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 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: January 3, 2024

FILED WITH LRC: January 4, 2024 at 11:50 a.m.

PUBLIC HEARING AND 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, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.