CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary

(New Administrative Regulation)

915 KAR 1:100. Packaging and labeling of medicinal cannabis.

RELATES TO: KRS Chapter 218

STATUTORY AUTHORITY: KRS 218B.140, 15 U.S.C. secs. 1471 to 1476

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet for Health and Family Services to promulgate administrative regulations establishing standards for the packaging and labeling of medicinal cannabis transferred, sold, or distributed by cannabis businesses. This administrative regulation establishes those standards.

Section 1. General requirements for packaging and labeling of medicinal cannabis.

(1) Packaging and labeling of any medicinal cannabis or medicinal cannabis product shall not bear:

(a) Any resemblance to the trademarked, characteristic, or product-specialized packaging of any commercially available food or beverage product and not be visually reminiscent of major brands of edible noncannabis products;

(b) Any statement, artwork, or design that could reasonably lead an individual to believe that the package contains anything other than medicinal cannabis;

(c) The logo of the cabinet or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead an individual to believe that the product has been endorsed,

manufactured, or approved for use by any state, county, or municipality or any agency thereof; and

(d) Any cartoon, image, graphic, or feature that may make the package attractive to children or minors.

(2) A cannabis business shall package and label at its facility each form of medicinal cannabis prepared for sale to cardholders. The original seal of a package may not be broken, except:

(a) For testing at a safety compliance facility;

(b) By a dispensary for the purpose of displaying product examples for the benefit of cardholders; or

(c) As needed by the cabinet or its authorized agents as part of an inspection or investigation.

Section 2. Packaging of medicinal cannabis for sale to cardholders.

(1) Pursuant to KRS 218B.140(1)(c)(13), a cannabis business shall comply with 15 U.S.C. secs. 1471 to 1476 when packaging and labeling medicinal cannabis and medicinal cannabis products for sale to cardholders.

(2) When packaging medicinal cannabis and medicinal cannabis products for sale to cardholders, a cannabis business shall ensure each product package:

(a) Is child-resistant and requires at least a two (2) step process of initial opening;

(b) Has a tamper-evident seal;

(c) Minimizes exposure to oxygen;

(d) Contains the following warnings:

1. The typical length of time for the medicinal cannabis to take effect;

2. The statements "For medicinal use by cardholders only. KEEP OUT OF REACH OF CHILDREN"; and

3. For raw plant material packaged for sale to a cardholder, the statement "NOT INTENDED FOR CONSUMPTION BY SMOKING";

(e) Discloses the strain of medicinal cannabis, form of medicinal cannabis, and standard amount of delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD) in the medicinal cannabis, including:

1. If the medicinal cannabis product is intended for oral consumption as an edible, oil, or tincture, potency shall be stated as milligrams per serving for total THC and total CBD, as applicable, and milligrams per package for total THC and total CBD, as applicable; and

2. For concentrates, total THC and total CBD, as applicable, shall be stated in percentages;

(f) Discloses the amount of medicinal cannabis the product is considered the equivalent to, if applicable;

(g) Discloses any possible allergens;

(h) Is light-resistant and opaque;

(i) Clearly and conspicuously displays the standardized symbol in navy blue provided in Appendix A, which is incorporated by reference, indicating that a product contains medicinal cannabis;

(j) Is resealable, if applicable;

(k) Contains the name, address, and license number of the cannabis business packaging the medicinal cannabis;

(l) Protects the medicinal cannabis from contamination;

(m) Does not impart any toxic or deleterious substance to the medicinal cannabis; and

(n) Provides the telephone number for the National Poison Control Center.

Section 3. Labeling of medicinal cannabis for sale to cardholders.

(1) Medicinal cannabis and medicinal cannabis products prepared for sale to cardholders shall include a label that is firmly affixed to the packaging holding medicinal cannabis or firmly affixed to any outer packaging if used.

(2) The label required by this section may contain a quick response (QR) code that links to some or all of the information required under this section. The QR code shall be:

(a) Labeled as "Specific Product Information" directly above or below the QR code; and

(b) Large enough to be smart-phone readable.

(3) The label required by this section shall:

(a) Be made of weather-resistant and tamper-resistant materials;

(b) Be legible;

(c) List the strain, form, and net weight of the medicinal cannabis included in the package;

(d) List any ingredients;

(e) List the specific amount of THC and CBD in the medicinal cannabis included in the package as stated on the certificate of analysis for the medicinal cannabis's harvest batch or production batch. The specific amount of THC and CBD may be expressed in milligrams or by percentage, as applicable;

(f) List the percentage of total terpenes and the three (3) most prevalent terpenes expressed in the medicinal cannabis, as applicable;

(g) Provide the name and license number of the cannabis business that cultivated the medicinal cannabis;

(h) Provide the name and license number of the cannabis business that processed the medicinal cannabis, if applicable;

(i) Provide the identifier that is unique to the particular harvest batch or production batch of medicinal cannabis in the package;

(j) List the date the medicinal cannabis was harvested or processed;

(k) List the date the medicinal cannabis was packaged;

(l) List the name and license number of the safety compliance facility that tested the medicinal cannabis and the date the medicinal cannabis was tested;

(m) List the expiration date of the medicinal cannabis; and

(n) If the medicinal cannabis product is intended for oral consumption as an edible, oil, or tincture, provide a nutritional fact panel, the number of individual servings contained within the package, and the amount of THC per serving, which shall not exceed ten (10) milligrams per serving.

Section 4. Packaging and labeling requirements for sale or transfer of medicinal cannabis between cannabis businesses.

(1) All medicinal cannabis sold or otherwise transferred between cannabis businesses for the purpose of processing or packaging and labeling for retail sale to cardholders shall:

(a) Regarding packaging:

1. Fully enclose the medicinal cannabis so that it cannot be seen from outside the packaging;

2. Protect the medicinal cannabis from contamination; and

3. Not impart any toxic or deleterious substance to the medicinal cannabis.

(b) A label shall be firmly affixed to the packaging holding medicinal cannabis or firmly affixed to outer packaging if used that, at a minimum, contains the following information:

1. Name, address, phone number, and license number of the cannabis business that is selling or otherwise transferring the medicinal cannabis to another cannabis business;

2. Name, address, phone number, and license number of the cannabis business receiving the medicinal cannabis;

3. The type and amount of medicinal cannabis in the package;

4. An identifier that is unique to the particular harvest batch or production batch of medicinal cannabis in the package;

5. The date the medicinal cannabis was harvested and, if applicable, processed;

6. The date the medicinal cannabis was packaged; and

7. A statement confirming that the medicinal cannabis in the package has been tested, and:

a. Affix a QR code to the label that directs the purchaser to the certificate of analysis for the medicinal cannabis harvest batch or production batch contained in the package; or

b. Provide a hardcopy or electronic copy of the certificate of analysis for the medicinal cannabis harvest batch or production batch contained in the package to the purchaser at the time of sale.

(2) Any sale or transfer of medicinal cannabis between cannabis businesses shall be documented in the commonwealth's designated electronic monitoring system and seed to sale tracking system.

Section 5. Incorporation by reference. (1) "Appendix A: Standardized symbol indicating a product contains medicinal cannabis", dated January 4, 2024, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Cabinet for Health and Family Services, Office of the Secretary, 275 East Main Street, Frankfort, Kentucky, 40621, Monday through Friday, 8:30 AM to 4:30 PM. This material may also be viewed on the Kentucky Medical Cannabis Program's website at https://kymedcan.ky.gov.

915 KAR 1:100

REVIEWED:

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1/2/2024

Sam Flynn
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Cabinet for Health and Family Services

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APPROVED:

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Eric Friedlander
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1/2/2024

Eric C. Friedlander
Secretary
Cabinet for Health and Family Services

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on March 25, 2024, 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 March 18, 2024, 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 March 31, 2024. 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, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 915 KAR 1:100
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Contact Person: Krista Quarles
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(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes standards for the packaging and labeling of medicinal cannabis transferred, sold, or distributed by cannabis businesses.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to carry out the requirements of KRS Chapter 218B, specifically KRS 218B.140(1)(c)(13).

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 218B.140 authorizes the Cabinet for Health and Family Services to promulgate administrative regulations establishing standards for the packaging and labeling of medicinal cannabis transferred, sold, or distributed by cannabis businesses. This administrative regulation sets out those procedures.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides standards for the packaging and labeling of medicinal cannabis transferred, sold, or distributed by cannabis businesses.

(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: Not applicable. This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: Not applicable. This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: Not applicable. This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: Not applicable. 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: This administrative regulation affects cannabis businesses that have applied for and subsequently received licenses to conduct medicinal cannabis activities in the commonwealth.

(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: Cannabis businesses shall review and comply with the packaging and labeling standards contained in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Cannabis businesses will be able to properly package and label medicinal cannabis and medicinal cannabis products.

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

(a) Initially: It is anticipated that an increase in funding will be necessary to implement this administrative regulation as additional staff and resources are necessary to administer and enforce packaging and labeling requirements. The cabinet estimates that the total staffing costs for the program in the first year will be approximately $1,800,000, and a portion of those staffing costs will go toward regulating packaging and labeling requirements.

(b) On a continuing basis: It is anticipated that an increase in funding will be necessary to administer this administrative regulation as additional staff and resources are necessary to enforce packaging and labeling requirements. The cabinet estimates that the total staffing costs for the program on a continuing basis following the first year will be approximately $2,400,000, and a portion of those staffing costs will go toward regulating packaging and labeling requirements.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds provided by the commonwealth.

(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: It is anticipated that an increase in funding will be necessary to implement this regulation as additional staff and resources are necessary to administer and enforce this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied. All cannabis businesses will be treated equally.

FISCAL NOTE

Administrative Regulation: 915 KAR 1:100
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(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 Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218B.010, 218B.095, 218B.100, 218B.105, 218B.110, 218B.115, 218B.120, 218B.125, 218B.140.

(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 administrative regulation is not expected to generate revenue for state or local government in the first year.

(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 administrative regulation is not expected to generate revenue for state or local government for subsequent years.

(c) How much will it cost to administer this program for the first year? It is anticipated that an increase in funding will be necessary to implement this administrative regulation as additional staff and resources are necessary to administer and enforce the transportation procedures. The cabinet estimates that the total staffing costs for the program in the first year will be approximately $1,800,000, and a portion of those staffing costs will go toward regulating packaging and labeling requirements.

(d) How much will it cost to administer this program for subsequent years? It is anticipated that an increase in funding will be necessary to administer this administrative regulation as additional staff and resources are necessary to enforce the transportation procedures. The cabinet estimates that the total staffing costs for the program on a continuing basis following the first year will be approximately $2,400,000, and a portion of those staffing costs will go toward regulating packaging and labeling requirements.

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

Revenues (+/-):

Expenditures (+/-):
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? The cabinet does not anticipate any cost savings in the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? The cabinet does not anticipate any cost savings in subsequent years.

(c) How much will it cost the regulated entities for the first year? Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation.

(d) How much will it cost the regulated entities for subsequent years? Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation.

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: Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation.

(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)] The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is $9,135,398. A significant portion of those funds will go toward licensing and enforcement of cannabis businesses operating in the commonwealth as well implementation and continued operation of the electronic monitoring system and seed to sale tracking system required by KRS 218B.140. The Kentucky Medical Cannabis Program will have a major economic impact on the Cabinet for Health and Family Services, and it is anticipated that an increase in funding will be necessary to administer all of the administrative regulations contained in 915 KAR Chapter 1 related to cannabis businesses.

FEDERAL MANDATE ANALYSIS COMPARISON

Administrative Regulation: 915 KAR 1:100
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(1) Federal statute or regulation constituting the federal mandate. 15 U.S.C. secs. 1471 to 1476 ("Special Packaging of Household Substances for Protection of Children").

(2) State compliance standards. KRS 218B.140(1)(c)(13) states that the cabinet shall promulgate administrative regulations to establish standards "for the packaging and labeling of medicinal cannabis sold or distributed by cannabis businesses which shall comply with 15 U.S.C. secs. 1471 to 1476 and shall include: a. Standards for packaging that requires at least a two (2) step process of initial opening; b. A warning label which may include the length of time it typically takes for the product to take effect, how long the effects of the product typically last, and any other information deemed appropriate or necessary by the cabinet; c. The amount of medicinal cannabis the product is considered the equivalent to; d. Disclosing ingredients, possible allergens, and certain bioactive components, including cannabinoids and terpenoids, as determined by the cabinet; e. A nutritional fact panel; f. Opaque, child-resistant packaging; g. A requirement that all raw plant material packaged or sold in this state be marked or labeled as "NOT INTENDED FOR CONSUMPTION BY SMOKING"; h. A requirement that medicinal cannabis products be clearly marked with an identifiable and standardized symbol indicating that the product contains cannabis; i. A requirement that all medicinal cannabis product packaging include an expiration date; and j. A requirement that medicinal cannabis products and their packaging not be visually reminiscent of major brands of edible noncannabis products or otherwise present an attractive nuisance to minors[.]"

(3) Minimum or uniform standards contained in the federal mandate. The Consumer Product Safety Commission ("Commission") may establish standards for child-resistant or "special" packaging of household substances, including food, drugs, or cosmetics, if it finds that special packaging is required to protect children from serious personal injury or serious illness from using or ingesting the substance and the special packaging required is technically feasible, practicable, and appropriate for such substance. Child-resistant or special packaging must be designed or constructed to be: (1) significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time; and (2) not difficult for normal adults to use properly. The Commission promulgated performance requirements for special packaging in 16 CFR 1700.15 and 1700.20.

(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 imposes additional requirements. It requires packages containing

medicinal cannabis for sale to cardholders to be child-resistant. This administrative regulation also includes additional packaging requirements provided in KRS 218B.140(1)(c)(13), including a two (2) step process of initial opening, a warning label, disclosing ingredients, and opaque packaging marked with an identifiable and standardized symbol indicating that the product contains medicinal cannabis.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. KRS 218B.140(1)(c)(13) expressly provides that medicinal cannabis packaging comply with 15 U.S.C. secs. 1471 to 1476, meaning be properly child-resistant, and include the additional items listed above in paragraph (2). This administrative regulation establishes standards for the packaging and labeling of medicinal cannabis in compliance with KRS 218B.140(1)(c)(13).

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF THE SECRETARY

915 KAR 1:100
Packaging and labeling of medicinal cannabis.
Summary of Material Incorporated by Reference

The "Appendix A: Standardized symbol indicating a product contains medicinal cannabis", dated January 4, 2024, contains the identifiable and standardized symbol indicating that a product contains medicinal cannabis. Packages containing medicinal cannabis for sale to cardholders will be clearly marked with this symbol as required by KRS 218B.140(1)(c)(13)(h). The Appendix contains one (1) page.

The total number of pages incorporated by reference for this administrative regulation is one (1) page.

APPENDIX A

STANDARDIZED SYMBOL INDICATING A PRODUCT CONTAINS MEDICINAL CANNABIS: