

March 5, 2024

INFORMATIONAL COPY OF MAR NOTICE NO. 42.1073 PROVIDED TO ECONOMIC AFFAIRS INTERIM COMMITTEE

PRESENTATION FORMAT

Black interline (strikethrough) and <u>underline</u> = original proposed new or amendments to existing rules

RED INTERLINE (STRIKETHROUGH) AND <u>UNDERLINE</u> = RULE TEXT REVISED UPON ADOPTION BASED ON TESTIMONY RECEIVED AT THE PUBLIC HEARING OR COMMENTS RECEIVED IN WRITING

NEW RULES PROPOSED TO BE ADOPTED:

<u>NEW RULE I (42.39.322) LABELING OF SEEDS OR PLANTS</u> (1) Each package of marijuana seeds or plants shall be labeled with the following information:

(a) name and license number of the dispensary selling the seeds or plants and the cultivator that produced the seeds or plants;

(b) net weight or number of individual seeds <u>OR NUMBER OF PLANTS, AS</u> <u>APPLICABLE</u>;

(c) number or plants;

(d) (C) name of the strain; and

(e) (D) the universal marijuana symbol as required in ARM 42.39.314.

AUTH: 16-12-112, 16-12-208, MCA IMP: 16-12-122, 16-12-208, 16-12-223, MCA

NEW RULE II (42.39.321) WHOLESALE PACKAGE AND LABEL

<u>APPLICATIONS</u> (1) For purposes of this rule and ARM 42.39.320, "wholesale" means the act of a licensed cultivator, manufacturer, or dispensary engaged in selling marijuana or marijuana products in bulk or in quantities sufficient for resale, repackaging, or distribution by another licensee. The term does not include the sale of marijuana flower from licensed cultivator to licensed cultivator.

(2) Wholesalers of marijuana or marijuana products must comply with the package and label application requirements of ARM 42.39.320.

(3) All label and package applications for wholesale marijuana and marijuana products must contain photographs or accurate renderings of proposed labels and packages.

(4) A <u>MARIJUANA</u> wholesaler must apply and receive <u>DEPARTMENT</u> approval to use all wholesale packaging and labels before distributing <u>ANY PACKAGED AND</u> <u>LABELED</u> wholesale products <u>FOR FINAL SALE TO CUSTOMERS</u>. <u>PACKAGE AND</u> <u>LABEL APPROVAL IS NOT REQUIRED FOR WHOLESALE PRODUCTS THAT WILL</u> <u>RECEIVE ADDITIONAL PROCESSING OR WILL BE REPACKAGED AND</u> <u>RELABELED BY ANOTHER LICENSEE</u>.

AUTH: 16-12-112, 16-12-208, MCA IMP: 16-12-112, 16-12-208, MCA

RULES AS PROPOSED TO BE AMENDED:

<u>42.39.102</u> DEFINITIONS The following definitions apply to this chapter:

(1) "Act" means the Marijuana Regulation and Taxation Act, codified at 16-12-101, MCA, et. seq.

(2) "Authorized employee" means:

(a) an employee of the department who has received written authorization from the department director or the director's designee to obtain individual names and other identifying information from the marijuana registry;

(b) an employee of a state or local law enforcement agency who is authorized to obtain marijuana registry information through the Montana Criminal Justice Information Network (CJIN)/marijuana registry interface; or

(c) an employee of a state or local government agency, including a state or local law enforcement agency, who has received authorization to obtain marijuana registry information.

(3) "Batch" means:

(a) a quantity of usable marijuana from a harvest lot; or

(b) a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

(4) "CBD" means cannabidiol.

(5) "CBDA" means cannabidiolic acid.

(6) "Certificate of analysis" means the report prepared by a marijuana testing laboratory about the analytical testing performed and the results obtained by the laboratory.

(7) "Chemical manufacturing" means the use of chemical compounds such as, but not limited to, hydrocarbon solvents or food grade nonhydrocarbon solvents to separate cannabinoids or marijuana analytes of interest from marijuana.

(8) "Child resistant" means packaging designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly. The standard for child-resistant packaging is set by the federal consumer product safety commission (CPSC) and the testing procedures found in 16 CFR 1700.20 (2012).

(9) "Compliance audit" means a department review of aspects of a licensee's business without conducting a physical on-site inspection, including but not limited to website compliance checks, review of seed-to-sale tracking system records, permit compliance checks, and local ordinance compliance checks.

(10) "Cultivate" means to grow, propagate, clone, or harvest marijuana for use by registered cardholders or consumers.

(11) "Customer" means, collectively, adult use consumers and registered cardholders.

(12) "Edible marijuana-infused product" or "edible" means an ingestible marijuana-infused product that is intended to be taken by mouth, swallowed, and primarily absorbed through the gastrointestinal tract. Edible marijuana-infused products may be psychoactive when used as intended. Without limitation, edible marijuana-infused products may be in the form of a food, beverage, capsule, or tablet, or tincture.

(13) "Employee" as defined in 16-12-102, MCA, includes an independent contractor that performs work for any aspect of a marijuana business.

(14) "Existing outdoor cultivation space" means outdoor space used to grow live marijuana plants in an area exposed to natural sunlight and environmental conditions including variable temperature, precipitation, and wind, licensed on or before November 3, 2020.

(15) "Exit package" means a sealed container or package provided at the retail point of sale, in which any marijuana item already within a container is placed.

(16) "Fee" means the mandatory fees required by the department.

(17) "Fingerprint card" means an FD-258 fingerprint card utilized to facilitate a Federal Bureau of Investigation (FBI) fingerprint and background check.

(18) "Food-Grade" means the processing and packaging has been done with clean equipment and can be safely eaten.

(19) "Green county" means a county where the majority of voters voted to approve Initiative Measure No. 190 in the November 3, 2020 general election or where the local government approval provisions of 16-12-301, MCA, have been satisfied. This definition does not include a municipality that has approved or disapproved a category or categories of marijuana businesses, as authorized in 16-12-301, MCA.

(20) "Ingestible marijuana-infused product" or "ingestible" means a product that contains marijuana and at least one other ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended to be taken into the body, and is either categorized as an edible marijuana-infused product or a transmucosal marijuana-infused product.

(21) "Ingredient" means any substance that is added to marijuana items that changes its final form including but not limited to flavorings, aromatic oils, colorants, food items, spices, sweeteners, and preservatives.

(22) "Label" or "labeling" means the written, printed, <u>analytical information</u> <u>pertaining to the marijuana flower or marijuana product</u> or graphic matter displayed on

the packaging in which marijuana or a marijuana product is dispensed or displayed to a customer.

(23) "Licensee" means any person licensed by the department.

(24) "Limited access area" means a building, room, or other contiguous area upon the licensed premises where marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under the control of the licensee.

(25) "Major food allergen" or "allergen" means milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, <u>sesame</u>, and soybeans, any additional ingredient <u>identified by the United States Food and Drug Administration</u>, and any ingredient containing a protein derived from these foods.

(26) "Manufacture" means the act of preparing and processing usable marijuana into a marijuana-infused product. A marijuana-infused product must be labeled as to indicate that it contains marijuana.

(27) "Marijuana" means the same as the definition in 16-12-102, MCA, and includes the biomass of the marijuana plant which contains greater than 0.3% total THC concentration and appreciable concentrations of other cannabinoids of interest including flower, bud, shake, trim, and manicure.

(28) "Marijuana concentrate and extract" or "concentrate and extract" means the same as the definition in 16-12-102, MCA, and includes a substance obtained by separating and/or concentrating naturally occurring chemical constituents of marijuana, such as, but not limited to, cannabinoids, from marijuana plant material by mechanical, physical, chemical, or other processes that may:

(a) contain solvents in allowable amounts and ingredients used to promote a desired physical state, texture, or flavor in the marijuana concentrate, but no other ingredients; or

(b) be intended for use in the production of marijuana-infused products; or

(c) be a finished product intended for consumption or use.

(29) "Marijuana-infused product" means the same as the definition in 16-12-102, MCA, and includes the infusion of cannabinoids of interest using marijuana or marijuana concentrate or extract into existing products, substances, or consumer goods, and as an ingredient in the production of consumer goods that would not naturally or ordinarily contain cannabinoids of interest.

(30) "Marijuana items" means:

(a) marijuana;

(b) usable marijuana;

(c) dried leaves and flowers of the marijuana plant;

(d) marijuana derivatives, concentrates, extracts, resins, infused products, edible products, ointments, tinctures, suppositories, topicals; and

(e) other marijuana-related products.

(31) "Marijuana laws" for the purposes of these rules, means any combination of regulatory authority pursuant to the Montana Marijuana Regulation and Taxation Act (Title 16, chapter 12, MCA), rules of the department, rules of the Department of Public

Health and Human Services regarding marijuana testing laboratories, or local ordinances applicable to marijuana businesses.

(32) "Marijuana product category" means a defined group of marijuana products that are in the same form. Marijuana product categories are:

- (a) marijuana flower;
- (b) marijuana concentrates; and
- (c) marijuana-infused products, including the following subcategories:
- (i) ingestible marijuana-infused products, including the following subcategories:
- (A) edible; and
- (B) transmucosal;

(ii) non-ingestible marijuana-infused products, including the following subcategories:

- (A) topical; and
- (B) transdermal.

(33) "Mechanical manufacturing" means the use of mechanical methods to produce or refine marijuana concentrates and extracts, such as but not limited to a press, centrifuge, or evaporation.

(34) "Mixed strain" means multiple strains of marijuana.

(34) (35) "Monthly" means, for purposes of determining a registered cardholder's maximum monthly amount of usable marijuana, a period of 30 consecutive days.

(35) (36) "Motor vehicle," for purposes of these rules, means a vehicle propelled by its own power and designed or used to transport persons or property on the highways of the state with an interior passenger compartment.

(36) (37) "Non-ingestible marijuana-infused product" or "non-ingestible" means a product that contains marijuana and at least one other ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended for external use only, and is either a topical marijuana-infused product or a transdermal marijuana-infused product.

(37) (38) "Opaque" means packaging that does not allow the contents to be seen when unopened. Packaging may be opaque by virtue of the specific properties of the material of which it is composed, including any coating applied to it, or by means of a secondary opaque covering, such as a sticker.

(38) (39) "Package" or "packaging" means the immediate container in which a finished marijuana product is placed for retail sale to consumers and any outer container or wrapping used in the retail display of the marijuana or marijuana product to customers, and includes graphics, logos, and design elements.

(39) (40) "Performing work on behalf of any aspect of a marijuana business" means and includes:

(a) possessing, handling, producing, propagating, processing, securing, or selling marijuana or marijuana products at the licensed premises;

(b) recording of the possession, handling, production, propagation, processing, securing, or selling of marijuana or marijuana products at the licensed premises; and

(c) the direct supervision of a person described in (a) or (b).

(40) (41) "Physician statement" means a written statement by a Montana licensed physician on department forms certifying the registered cardholder applicant's debilitating condition. Physician statement forms include:

(a) Physician Statement for Debilitating Condition; or

(b) Physician Statement for Minors.

(41) (42) "Property owner permission form" means a completed, signed, and notarized form which gives an applicant or licensee who is renting or leasing the property where marijuana will be cultivated and manufactured permission to do so by the property owner. The form must be provided by the department.

(42) (43) "Psychoactive" means capable of affecting mental processes or cognition when used as intended. A marijuana product is considered *per se* psychoactive if it is not a topical marijuana-infused product and the labeled potency is greater than .3% THC.

(44) "Reconcile" for purposes of seed-to-sale tracking means to ensure that what is recorded in the seed-to-sale tracking system is consistent with what is physically located at the licensed premises.

(43) (45) "Red county" means a county where the majority of voters voted against approval of Initiative Measure No. 190 in the November 3, 2020 general election or where the local government has voted to prohibit all marijuana businesses pursuant to 16-12-301, MCA. This definition does not include a municipality that has approved or disapproved a category or categories of marijuana businesses, as authorized in 16-12-301, MCA.

(44) (46) "Registered premises" has the same meaning as "licensed premises."

(45) (47) "Registry" means the department's confidential record identifying registered cardholders.

(46) (48) "Resident" means a person determined to be a resident of Montana for tax purposes, pursuant to ARM 42.15.109.

(49) "Safety Data Sheet (SDS)" means a summary document that provides information about the hazards of a product and advice about safety precautions written by the manufacturer or supplier of the product. An SDS must be provided by a supplier of a hazardous product at the time of sale.

(47) (50) "Seed-to-sale tracking system" means the system provided in 16-12-105, MCA, for tracking inventory of marijuana, marijuana concentrate, and marijuanainfused products from either the seed or the seedling stage until the marijuana or marijuana product is sold to a consumer.

(51) "Standard operating procedure (SOP)" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

(52) "Strain" means a pure breed or hybrid variety of cannabis reflecting similar or identical combinations of properties such as appearance, taste, color, smell, cannabinoid profile, and potency. (48) (53) "Test Batch" means a portion of a harvest or process lot that has been submitted for quality assurance testing.

(49) (54) "THC" means delta-9 tetrahydrocannabinol.

(50) (55) "THCA" means tetrahydrocannabinolic acid.

(51) (56) "Topical marijuana-infused product" or "topical" means a non-ingestible marijuana-infused product that is not psychoactive when used as intended. Topicals include but are not limited to creams, salves, bath soaks, and lotions.

(52) (57) "Total potential psychoactive THC" or "Total THC" means the highest theoretical concentration of psychoactive THC available in a marijuana item achievable only through the complete conversion of THCa to THC with the application of heat during administration/consumption. Total potential psychoactive THC is the sum of THC and THCa calculated using the following equation: Total potential psychoactive THC = (THCa x 0.877) + THC.

(53) (58) "Transdermal marijuana-infused product" or "transdermal" means a non-ingestible marijuana-infused product that contains at least one skin-permeationenhancing ingredient to facilitate absorption through the skin into the bloodstream, and may be psychoactive when used as intended. Transdermal products include but are not limited to adhesive patches applied to the skin.

(54) (59) "Transmucosal marijuana-infused product" means an ingestible marijuana-infused product that is intended to be placed in a body cavity and absorbed through the mucosal lining of the cavity, and may be psychoactive when used as intended. Transmucosal marijuana-infused products include, but are not limited to, marijuana-infused tinctures, anal suppositories, lozenges, and nasal sprays.

AUTH: 16-12-112, MCA

IMP: 16-12-101, 16-12-102, 16-12-104, 16-12-105, 16-12-112, 16-12-201, 16-12-207, 16-12-208, 16-12-210, 16-12-301, 16-12-501, 16-12-503, 16-12-508, 16-12-515, 16-12-533, MCA

<u>42.39.123</u> ADVERTISING (1) A licensee may promote its business and market its brand but may not advertise marijuana or marijuana products except in electronic advertising.

(2) "Advertise or advertising" means the publication, dissemination, solicitation, or circulation of visual, oral, or written communication to directly induce any person to purchase or consume marijuana or marijuana products. Advertising includes the promotion of special pricing, events, sales, or discounts ON MARIJUANA AND MARIJUANA PRODUCTS. Advertising does not include branding, marketing, or packaging and labeling of marijuana and marijuana products <u>OR INFORMATION REGARDING SPECIAL PRICING, SALES, OR DISCOUNTS ON DISPLAY WITHIN A LICENSED PREMISES</u>.

(3) "Billboard" means a sign that directs attention to a business, commodity, service, entertainment, or attraction sold, offered, or existing elsewhere than upon the same premises where such sign is displayed.

(4) "Brand" or "branding" means creating a unique identity for a business to target an audience or consumers. Branding does not include references to specific marijuana or marijuana products.

(5) "Market" or "marketing" means an action a business uses to promote their brand, location, or services. Marketing does not include references to specific marijuana or marijuana products.

(4) (6) A licensee may use the phrase "marijuana" or "cannabis" in its signage or in its electronic advertising.

(5) (7) A licensee's outdoor signage may not use colloquial terms for marijuana or marijuana products (e.g., pot, reefer, ganja, weed) and may not use an image or visual representation of useable marijuana, marijuana-infused products, marijuana concentrates, marijuana paraphernalia, or an image that indicates the presence of a product such as smoke, edibles, etc.

(6) (8) A licensee's outdoor signage must comply with any applicable local jurisdiction sign ordinances and regulations.

(7) (9) A marijuana business that maintains a webpage must utilize appropriate measures to verify that individuals visiting the webpage are 21 years of age or older.

(8) (10) Marijuana business social media accounts that advertise marijuana or marijuana products must be private and must contain a clearly visible notice on the main page stating that only persons 21 years of age or older may follow the account. <u>A</u> <u>marijuana business that uses a QR code in an electronic advertisement must utilize</u> <u>appropriate measures to verify that individuals visiting the QR code's webpage are 21</u> <u>years of age or older.</u>

(9) (11) A marijuana business may not:

(a) engage in advertising via marketing directed towards location-based devices, including, but not limited to cellular phones, unless users affirmatively opt in to receiving push notifications related to marijuana or marijuana-related products;

(b) utilize unsolicited pop-up or push-to advertising on the internet;

(c) advertise on television, radio, or in print such as newspapers, magazines, flyers, and mailers;

(d) engage in advertising or utilize signage that asserts its products are safe;

(e) utilize a billboard;

(f) use objects such as toys or inflatables, movie or cartoon characters, or any other depiction or image likely to be appealing to youth, where the objects, images, or depictions indicate an intent to cause youth to become interested in the purchase or consumption of marijuana products; or

(g) use or employ a commercial mascot outside of, and in proximity to, a licensed marijuana business. A "commercial mascot" means a live human being, animal, or mechanical device used for attracting the attention of motorists and

passersby so as to make them aware of marijuana products or the presence of a marijuana business. Commercial mascots include, but are not limited to, inflatable tube displays, persons in costume, or wearing, holding, or spinning a sign with a marijuana-related commercial message or image, where the intent is to draw attention to a marijuana business or its products.

(10) (12) The prohibition in (9)(11)(c) does not prohibit the use of informational pamphlets for dissemination at marijuana trade conferences or the use or distribution of business cards. Nothing in this rule shall be construed to allow the sale or possession of marijuana or marijuana products outside of a licensed premises, including at tradeshows.

(11) (13) The prohibition in (9)(11)(d) does not prohibit a marijuana business from asserting that its products have been tested by a licensed marijuana testing laboratory.

AUTH: 16-12-112, 16-12-211, MCA IMP: 16-12-112, 16-12-211, MCA

<u>42.39.314 GENERAL LABELING REQUIREMENTS</u> (1) Labeling requirements apply to marijuana and marijuana products sold from a dispensary to customers <u>and</u> <u>wholesale PRODUCTS INTENDED FOR FINAL SALE TO CUSTOMERS</u> from one <u>licensee to another</u>. A licensee that sells marijuana or marijuana products to other <u>licensees is not required to comply with labeling requirements</u>.

(2) All information required on the label of marijuana or a marijuana product shall be:

(a) unobstructed and conspicuous. A licensee may affix multiple labels to a package, or use a booklet, accordion, or other type of label, provided that no required information is completely and permanently obstructed;

(b) displayed in a legible font, such as Times New Roman, Arial, or Helvetica. The lowercase letter "o" must be at least one-sixteenth of an inch in height;

(c) displayed in a color that contrasts conspicuously with the background; and

(d) displayed in English, although a licensee may choose to display required information in additional languages.

(3) All marijuana or marijuana products shall be labeled with the following information:

(a) <u>the</u> strain name, <u>except when the marijuana or marijuana product contains a</u> <u>mixed-strain, then indicate mixed-strain;</u>

(b) the common or usual name of the marijuana product (e.g., flower, inhaled extract, edible, cookie, or drinkable, topical, transdermal patch);

(c) the name of the marijuana dispensary that sold the product and the license number or numbers of the cultivator and manufacturer, as applicable;

(d) (C) the unique identification number generated from the seed-to-sale tracking system <u>correlated to the marijuana or marijuana product's final form testing results;</u>

(e) (D) date of harvest for marijuana flower or date of manufacture for marijuana products;

(f) (E) the net quantity of contents of the marijuana product. The statement of quantity shall be:

(i) stated in U.S. Customary Units and Metric (SI) Units, with the latter enclosed in parentheses;

- (ii) if the product is a liquid:
- (A) expressed in terms of fluid measure; and
- (B) preceded by the phrase "Net Contents" or "Net"; or
- (iii) if the product is a solid, semi-solid, or viscous:
- (A) expressed in terms of weight; and
- (B) preceded by the phrase "Net Weight," the abbreviation "Nt. Wt.," or "Net."

(iv) In addition to weight or fluid measure, a licensee shall include the number of servings in the net quantity of contents statement if the product is a multi-serving marijuana product (e.g., Net Weight: 2 oz. (56.7 g) (10 cookies), Net Contents: 2 fl. oz. (2 mL or milliliters));

(g) (F) the following statement: "This product has been tested and meets the requirements of the state of Montana."

(h) (G) a QR code that links to the product's certificate of analysis with a statement informing customers they can scan the code to see additional product information;

(i) (H) the universal symbol, available from the department's website. <u>The</u> <u>universal symbol may be a sticker if the sticker meets the requirements of this section.</u> The universal symbol:

(i) shall be at least .33 inches wide and .33 inches high;

(ii) may be downloaded from the department's website; and

(iii) may not be colored by hand and/or using a highlighter, marker, etc.; and

(iii) (iv) shall be in the following form:



(4) All marijuana and marijuana products shall be labeled <u>verbatim</u> with the following warnings:

- (a) "Keep out of reach of children and pets";
- (b) "This product may be addictive"; and

(c) "This product may have intoxicating effects. Do not drive while under the influence of marijuana."

(5) Marijuana or marijuana product labeling shall not contain any statement or information that is false or misleading.

(6) The label of manufactured marijuana products must identify the method of manufacturing (e.g., mechanical, chemical) and for chemical manufacturing must identify the solvent(s) used in the manufacturing process.

(7) Marijuana or marijuana products that, because of their size, do not have sufficient space for all of the information required for compliance with the Act and department rules may, if approved by the department pursuant to 16-12-208, MCA, display the information required in (3) in a legible font that does not meet the minimum size requirement established in (2)(b).

(8) Marijuana or marijuana products in excess of the THC limits in 16-12-224, MCA, may only be sold to registered cardholders and must contain the following additional information <u>verbatim</u>:

(a) "For medical use only"; and

(b) "This product is not approved by the U.S. Food and Drug Administration to treat, cure, or prevent any disease."

(9) Marijuana or marijuana products that do not require heat to administer or consume shall not have a total THC or total potential psychoactive THC value listed on the marijuana facts panel.

AUTH: 16-12-112, MCA IMP: 16-12-101, 16-12-112, 16-12-208, 16-12-224, MCA

42.39.315 LABELING REQUIREMENTS FOR MARIJUANA FLOWER

(1) For purposes of the rule and ARM 42.39.318, "flower" includes marijuana pre-rolls, but excludes infused marijuana pre-rolls.

(1) (2) In addition to the general labeling requirements set forth in ARM 42.39.314, each package of marijuana flower sold to a customer shall be labeled with a marijuana facts panel.

(2) (3) A marijuana facts panel shall include the percentage of concentration of:

(a) total potential psychoactive THC;

(b) THC;

(c) THCa;

(d) CBD; and

(e) CBDa.

(3) (4) A marijuana facts panel may include the percentage concentration of each additional marketed cannabinoid or terpene, if applicable.

AUTH: 16-12-112, MCA IMP: 16-12-101, 16-12-112, 16-12-208, MCA

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42.39.316 LABELING OF INGESTIBLE MARIJUANA-INFUSED PRODUCTS

(1) In addition to the general labeling requirements set forth in ARM 42.39.314, each package of ingestible marijuana-infused product sold to a customer shall be labeled with the following information:

(a) an ingredients list that shall include all ingredients in the ingestible marijuanainfused product listed by common or usual name in descending order of predominance by weight and the word "marijuana" followed by the part of the plant (e.g., flower, trim) or form of concentrate (e.g., oil, infused butter) used as an ingredient in the manufacturing process. Any substance that is present in an ingestible marijuanainfused product in an insignificant amount and that does not have any technical or functional effect in the finished product may be excluded from the ingredients list;

(b) an allergen statement that shall <u>must</u> declare the presence, <u>or absence</u>, of major food allergens in plain language;

(c) a marijuana facts panel containing the following information:

(i) the <u>actual</u> milligrams per serving size or dose of:

(A) THC;

(B) THCa;

(C) CBD; and

(D) CBDa;

(ii) the number of servings or doses per package; and

(iii) for multi-serving packages, the total <u>actual</u> milligrams per package of:

- (A) THC;
- (B) THCa;

(C) CBD; <u>and</u>

(D) and CBDa;

(d) in addition to the required warnings in ARM 42.39.314, each package of ingestible marijuana-infused product sold to a customer shall be labeled with the following information: "The intoxicating effects of this product may be delayed by two or more hours."

(2) A marijuana facts panel for ingestible marijuana-infused products may not contain information on the total potential psychoactive THC, total THC, or otherwise mislead customers into believing the product has higher THC levels than it does.

(3) A marijuana facts panel may include the milligrams of each additional marketed cannabinoid and terpene per serving size, dose, or package.

AUTH: 16-12-112, MCA IMP: 16-12-101, 16-12-112, 16-12-208, MCA

<u>42.39.317</u> LABELING OF NON-INGESTIBLE MARIJUANA-INFUSED <u>PRODUCTS</u> (1) In addition to the general labeling requirements set forth in ARM

42.39.314, each packaging of non-ingestible marijuana-infused products shall be labeled with the following information:

(a) an ingredients list that shall include all ingredients in the non-ingestible marijuana-infused product listed by common or usual name in descending order of predominance by weight and the word "marijuana" followed by the part of the plant (e.g., flower, trim) or form of concentrate (e.g., oil, infused butter) used as an ingredient in the manufacturing process. Any substance that is present in a non-ingestible marijuana-infused product in an insignificant amount and that does not have any technical or functional effect in the finished product may be excluded from the ingredients list;

(b) an allergen statement that must declare the presence, or absence, of major food allergens in plain language; and

(b) (c) a marijuana facts panel containing the following information:

(i) the milligrams per application size or dose of:

(A) THC;

(B) THCa;

(C) CBD; and

(D) CBDa;

(ii) the number of applications or doses per package; and

(iii) for multi-dose packages, the total milligrams per package of:

(A) THC;

(B) THCa;

(C) CBD; and

(D) CBDa.

(2) A marijuana facts panel for non-ingestible marijuana-infused products may not contain information on the total potential psychoactive THC, total THC, or otherwise mislead customers into believing the product has higher THC levels than it does.

(3) A marijuana facts panel may include information about each additional marketed cannabinoid and terpene expressed in terms of milligrams per serving size, dose, or package.

AUTH: 16-12-112, MCA IMP: 16-12-101, 16-12-112, 16-12-208, MCA

<u>42.39.318</u> LABELING REQUIREMENTS FOR MARIJUANA CONCENTRATES AND EXTRACTS (1) In addition to the general labeling requirements set forth in ARM 42.39.314, each package of marijuana concentrate, including infused marijuana prerolls, sold to a customer shall be labeled with the following information:

(a) an ingredients list that shall include all ingredients in the marijuana concentrate listed by common or usual name in descending order of predominance by weight and the word "marijuana" followed by the part of the plant (e.g., flower, trim) from which the marijuana concentrate is derived. Any substance that is present in a

marijuana concentrate in an insignificant amount and that does not have any technical or functional effect in the finished product may be excluded from the ingredients list;

(b) an allergen statement that shall declare the presence, or absence, of major food allergens in plain language unless the marijuana concentrate is not intended to be cooked with, eaten, or otherwise swallowed and digested;

(c) a marijuana facts panel containing the following information:

(i) for marijuana concentrates that require the application of heat before they are administered or consumed:

(A) the percentage concentration of:

(I) total potential psychoactive THC;

(II) THC;

(III) THCa;

(IV) CBD; and

(V) CBDa;

(B) the number of servings or doses per package, except for vapes and other smokable marijuana products;

(ii) for marijuana concentrates that do not require the application of heat before they are administered or consumed:

(A) the percentage concentration of:

(I) THC;

(II) THCa;

(III) CBD; and

(IV) CBDa; <u>or</u>

(B) the milligrams per serving size or dose of:

<u>(I) THC;</u>

<u>(II) THCa;</u>

(III) CBD; and

(IV) CBDa; and

(B) (C) the number of servings or doses per package;

(d) in addition to the required warnings in ARM 42.39.314, each package of activated concentrate that is intended to be cooked with, eaten, or otherwise swallowed and digested shall be labeled with the following: "The intoxicating effects of this product may be delayed by two or more hours."

(2) A marijuana facts panel for marijuana concentrates that do not require the application of heat to be administered or consumed may not contain information on the total potential psychoactive THC, total THC, or otherwise mislead customers into believing the product has higher THC levels than it does.

(3) A marijuana facts panel may include information about each additional marketed cannabinoid and terpene, expressed in percentage of concentration by weight or by volume or in milligrams.

AUTH: 16-12-112, MCA

IMP: 16-12-101, 16-12-112, 16-12-208, MCA

<u>42.39.319 PACKAGING REQUIREMENTS</u> (1) All packaging of marijuana and marijuana products shall:

(a) protect the product from contamination and shall not impart any toxic or deleterious substance to the marijuana or marijuana product;

(b) be capable of being resealed if the package contains more than one serving size;

(c) not primarily appeal to children. Packaging that primarily appeals to children includes but is not limited to packaging that:

(i) depicts a child;

(ii) portrays objects, images, celebrities, or cartoon figures that primarily appeal to children or are commonly used to market products to children; or

(iii) otherwise has special attractiveness for children beyond the general attractiveness for adults;

(d) not bear any reasonable resemblance to the trademarked or characteristic packaging of any commercially available product including but not limited to candy, snacks, baked goods, or beverages.

(2) All marijuana and marijuana products provided to customers at the point of sale shall be in exit packaging that:

(a) is child resistant as defined in ARM 42.39.102;

(b) is opaque; and

(c) contains the warnings required by 16-12-215, MCA, in the format required by 16-12-208, MCA.

(3) Drinkable marijuana products that contain more than one serving per package must include a device or mechanism for measuring a single serving of the product.

(4) Exit packaging of marijuana and marijuana products provided to customers at the point of sale may not contain any other information or design elements than what is allowed under 16-12-208(6)(b)(ii), MCA. <u>Exit packaging may not reference specific or general marijuana or marijuana products and may not include advertisements, including the promotion of events, sales, or special pricing.</u>

(5) Exit packaging of marijuana and marijuana products provided to customers at the point of sale may contain:

(a) a QR code provided, the code utilizes appropriate measures to verify that individuals visiting the QR code's webpage are 21 years of age or older;

(b) a licensee's phone number or address;

(c) marketing and branding elements.

AUTH: 16-12-112, MCA IMP: 16-12-101, 16-12-112, 16-12-208, MCA

<u>42.39.320 PACKAGING AND LABELING APPLICATIONS, FEES AND</u> <u>DEPARTMENT APPROVAL PROCESSES; EXIT PACKAGE APPROVAL; INITIAL</u> <u>REQUIREMENTS APPLICABLE TO ALL LICENSEES</u> (1) For purposes of this rule, "marijuana product categories" mean any of the marijuana and marijuana products described in ARM 42.39.315 through 42.39.318 that are subject to the packaging and labeling requirements of 16-12-208, MCA.

(2) For purposes of this rule, a "unique marijuana product package" means a custom package that contains variations in graphic or design elements including logos. For example, boxes used for pre-rolls with a graphic for "Grape Ape" and a different graphic for "Cherry Pie" are unique marijuana product packages.

(3) A unique marijuana product package does not mean a package with variations in language, such as product information or instructions, or a package that depicts flavor variation without an accompanying change in graphic or design, or a different size, shape, or color. For example, mylar bags used for marijuana flower with different colors for indica, sativa, or hybrid used in various sizes are not unique marijuana product packages.

(4) For purposes of this rule "generic package" or "generic packaging" means packaging without any graphic or design elements, including logo, whether preprinted on the package or affixed later with an adhesive, sticker, or by other means.

(5) All applicants, whether as an initial license applicant or existing licensee, must submit an application <u>apply</u> to the department for approval of the labeling of each marijuana product category intended for sale to customers.

(6) An applicant must submit a separate application for each label - up to a maximum of eight <u>nine</u> total label applications - based on the applicant's sale of some or all of the following marijuana or marijuana product categories:

(a) seed/plants;

- (a) (b) adult-use flower;
- (b) (c) medical flower;
- (c) (d) adult-use ingestible marijuana-infused products;
- (d) (e) medical ingestible marijuana-infused products;
- (e) (f) adult-use non-ingestible marijuana-infused products;
- (f) (g) medical non-ingestible marijuana-infused products;
- (g) (h) adult-use marijuana concentrates and extracts; and
- (h) (i) medical marijuana concentrates and extracts.
- (7) An applicant will be given the following labeling options for the product categories listed in (6):
- (a) selecting and affirming its use of a pre-approved template label available for download from the department, at no cost to the applicant, as provided in (15) (16); or
- (b) use of a custom label design and pay the custom label application fee, as provided in (15) (16).

(8) An applicant that elects to use its custom (i.e., non-department template) label design must submit only one template label for each marijuana product category.

(9) Except as provided in (10), a new label application is not required when the marijuana facts panel information changes for disclosures such as levels of total potential psychoactive THC, THC, THCa, CBD, or CBDa, date of harvest, strain name, or ingredients.

(10) An applicant that sells marijuana products to registered cardholders with THC levels in excess of the limits set in 16-12-224, MCA, must submit a separate application and label template for each of the marijuana product categories sold.

(11) All applicants, whether as an initial license applicant or existing licensee, must submit an application to the department for approval for the packaging of each marijuana product category intended for sale to customers.

(12) An applicant will be given the following packaging options for the product categories listed in (6):

(a) selecting and affirming its use of generic packaging. The applicant shall identify on the application which marijuana or marijuana products will be placed in generic packaging; or

(b) use of custom packaging with graphic or design elements, including logo, whether preprinted on the package or affixed with an adhesive, a sticker, or by other means. In this case, the applicant must provide a picture or accurate, detailed rendering of the packaging. Further, the applicant shall identify on the application which marijuana or marijuana products will be placed in each unique marijuana product package.

(13) All applicants, whether as an initial license applicant or existing licensee, must submit an application to the department for approval for each exit package type it will use. If the applicant intends to use the same exit package type in multiple sizes, it may submit each size under one application.

(a) Exit packaging must comply with ARM 42.39.319(2).

(b) Exit packaging must comply with federal child-resistant packaging standards pursuant to 16-12-208(6), MCA.

(14) All applications and required attachments, such as photographs and renderings shall be submitted electronically to the department via its online portal.

(15) Licensees do not need to apply for package and label approvals for products purchased wholesale that have been previously approved by the department.

(15) (16) Except as provided in (17), A an applicant must submit the following fees to the department:

(a) no charge (0.00) for label applications described in (7)(a) or packaging applications in (12)(a);

(b) \$25 per label application described in (7)(b) for custom label design;

(c) \$10 per package application described in (12)(b); and

(d) \$10 per exit package application.

(17) Wholesale label applicants must submit the following fees to the

department:

(a) no charge (\$0.00) for label applications described in (7)(a) or packaging applications in (12)(a);

(b) \$100 \$25 per label application described in (7)(b) for custom label design; and

(c) \$50 \$10 per package application described in (12)(b).

(16) (18) The department shall review each application and shall notify an applicant, in writing, whether the packaging, label, or exit package has been approved or rejected.

(17) (19) Whenever the department returns any application for correction, it shall notify an applicant, in writing, of the deficiencies or issues with the application or submitted materials.

(18) (20) An applicant will receive an invoice for all application fees upon the department's approval of the application(s). The applicant shall pay all invoiced application fees to the department within ten days of receipt. An applicant's failure to pay all invoiced application fees may result in the reversal of application approval and denial of the application.

(19) (21) An applicant whose application is denied under (5) or (11) must reapply.

(20) In order to fully implement the packaging and labeling requirements of the Act, all licensees must submit their packaging and label applications to the department by August 1, 2022. Licensees may continue to use packaging and labeling that is compliant with the former Montana Medical Marijuana Act (Title 50, chapter 46, MCA) during the pendency of the department's approval(s), provided the licensee's applications were submitted by August 1, 2022.

(21) A licensee that fails to submit applications for approval of packaging and labeling by August 1, 2022 shall be subject to disciplinary proceedings.

(22) A licensee shall be subject to disciplinary proceedings when:

(a) it affirms to the department that it is using a pre-approved department template label but then uses any other label without submitting an application, applicable fees, and receiving department approval; or

(b) it affirms to the department that it is using generic packaging, but then uses any other product packaging, with graphic or design elements, including logo, whether preprinted on the package or affixed later with an adhesive, sticker, or by other means, without submitting an application, applicable fees, and receiving department approval.

(23) All marijuana and marijuana products must be in approved packaging and affixed with approved labeling no later than January 1, 2023. Licensees shall repackage and/or relabel all marijuana and marijuana products on or before January 1, 2023, as necessary, to comply with this provision.

(24) A licensee must maintain approval letters for all product packaging, labels, and exit packages at the licensed premises and shall make those letters available to department inspectors upon request.

> AUTH: 16-12-112, MCA IMP: 16-12-112, 16-12-208, 16-12-215, 16-12-224, MCA

> > END

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