CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary
(Amended After Comments)

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) **Medicinal cannabis shall be prepared, packaged, and labeled by cannabis businesses at their licensed locations.** ~~**[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 **in bold** "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, **including whether it is a sativa, indica, or hybrid,** form of medicinal cannabis, and standard amount of delta-9 tetrahydrocannabinol (THC)**, terpenes,** 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 **and raw plant material**, total THC**, total terpenes,** 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**, with writing no smaller than one-sixteenth of an inch in height,** 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. **For concentrates,** the specific amount of THC and CBD **shall[may]** be expressed in milligrams **and[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**. For concentrates, the specific amount of terpenes shall be expressed in milligrams and by percentage, 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**, as applicable**;

(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) **The method of extraction, if applicable;**

(o) If the product contains multiple servings, the statement in bold "MULTIPLE SERVINGS";

(p) Directions for use for concentrates and THC infused medicinal cannabis products; and

(q) 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.

(3) Quick response (QR) codes. The label required by this section may contain a QR code that links to information required under this section.

(a) Any QR code shall be:

1. Labeled as "Specific Product Information" directly above or below the QR code; and

2. Large enough to be smart-phone readable.

(b) The information available through use of a QR code may include:

1. The name and license number of the cannabis business that cultivated the medicinal cannabis;

2. The name and license number of the cannabis business that processed the medicinal cannabis, if applicable;

3. The name and license number of the cannabis business that packaged the medicinal cannabis;

4. The method of extraction, if applicable; and

5. The date the medicinal cannabis was packaged.

(c) If a cannabis business makes any of the items listed in subsection 3(b) of this section available through use of a QR code on the product label, the cannabis business is not required to include that information directly on the product label.

(4) A dispensary shall affix a sticker to each package of medicinal cannabis sold at its licensed location that contains the dispensary's name, license number, and telephone number.

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) **Be accompanied by all tracking tags required by the state's designated seed to sale tracking system for the medicinal cannabis contained in the transfer. The tracking tag required by the state's designated seed to sale tracking system shall**

be firmly affixed to the outer most packaging of the respective package containing the medicinal cannabis identified by the tag. A transport manifest shall also accompany transfers of medicinal cannabis between cannabis businesses as required by 915 KAR 1:080(1)(g). ~~[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. **Voluntary Packaging and Labeling Compliance Review.**

(1) Cannabis businesses shall comply with the packaging and labeling requirements established in this administrative regulation.

(2) Cannabis businesses may submit proposed packaging and labels for medicinal cannabis and medicinal cannabis products intended for sale to cardholders to the cabinet for a voluntary compliance review. Cannabis businesses shall submit proposed packaging and labels in the manner prescribed by the cabinet and made available through the Web site for the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov.

(3) A cannabis business requesting a voluntary compliance review for a product shall provide the following to the cabinet at the time of submission:

(a) Documentation from the packaging company confirming the proposed packaging is child-resistant and has at least a two (2) step process of initial opening;

(b) A clear digital proof or photograph of the product packaging with a file size no greater than twenty-five (25) megabytes;

(c) A clear digital proof or photograph of the product label with a file size no greater than twenty-five (25) megabytes; and

(d) The category of product being submitted, such as raw plant material, concentrate, or infused product.

(4) If the cabinet determines that a voluntary compliance review request is lacking sufficient information upon which to make a determination, the cabinet shall notify the cannabis business in writing of the additional information and documentation

needed to complete the review. The cannabis business shall have seven (7) calendar days from the date of the notice to provide the requested information and documentation to the cabinet. If a cannabis business fails to provide the requested information to the cabinet by the deadline, the cabinet shall not provide a compliance determination to the cannabis business for the product submitted.

(5) The nonrefundable fee for the voluntary compliance review established in this section is $200 per product submission and shall be paid by the cannabis business at the time of submission via credit card or automated clearing house (ACH) transfer.

(6) The cabinet shall complete a product packaging and labeling compliance review within twenty-one (21) calendar days of submission to the cabinet, unless additional information is requested by the cabinet as provided in subsection (4) of this section.

(7) Upon completion of its review, the cabinet shall:

(a) For compliant submissions, provide the cannabis business with an electronic notification stating the submitted product packaging and label is in compliance with 915 KAR 1:100. This compliance determination shall only apply to the specific product package and label submitted to the cabinet for review and shall not apply to any variations of that product package or label; or

(b) For non-compliant submissions, provide the cannabis business with an electronic notification stating the submitted product packaging and label is not in compliance with 915 KAR 1:100 and the reasons for that determination. A cannabis business may correct a product package and label previously found to be non-compliant by the cabinet and resubmit that package and label for an additional voluntary compliance review upon payment of the fee established in subsection (5) of this section.

Section 6. 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 a.m. to 4:30 p.m.. This material may also be viewed on the Kentucky Medical Cannabis Program's Web site at https://kymedcan.ky.gov.

SAM FLYNN, Executive Director
ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: May 14, 2024

FILED WITH LRC: May 15, 2024 at 11:15 a.m.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes standards for the packaging and labeling of medicinal cannabis transferred, sold, or distributed by cannabis businesses. In response to comments received by the cabinet, the Amended After Comments version of the administrative regulation will clarify the required items to include on a product label, what may be accessed through a QR code on a label, and the labeling requirements for business-to-business transfers of medicinal cannabis. The Amended After Comments version will also include a new section regarding voluntary packaging and labeling compliance review.

(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 establishes a voluntary fee of $200 if a cannabis business decides to request cabinet review any proposed packaging and labeling for compliance with this administrative regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied. All cannabis businesses will be treated equally.

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 218B.140(1)(c)(13).

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

This administrative regulation is promulgated by the Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(a) Estimate the following for the first year:

Expenditures: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.

Revenues:This administrative regulation is not expected to generate significant revenue in the first year though its voluntary packaging and labeling compliance review program.

Cost Savings:The cabinet does not anticipate any cost savings in the first year.

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

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. This administrative regulation is not expected to generate significant revenue in subsequent years though its voluntary packaging and labeling compliance review program. The cabinet does not anticipate any cost savings in subsequent years.

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

If its application is approved, a proposed cannabis business will locate within a city or county in the commonwealth and be subject to the packaging and labeling requirements contained in this administrative regulation.

(a) Estimate the following for the first year:

Expenditures:Unknown at this time. This response will depend on the number of licensed cannabis businesses located in a respective city or county and any ordinances established by local authorities regulating licensed cannabis businesses in their jurisdiction as allowed by KRS 218B.130.

Revenues:Unknown at this time. This response will depend on the number of licensed cannabis businesses located in a respective city or county and any ordinances and fees established by local authorities regulating licensed cannabis businesses in their jurisdiction as allowed by KRS 218B.130.

Cost Savings:The cabinet does not anticipate any cost savings in the first year.

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

Unknown at this time. This response will depend on the number of licensed cannabis businesses located in a respective city or county and any ordinances and fees established by local authorities regulating licensed cannabis businesses in their jurisdiction as allowed by KRS 218B.130.

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

Licensed cannabis businesses.

(a) Estimate the following for the first year:

Expenditures:Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation and determine whether to participate in the cabinet's voluntary packaging and labeling compliance review program.

Revenues:This administrative regulation is not expected to generate revenue in the first year.

Cost Savings:The cabinet does not anticipate any cost savings in the first year.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
Each cannabis business will decide how to package and label medicinal cannabis in accordance with this administrative regulation and determine whether to participate in the cabinet's voluntary packaging and labeling compliance review program.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
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. A portion of the estimated staffing costs will go toward regulating packaging and labeling of medicinal cannabis.

(b) Methodology and resources used to determine the fiscal impact:
As part of its Biennial Budget Request, the Cabinet for Health and Family Services analyzed the cost to administer all aspects of the Kentucky Medical Cannabis Program, including estimated costs for staffing and implementation and ongoing maintenance and operations costs for the electronic monitoring system and seed to sale tracking system required by KRS 218B.140.

(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 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.

(b) The methodology and resources used to reach this conclusion:
As part of its Biennial Budget Request, the Cabinet for Health and Family Services analyzed the cost to administer all aspects of the Kentucky Medical Cannabis Program, including estimated costs for staffing and implementation and ongoing maintenance and operations costs for the electronic monitoring system required by KRS 218B.140.