CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary
(Amended at ARRS Committee)

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 or 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; or

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

(2) Medicinal cannabis shall be prepared, packaged, and labeled by a cannabis business at its licensed locations. 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 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 shall:

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

(b) Be legible;

(c) List the strain 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 be expressed in milligrams and by percentage, as applicable;

(f) List the percentage of total terpenes and the 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;

(n) List the method of extraction, if applicable;

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

(p) Include 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) The 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 shall not be 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; and

(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).

(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) At the time of submission, a cannabis business requesting a voluntary compliance review for a product shall provide to the cabinet:

(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 by 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.

(50 Ky.R. 1842, 2450; 51 Ky.R. 315; eff. 8-28-2024.)

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