establishment.

#### Section 4. Inspection and Enforcement.

- (1)
  - (a) Retail establishments offering adult-use cannabinoid products shall be inspected by the cabinet or its duly authorized agent; and
  - (b) Retail establishments offering only non-intoxicating cannabinoid products may be inspected by the cabinet or its duly authorized agent upon complaint, receipt of a report of a serious adverse event, or at the discretion of the cabinet.
- (2) The location of the permitted establishment, all general business records, including employee records, and vehicles utilized to transport products are subject to reasonable inspection.
- (3) All cannabinoid establishments, whether permitted or not, shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, requests for information or data, in order to verify compliance with this administrative regulation.
- (4)
  - (a) Products not in compliance with this administrative regulation shall be seized ~~and destroyed~~ by the cabinet or its duly authorized agent.**
  - (b) The permit holder shall be given notice that they have ten (10) days to file an appeal pursuant to subsection (12) of this section.**
  - (c) If no request for an appeal is filed, seized products shall be destroyed.**
- (5) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.
- (6)
  - (a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if product, product packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.
  - (b) Notification to the cabinet shall be made by:
    1. Email to [food.safety@ky.gov](mailto:food.safety@ky.gov); or
    2. Phone to (502) 564-7181.
- (7) If the cabinet has evidence that a permit holder has failed to act to correct an imminent health hazard:
  - (a) The permit shall be suspended immediately; and
  - (b) The permit holder may request an administrative hearing in accordance with KRS Chapter 13B.

(8) A permit holder shall notify the cabinet within twenty-four (24) hours~~one (1) business day~~ of becoming aware of any serious adverse event to a cannabinoid product sold or transferred by the permit holder.

(9) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(10) If a permit holder has failed to comply with the written notice within the timeframe granted, the cabinet shall issue a notice of intent to suspend the permit.

(11)

(a) The notice in subsection ~~(2)~~~~(11)~~ of this section shall include notification that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for an administrative hearing is filed with the cabinet by the permit holder within the ten (10) day period; and

(b) The administrative hearing shall be conducted in accordance with KRS 13B.080.

(12) For a permitted establishment that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

(13) Any person who knowingly violates any provision of this administrative regulation may be fined, found guilty ~~of~~~~for~~ a criminal offense, or both pursuant to KRS 217.992.

(14) State and local law enforcement officers shall have concurrent jurisdiction to enforce violations of this section.

*STEVEN J. STACK, MD, MBA, Commissioner*

*ERIC C. FRIEDLANDER, Secretary*

APPROVED BY AGENCY: September 9, 2024

FILED WITH LRC: September 10, 2024 at 2:00 p.m.

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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

**Contact Person: Krista Quarles or Julie Brooks**

**(1) Provide a brief summary of:**

**(a) What this administrative regulation does:**

This administrative regulation establishes the requirements for retail sale of hemp-derived cannabinoid products, and methods for use of hemp-derived cannabinoid as an additive to food products. The amended after comments version clarifies that all retailers registered with the department prior to December 31, 2024, will be exempted from the permit fee for one year and exempted from the location requirements, adds that retailers permitted by the department will be exempted from the special event permit fee, revises the enforcement procedures to allow due process proceedings, if requested, to be requested before seized products are destroyed, and makes other changes for compliance with KRS chapter 13A.

**(b) The necessity of this administrative regulation:**

This new administrative regulation is necessary because many hemp-derived cannabinoid products sold in Kentucky remain unregulated by both the state and the federal Food and Drug Administration. Some products containing hemp-derived cannabinoids have concentrations that produce a psychoactive effect and are unsafe if consumed in large quantities. This administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced and sold in the state are safe for human consumption, and are not targeted for sale to persons under the age of twenty-one (21).

**(c) How this administrative regulation conforms to the content of the authorizing statutes:**

KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale.

**(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:**

This new administrative regulation will ensure proper oversight of the sale of hemp-derived cannabinoids and will help to ensure these products are safe for human consumption.

**(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 is a new administrative regulation.

**(b) The necessity of the amendment to this administrative regulation:**

This is a new administrative regulation.

**(c) How the amendment conforms to the content of the authorizing statutes:**

This is a new administrative regulation.

**(d) How the amendment will assist in the effective administration of the statutes:**

This is a new administrative regulation.

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

The department is unsure of the total number of retail establishments offering hemp-derived cannabinoids for sale at this time.

**(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:**

Retail establishments and food service establishments will need to be aware of the registration requirements, will need to ensure the products are properly labeled and registered with the department, will need to obtain the required paperwork, and will need to take the necessary precautions to limit the sale of adult use products to individuals under the age of twenty-one (21).

**(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):**

Retail establishments that offer adult-use cannabinoid products will pay a \$2,000 permit fee. The retail establishment has the option of registering the product for the processor or manufacturer and may have a cost associated with that process.

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

Retail establishments and food service establishments will be able to ensure the products offered to consumers are safe for human consumption.

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

**(a) Initially:**

The current budget for the food manufacturing permitting and inspection program is \$1,080,900. The increase in required permitting and inspection processes to implement this administrative regulation will cost the department an additional \$1,551,397 in the first year.

**(b) On a continuing basis:**

The department will continue to need an additional \$1,551,397, at a minimum, in subsequent years. An increase in permitted facilities requiring inspection will result in increased costs.

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

State general fund dollars and revenue received from permitting and product registration are the sources of funding for this administrative regulation.

**(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:**

An increase in fees and funding is necessary to implement the registration, permitting and inspection requirements of this new administrative regulation.

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

This new administrative regulation does establish a new fee for retail establishments that offer adult-use cannabinoid products for sale. This increase is necessary to help offset the costs associated with the registration, permitting, and inspection processes.

**(9) TIERING: Is tiering applied?**

Tiering is applied. Only retail establishments that offer adult-use cannabinoid products are required to register with the department. However, all products sold are to be in compliance with this administrative regulation.

## 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 217.125, 217.127, 217.135, and 217.155.

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

The Department for Public Health, Division of Public Health Protection and Safety is the promulgating agency. The department has coordinated with the Department of Alcoholic Beverage Control in the Public Protection Cabinet for retail inspection activities.

**(a) Estimate the following for the first year:**

**Expenditures:**Expenditures for the department to implement this administrative regulation will be approximately \$1,551,397 per year.

**Revenues:**The amount of revenue cannot be determined. While retail establishments are required to register with the department, they are not assessed a fee at this time and less than 100 stores are registered.

**Cost Savings:**This administrative regulation does not generate cost savings.

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

Expenditures in subsequent years will be dependent on changes in the salary, fringe, and benefit cost. Changes in revenue cost in subsequent years will be dependent on the number of permits issued and the number of products registered.

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

Local law enforcement entities may be affected by this administrative regulation.

**(a) Estimate the following for the first year:**

**Expenditures:**The department is not able to calculate the expenditures for affected local entities at this time.

**Revenues:**This administrative regulation will not generate revenue for affected local entities.

**Cost Savings:**This administrative regulation does not result in cost savings.

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

The department is not able to determine changes in expenditures, revenues or cost savings for affected local entities.

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

Additional regulated entities include retail establishments and food service establishments that offer cannabinoid products for sale.

**(a) Estimate the following for the first year:**

**Expenditures:**The expenditure for retail establishments that sell adult-use cannabinoid products will be \$2,000 per year to obtain a permit from the department. Food service establishments will pay the permit fee according to 902 KAR 45:110.

**Revenues:**The total revenue for retail establishments and food service establishments cannot be determined.

**Cost Savings:**This administrative regulation does not result in cost savings.

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

The expenditures will not change in subsequent years without an amendment to this administrative regulation.

**(5) Provide a narrative to explain the:**

**(a) Fiscal impact of this administrative regulation:**

This administrative regulation may generate 1.4 million in revenue. Additional revenue will be generated by the product registration fee, but that total cannot be determined at this time. The cost to the department to administer this administrative regulation is \$1,551,397.

**(b) Methodology and resources used to determine the fiscal impact:**

The total range for the potential revenue was calculated by multiplying the approximate number of retail locations that sell adult-use products by the suggested permit fee of \$2,000. If the approximate number of retail locations that sell adult use products is 700 the multiplying that by the \$2,000 permit fee equals \$1,400,000. The total expenditure was calculated based on the need for thirteen (13) additional environmental management staff to oversee the permitting and inspection activities. The thirteen (13) additional staff include a branch manager, administrative support staff, two (2) supervisors, two (2) processing/manufacturing inspectors, five (5) retail inspectors, and two (2) enforcement staff. (b) Methodology and resources used to determine the fiscal impact: The total range for the potential revenue was calculated by multiplying the current number of permitted facilities times the lowest and highest permit fee amounts, which is 38x1,000 and 38x3,000 respectively. The total expenditure was calculated based on the need for thirteen (13) additional environmental management staff to oversee the permitting and inspection activities. The thirteen (13) additional staff include a branch manager, administrative support staff, two (2) supervisors, two (2) processing/manufacturing inspectors, five (5) retail inspectors, and two (2) enforcement staff. The breakdown of expenditures is as follows: -- Administrative Clerk: Program Coordinator (Grade 14); Annual Salary + 5% Probationary increase: \$59,213.70; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: \$53,711.55; Total Annual Salary and Fringe Benefits: \$112,925.25 x 1 Employee = Total Amount: \$112,926.25 ---- Retail Inspectors: Program Evaluator (Grade 14); Annual Salary + 5% Probationary increase: \$59,213.70; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: \$53,711.55; Total Annual Salary and Fringe Benefits: \$112,925.25 x 5 Employees = Total Amount: \$564,626.27 ---- Processor/manufacturing Inspectors, Enforcement staff, and Supervisors: Program Administrator (Grade 15); Annual Salary + 5% Probationary increase: \$65,135.20; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: \$58,082.80; Total Annual Salary and Fringe Benefits: \$123,218.00 x 6 Employees = Total Amount: \$739,307.99 ---- Manager: Branch Manager (Grade 16); Annual Salary + 5% Probationary increase: \$71,646.12; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: \$62,889.17; Total Annual Salary and Fringe Benefits: \$134,535.29 x 1 Employee = Total Amount: \$134,535.29 ---- TOTAL AMOUNT = \$1,551,396.79

**(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)**

The expenditures for the department will exceed \$1,000,000, resulting in an overall negative or adverse major economic impact. The overall economic impact for the

regulated entities cannot be determined. While these entities will have expenditures associated with the permit and product registration, these will be offset by the revenue received in product sells.

**(b) The methodology and resources used to reach this conclusion:**

Legislation has delegated new authority to the Kentucky Department for Public Health (KDPH) to regulate recreational adult-use products, such as delta-8 THC, for the safety of Kentuckians. These products, which may only be sold to adults aged 21 years or older, are increasingly complex, diverse, and evolving. An estimated 1,000-1,500 retailers and 40 manufacturers of recreational adult-use drugs are believed to be operating in Kentucky. Manufacturers of hemp THC products use complex chemistry conversion methods to process distillates, which increases the technical training required for inspection. Due to the intricacies involved, the successful oversight and regulation of these products in Kentucky will require additional staffing and the use of a hybrid approach that blends the traditional roles of the Department of Alcoholic Beverage Control, such as the enforcement of laws and age verification, with the expertise of the Food and Drug Administration (FDA). In order to adequately oversee the manufacture and retail sale of these products, the department would propose establishing a new branch with specialized staff. An estimated additional thirteen (13) staff will be needed to carry out the following activities: Regulatory Oversight: Establish and enforce standards for product manufacturing, packaging, and labeling for human consumption; Establish and enforce distribution controls to consumers to prohibit and prevent sales of adult-use products to individuals under 21 years of age; Prohibit the manufacture and sale of unallowable products; Protect consumers from harmful exposure to chemicals, contaminants, and adulterants that would have an adverse impact on human health; Evaluate the use of chemicals when added to products, such as food ingredients and substances that come into contact with food through food processing, manufacturing, packaging, storage, or other handling to ensure these uses are safe; Monitor products for contaminants and take action when the level of a contaminant causes a product to be unsafe. Licensing and Inspections: Administer licensure and registration for processors, manufacturers, distributors, and retailers and conduct regular inspections to ensure compliance with regulatory requirements. Surveillance and Monitoring: Collect and analyze data on adverse events and product quality to guide decision-making and interventions. Collaboration and Partnerships: Collaborate with federal/state agencies, professional organizations, academic institutions, and industry stakeholders to exchange information, share best practices, and coordinate efforts to address common challenges.