

NEW RULE I LICENSE, APPLICATION, AND RENEWAL FEES (1) Initial

licensure and renewal fees for the following license types and endorsements are:

- (a) Two-year marijuana transporter license: \$10,000.
 - (b) Combined-use marijuana license: \$7,500.
 - (c) Marijuana testing laboratory license: \$5,000 per licensed premises.
 - (d) Marijuana dispensary license: \$5,000 per licensed premises.
 - (e) Cultivator license:
 - (i) \$1,000 for a cultivator with a micro tier canopy license;
 - (ii) \$2,500 for a cultivator with a tier 1 canopy license;
 - (iii) \$5,000 for a cultivator with a tier 2 canopy license;
 - (iv) \$7,500 for a cultivator with a tier 3 canopy license;
 - (v) \$10,000 for a cultivator with a tier 4 canopy license;
 - (vi) \$13,000 for a cultivator with a tier 5 canopy license;
 - (vii) \$15,000 for a cultivator with a tier 6 canopy license;
 - (viii) \$17,500 for a cultivator with a tier 7 canopy license;
 - (ix) \$20,000 for a cultivator with a tier 8 canopy license;
 - (x) \$23,000 for a cultivator with a tier 9 canopy license;
 - (xi) \$27,000 for a cultivator with a tier 10 canopy license;
 - (xii) \$32,000 for a cultivator with a tier 11 canopy license; and
 - (xiii) \$37,000 for a cultivator with a tier 12 canopy license.
 - (f) Manufacturer license:
 - (i) \$5,000 for each manufacturing facility that produces, on a monthly basis, less than ten pounds of concentrate;
 - (ii) \$10,000 for each manufacturing facility that produces, on a monthly basis, between ten pounds of concentrate and 15 pounds of concentrate; and
 - (iii) \$20,000 for each manufacturing facility that produces, on a monthly basis, 15 pounds of concentrate.
 - (iv) any licensee that produces, on a monthly basis, more than 15 pounds of concentrate, shall pay an additional \$1,000 per pound.
 - (g) Storage facility endorsement: \$1,000 per licensed storage facility.
- (2) At the time of the initial application and at renewal, an applicant shall pay the department a nonrefundable processing fee equal to 20 percent of the license fee identified in (1). The department will not begin processing an application until it receives all processing fees. A licensee shall pay the remaining 80 percent of the license fee upon approval of its application or renewal.
- (3) The fee for an initial worker permit and a renewal permit is \$50. A replacement permit is \$10.
- (4) The fee for an initial registry identification card and a renewal card is \$20. A replacement card is \$10.
- (5) Background checks: the department shall assess the applicant a fee of \$30 per background check. This fee is separate from and in addition to the nonrefundable processing fee assessed in (2).
- (6) Location changes: the fee for changing the location of any licensed premises is \$2,500.

AUTH: 16-12-112, 16-12-202, 16-12-204, 16-12-222, 16-12-226, 16-12-508, 16-12-533, MCA

IMP: 16-12-112, 16-12-204, 16-12-222, 16-12-226, 16-12-508, 16-12-533,
MCA

NEW RULE II MARIJUANA MANUFACTURER LICENSES (1) A marijuana manufacturer license allows a marijuana manufacturer to convert or to compound marijuana into marijuana products. A marijuana manufacturer licensee may buy marijuana and marijuana products from licensed marijuana cultivators and licensed marijuana manufacturers and may sell marijuana products to licensed marijuana dispensaries.

(2) The department shall begin accepting applications for marijuana manufacturers that are not former medical marijuana licensees, as defined in 16-12-102(14), MCA, on July 1, 2023.

(3) A licensee may continue to operate under their existing marijuana-infused products provider license and may apply for a marijuana manufacturer license at their next renewal date.

(4) Licensees will elect their tier level at their next renewal date and pay the fee provided in ARM 42.39.102.

(5) A marijuana manufacturer licensee that manufactures above its licensure level may be subject to administrative proceedings. In determining whether a marijuana manufacturer licensee has manufactured above its licensure level, the department will determine the average amount of concentrate produced each month over the previous 12 months.

(6) The licensed premises of a former medical marijuana licensee that is located in a red county is not eligible to apply to increase its licensure level until the local government approval process in 16-12-301, MCA, allows for marijuana manufacturing.

(7) A marijuana manufacturer licensee must take all reasonable measures and precautions to ensure the following:

(a) that the placement of equipment and storage of materials allow for the maintenance of sanitary operations for the manufacture of marijuana products;

(b) that all surfaces, including utensils and equipment used for the preparation of marijuana products, shall be cleaned and sanitized as frequently as is necessary to protect against contamination;

(c) that the water supply is safe and potable; and

(d) that the storage and transport of finished marijuana products shall be under conditions that will protect products against physical, chemical, and microbial contamination.

(8) A marijuana manufacturer licensee must:

(a) use equipment, counters, and surfaces for manufacturing that are food grade, do not react adversely with any solvent being used, reduce the potential for development of microbials, molds, and fungi, and can be easily cleaned;

(b) maintain detailed instructions for making each infused product, concentrate, or extract, which shall be kept confidential by the department; and

(c) conduct necessary safety checks prior to commencing processing.

(9) A marijuana manufacturer licensee that engages in chemical manufacturing must:

(a) use only hydrocarbon-based solvents that are at least 99 percent pure, except when using solvents outlined in (10)(b);

(b) only use nonhydrocarbon-based solvents that are food grade;

(c) use only potable water and ice made from potable water;

(d) use a professional grade closed-loop extraction system designed to recover the solvents;

(e) have equipment used in processing approved for use by the fire official having jurisdiction over the licensed premises;

(f) have an emergency eye-wash station in any room in which chemical manufacturing is occurring; and

(g) have all applicable safety data sheets readily available.

(10) A marijuana manufacturer licensee that engages in chemical manufacturing may use:

(a) a mechanical and/or physical extraction process;

(b) a chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol, or ethanol; or

(c) a chemical extraction process using the solvent carbon dioxide, provided that the process:

(i) does not involve the use of heat over 180 degrees Fahrenheit; and

(ii) uses a professional grade closed-loop carbon dioxide gas extraction system where every vessel is rated to a minimum of six hundred pounds per square inch.

(11) A marijuana manufacturer licensee that engages in chemical manufacturing may not use:

(a) class 1 solvents according to the Q3 Tables and List Guidance for Industry published by the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research;

(b) pressurized, canned fuel intended for use in camp stoves, handheld torch devices, refillable cigarette lighters, and similar products; or

(c) denatured alcohol.

(12) A marijuana manufacturer licensee shall not utilize a branded, commercially manufactured food product (e.g., Chex Mix, Nerds Ropes) as an edible marijuana product except when commercially manufactured food products are used as ingredients in an edible marijuana product in a way that renders them unrecognizable as the commercial food product in the final edible marijuana product; and the licensee does not state or advertise to the consumer that the final edible marijuana product contains the commercially manufactured food product.

(13) A marijuana manufacturer licensee may not infuse any food with marijuana that requires heated, time-temperature control or a hot holding unit to keep it safe for human consumption and may not serve hot or heated foods that promote onsite consumption.

(14) Any foods that require refrigeration or freezing to keep them safe for human consumption must be stored in a refrigerator or freezer until the time of sale and must be affixed with a label that indicates the product must be kept refrigerated or frozen, as appropriate.

(15) A marijuana manufacturer licensee may not treat or otherwise alter a marijuana product with any synthetic cannabinoid additive, including Delta-8 tetrahydrocannabinol, that would increase potency, toxicity, or addictive potential, or any additive that is added for purposes of making the product more appealing to children.

(16) A marijuana manufacturer licensee must have current, written standard operating procedures at the licensed premises and available for inspection for the following:

- (a) each category and type of marijuana product that it produces;
- (b) cleaning all equipment, counters, and surfaces thoroughly;
- (c) proper handling and storage of any solvent, gas, or other chemical used in processing or on the licensed premises;
- (d) proper disposal of any waste produced during processing; and
- (e) training employees on how to use the closed-loop system and handle and store the solvents and gasses safely.

(17) A marijuana manufacturer licensee and an employee of a marijuana manufacturer licensee may transport their marijuana and marijuana products in accordance with 16-12-222(4), MCA, and [NEW RULE V(4) through (15)] but may not transport the marijuana or marijuana products of other licensees without a marijuana transporter license.

AUTH: 16-12-112, MCA

IMP: 16-12-204, 16-12-222, MCA

NEW RULE III MARIJUANA CULTIVATOR LICENSES (1) A marijuana cultivator license allows a marijuana cultivator to plant, cultivate, grow, dry, package, and label marijuana and sell marijuana to licensed marijuana manufacturers, licensed dispensaries, and to other licensed marijuana cultivators, and to sell marijuana products to licensed dispensaries. **Marijuana cultivator licensees may not sell marijuana flower to other marijuana cultivator licensees.**

(2) The department shall begin accepting applications for marijuana cultivators that are not former medical marijuana licensees, as defined in 16-12-102(14), MCA, on July 1, 2023.

(3) A licensee may continue to operate under its existing license and may apply for a marijuana cultivator license at its next renewal date.

(4) The licensed premises of a former medical marijuana licensee that is located in a red county is not eligible to apply to increase its licensure level until the local government approval process in 16-12-301, MCA, allows for marijuana cultivation.

(5) A former medical marijuana licensee who engaged in outdoor cultivation before November 3, 2020, may continue to engage in outdoor cultivation but may not expand their existing outdoor cultivation space.

(6) For purposes of determining the appropriate canopy license tier:

(a) an existing outdoor cultivation space counts as a cultivation facility as used in (5) and its square footage counts toward the total allowable square footage under each tier;

(b) a canopy is measured horizontally starting from the outermost point of a plant on the perimeter of a dedicated growing space and continuing around the outside of all plants located within the dedicated growing space;

(c) a marijuana cultivator licensee may designate multiple canopy areas at a cultivation facility, but each canopy area must be separated by a physical boundary such as an interior wall or by at least eight feet of open space.

(6) A marijuana cultivator licensee that cultivates above its licensure level may be subject to administrative proceedings.

(7) A marijuana cultivator licensee must create and maintain a manual of written standard operating procedures to produce marijuana. The marijuana cultivator licensee must keep the manual at the licensed premises and make it available for department inspection at all times. The manual must include, at a minimum:

(a) when and how all pesticides or other chemicals are to be applied during the production process;

(b) water usage and wastewater disposal protocols; and

(c) a waste disposal plan.

(8) If a marijuana cultivator licensee makes a material change to the standard operating procedures, it must document the change and revise the written standard operating procedures manual accordingly.

(9) A marijuana cultivator licensee must maintain on the licensed premises:

(a) the material safety data sheet for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana at the licensed premises; and

(b) the original label, or a copy, for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana at the licensed premises.

(10) A marijuana cultivator licensee must maintain a log of all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana in the seed-to-sale tracking system.

(11) A marijuana cultivator licensee may not cultivate hemp at a licensed premises.

(12) A marijuana cultivator licensee and an employee of a marijuana cultivator licensee may transport their own marijuana and marijuana products in accordance with 16-12-222(4), MCA, and [NEW RULE V(4) through (15)] but may not transport the marijuana or marijuana products of other licensees without a marijuana transporter license.

AUTH: 16-12-112, MCA

IMP: 16-12-112, 16-12-203, 16-12-204, 16-12-210, 16-12-222, 16-12-223, MCA

NEW RULE IV MARIJUANA DISPENSARY LICENSES (1) A marijuana dispensary license allows a marijuana dispensary to sell marijuana and marijuana products to registered cardholders and to consumers 21 years of age and older and to purchase marijuana and marijuana products from licensed cultivators, licensed manufacturers, and other licensed dispensaries.

(2) The department shall begin accepting applications for marijuana dispensaries from applicants that are not former medical marijuana licensees as defined in 16-12-102, MCA, on July 1, 2023.

(3) A former medical marijuana licensee with a dispensary located in a green county may continue to sell to registered cardholders and may begin selling to adult use consumers on January 1, 2022, under its existing license and may apply for a marijuana dispensary license at its next renewal date.

(4) A former medical marijuana licensee with a dispensary located in a red county may only sell to registered cardholders under its existing license until the local government approval process in 16-12-301, MCA, allows for adult use dispensaries.

(5) The fee for a marijuana dispensary license is per licensed premises and is the same regardless of whether a marijuana dispensary licensee sells only to registered cardholders or to registered cardholders and consumers.

(6) A marijuana dispensary licensee and its employees must not sell marijuana or marijuana products to any person obviously or apparently under the influence of drugs or alcohol.

(7) A marijuana dispensary licensee and its employees may sell marijuana paraphernalia to registered cardholders 18 years of age and older and to consumers 21 years of age and older..

(8) Marijuana dispensary customers must not handle marijuana or marijuana products outside of its packaging prior to purchase. Customers may return marijuana or marijuana products but the dispensary must destroy those products and the destruction must be entered into the seed-to-sale tracking system. . Nothing in this rule prevents a marijuana dispensary licensee from refusing product returns.

(9) A marijuana dispensary licensee and its employees are prohibited from engaging in the unlicensed practice of medicine. A marijuana dispensary licensee and its employees must not:

(a) offer or undertake to diagnose or cure any human or animal disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, by use of marijuana or marijuana products or any other means or instrumentality; or

(b) recommend or suggest modification or elimination of any course of treatment that does not involve the medical use of marijuana or marijuana products.

(10) All sales of marijuana and marijuana products must be recorded in real time in the seed-to-sale tracking system.

(11) A marijuana dispensary licensee and its employees must refuse to sell marijuana or marijuana products at the medical marijuana tax rate to registered cardholders who do not possess and present a valid registry identification card or temporary registry identification card at the time of sale.

(12) A marijuana dispensary licensee and its employees must refuse to sell marijuana or marijuana products to any consumer unless the consumer possesses and presents one of the following forms of valid and unexpired photo identification showing that the consumer is 21 years of age or older:

(a) a driver's license or temporary driver's permit issued by Montana or any other state or territory of the United States;

(b) an identification card issued by Montana or any other state or territory of the United States for the purpose of proof of age of the holder of the card;

(c) United States military identification card;

(d) a Merchant Mariner Credential or other similar document issued by the United States Coast Guard;

(e) a passport issued by, or recognized by, the United States Government or a permanent resident card issued by the United States Citizenship and Immigration Services of the Department of Homeland Security; or

(f) a tribal identification card issued by a tribal government which requires proof of the age of the holder of the card for issuance.

(13) The prohibition in 16-12-208, MCA, on marijuana dispensaries selling hemp is limited to hemp flower and hemp plants.

(14) A marijuana dispensary licensee and its employees cannot sell marijuana or marijuana products in excess of the THC levels provided for in 16-12-224, MCA, except to registered cardholders.

(15) A marijuana dispensary licensee and an employee of a marijuana dispensary licensee may transport marijuana and marijuana products in accordance with 16-12-222(4), MCA, and [NEW RULE V(4) through (15)] but may not transport marijuana or marijuana products of other licensees without a marijuana transporter license.

(16) A marijuana dispensary licensee, its employees, or a commercial third party cannot deliver marijuana or marijuana products to consumers.

(17) A marijuana dispensary may continue to sell marijuana and marijuana products that have been tested under the Medical Marijuana program statutes and administrative rules.

AUTH: 16-12-112, 16-12-222, MCA

IMP: 16-12-112, 16-12-201, 16-12-222, 16-12-224, MCA

NEW RULE V MARIJUANA TRANSPORTER LICENSES (1) A marijuana transporter license allows a marijuana transporter to physically distribute and deliver marijuana and marijuana products to a licensed premises and to registered cardholders within the state of Montana that present a valid registry identification card.

(2) The department shall begin accepting applications for marijuana transporter licenses on January 1, 2022.

(3) Applicants for a marijuana transporter license must submit to the department proof of a valid Montana driver's license.

(4) All distribution and delivery of marijuana and marijuana products must:

(a) occur in a motor vehicle as defined by ARM 42.39.102;

(b) depart from a licensed premises and be delivered to a licensed premises or to a registered cardholder's address;

(c) be accompanied by a transport manifest derived from the seed-to-sale tracking system that contains the following information:

(i) the physical address and license number of the departure location;

(ii) the physical address and license number or registered cardholder number of the arrival location;

(iii) date and time of departure;

(iv) date and time of arrival;

(v) transporter's State Driver's License No, vehicle,, make, model, and license plate number;

(vi) name and signature of each licensee or its employee accompanying the transport; and

(vii) a complete description of the marijuana or marijuana product being transported. The description must include:

(A) the name and type of product being transported;

(B) amount of product being transported; and

(C) RFID tracking tag numbers of the product being transported;

(d) be accomplished within 48 hours from the date and time of departure.

(5) The transport manifest may not be voided or changed after leaving the departure location.

(6) A copy of the transport manifest must be given to each licensed premises receiving the inventory described in the transport manifest.

(7) A receiving licensed premises is prohibited from receiving any marijuana or marijuana products without a valid transport manifest.

(8) A receiving licensed premises is responsible for ensuring that the marijuana or marijuana products match the description in the transport manifest. A receiving licensed premises must immediately record receipt of the transported inventory.

(9) The receiving licensed premises must document any differences between the items described for transport in the transport manifest versus what was actually received and immediately report discrepancies to the department.

(10) While in transport, all marijuana and marijuana products must be shielded from public view and secured in a locked storage compartment inside the body of the transport vehicle.

(11) All vehicles used to transport marijuana or marijuana products:

(a) shall be considered a licensed premises for purposes of inspection by the department. Transport vehicles may be stopped and inspected by the department at any licensed premises or during transport;

(b) shall be lockable and equipped with a security alarm system;

(c) shall not leave the state of Montana while any amount of marijuana or marijuana product is in the motor vehicle; and

(d) shall not have any external markings, words, or symbols that indicate the vehicle is used for the transport of marijuana or marijuana products or that it is owned or leased by a marijuana business.

(12) A marijuana transporter licensee or employee of a marijuana transporter licensee must not sell marijuana or marijuana products; or transport marijuana or marijuana products directly to consumers.

(13) A marijuana transport licensee must contact the department within 24 hours if a vehicle transporting marijuana items is involved in an accident that involves product loss.

(14) Copies of the transport manifest and delivery receipts must be presented to law enforcement officers or authorized department employees, if requested.

(15) If a marijuana transporter licensee maintains a licensed premises to temporarily store marijuana or marijuana products, the licensee must have a marijuana storage facility endorsement for each storage facility as provided in [NEW RULE VIII].

AUTH: 16-12-112, 16-12-222, MCA

IMP: 16-12-112, 16-12-222, MCA

NEW RULE VI COMBINED USE LICENSES (1) A combined use license allows a federally recognized tribe located in the state or a business entity that is majority-owned by a federally recognized tribe located in the state to maintain a marijuana cultivation facility and marijuana dispensary on the same licensed premises.

(2) The department shall begin accepting applications for combined use licenses on January 1, 2022.

(3) A combined use licensee is subject to the marijuana laws, including 16-12-223, MCA

AUTH: 16-12-112, 16-12-225, MCA

IMP: 16-12-225, MCA

NEW RULE VII MARIJUANA TESTING LABORATORY LICENSES (1) A marijuana testing laboratory license allows a marijuana testing laboratory to provide testing of representative samples of marijuana and marijuana products and to provide information about the chemical composition and potency of a sample, as well as the presence of molds, pesticides, or other contaminants.

(2) Current marijuana testing laboratory licensees may continue to operate under their existing license and shall pay the fee provided for in New Rule I at their next renewal date.

(3) The department shall begin accepting applications for new marijuana testing laboratories on January 1, 2022.

(4) Applicants for marijuana testing laboratories must receive an endorsement from the Department of Public Health and Human Services' state testing laboratory before applying for licensure with the department. The department will accept the state laboratory's standard form of approval or endorsement for the applicant of a marijuana testing laboratory license to meet this requirement.

(5) Marijuana testing laboratories may transport samples of marijuana and marijuana products for testing in accordance with 16-12-222(4), MCA, and [NEW RULE V(4) through (15)].

(5) A laboratory licensee must provide and maintain, at its own expense, analytical testing laboratory professional liability insurance with an aggregate limit of one million dollars prior to the issuance of a license.

(6) A laboratory licensee must obtain and maintain a \$25,000 surety bond which names the department as loss payee in the event the laboratory licensee fails to adhere to the security plan approved by the department, or it otherwise operates the facility in a manner that allows for, or results in theft, loss, or diversion of marijuana items. A copy of the bond must be submitted to the department as part of its licensing application.

AUTH: 16-12-112, 16-12-202, MCA

IMP: 16-12-112, 16-12-202, 16-12-222, MCA

NEW RULE VIII MARIJUANA STORAGE FACILITY ENDORSEMENT (1) A marijuana transporter or a marijuana testing laboratory shall obtain a marijuana storage facility endorsement for any overnight storage of marijuana or marijuana products. A marijuana storage facility endorsement allows a marijuana transporter or marijuana testing laboratory to maintain a separate, off-site storage facility.

(2) A marijuana storage facility may only be used for the temporary storage of marijuana or marijuana products, not to exceed 48 hours. A storage facility may not be used to grow, process, test, manufacture, consume, or sell marijuana or marijuana products.

(3) A marijuana transporter licensee or marijuana testing laboratory with a marijuana storage facility endorsement may not share its storage facility with any other marijuana business.

(4) A marijuana storage facility may only be located in a jurisdiction that allows for the operation of a marijuana business pursuant to 16-12-301, MCA.

AUTH: 16-12-112, 16-12-222, MCA

IMP: 16-12-202, 16-12-222, MCA

NEW RULE IX WORKER PERMITS (1) A marijuana worker permit is required for any individual age 18 and over who performs work for or on behalf of any aspect of a marijuana business.

(2) Individuals with current, valid agent badges in good standing with the department may continue to work with their existing agent badge.

(3) All individuals required to have a worker permit shall undergo a criminal background before March 31, 2022, on a form provided by the department.

(4) If an individual fails to submit to a background check before March 31, 2022, their worker permit will be subject to suspension or revocation.

(5) Individuals may apply for worker permits under 16-12-226, MCA, at their next renewal date.

AUTH: 16-12-112, MCA

IMP: 16-12-112, 16-12-226, MCA

NEW RULE X GENERAL LABELING REQUIREMENTS (1) Labeling requirements apply to marijuana and marijuana products sold from a dispensary to customers. A licensee that sells marijuana or marijuana products to other licensees is not required to comply with labeling requirements.

(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) the common or usual name of the marijuana product (e.g., strain name (ex: Gorilla Glue), edible name (Ex: chocolate chip), extract/concentrate name (ex: mixed strain), drinkable name (ex: lemonade), topical name (shea butter));

(b) the product type of the marijuana product (e.g., flower, ingestible/non-ingestible marijuana concentrate, ingestible/non-ingestible marijuana infused product, topical, transdermal patch, inhalable extract);

(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) the unique identification number generated from the seed-to-sale tracking system;

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

(f) 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 servings));
- (f) the following statement: "This product has been tested and meets the requirements of the state of Montana."
- (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;
- (h) the universal symbol, available from the department's website. 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) shall be in the following form:



- (4) All marijuana and marijuana products shall be labeled 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 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:
 - (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: 16-1-101, 16-12-112, 16-12-208, 16-12-224, MCA

NEW RULE XI LABELING REQUIREMENTS FOR MARIJUANA FLOWER

(1) In addition to the general labeling requirements set forth in [NEW RULE X], each package of marijuana flower sold to a customer shall be labeled with a marijuana facts panel.

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

AUTH: 16-12-112, MCA

IMP: 16-1-101, 16-12-112, 16-12-208, MCA

NEW RULE XII LABELING OF INGESTIBLE MARIJUANA-INFUSED PRODUCTS (1) In addition to the general labeling requirements set forth in [NEW RULE X], 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 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 an 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 shall declare the presence of major food allergens in plain language;

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

(i) the 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 milligrams per package of:

(A) THC;

(B) THCa;

(C) CBD;

(D) and CBDa;

(d) in addition to the required warnings in [NEW RULE X], 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: 16-1-101, 16-12-112, 16-12-208, MCA

NEW RULE XIII LABELING OF NON-INGESTIBLE MARIJUANA-INFUSED PRODUCTS (1) In addition to the general labeling requirements set forth in [NEW RULE X], 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) a marijuana facts panel containing the following information:

(i) the 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 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: 16-1-101, 16-12-112, 16-12-208, MCA

NEW RULE XIV LABELING REQUIREMENTS FOR MARIJUANA CONCENTRATES AND EXTRACTS (1) In addition to the general labeling

requirements set forth in [NEW RULE X], each package of marijuana concentrate 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 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;

(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;

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

(d) in addition to the required warnings in [NEW RULE X], 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: 16-1-101, 16-12-112, 16-12-208, MCA

NEW RULE XV PACKAGING REQUIREMENTS (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.

AUTH: 16-12-112, MCA

IMP: 16-1-101, 16-12-112, 16-12-208, MCA

42.39.102 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.

(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.

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

(35) "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) "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) "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) "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.

(39) "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) "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) "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) "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.

(43) "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.

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

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

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

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

(47) "Test Batch" means a portion of a harvest or process lot that has been submitted for quality assurance testing.

(48) "THC" means tetrahydrocannabinol.

(49) "THCA" means tetrahydrocannabinolic acid.

(50) "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.

(51) "Total potential psychoactive 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.

(52) "Transdermal marijuana-infused product" or "transdermal" means a non-ingestible marijuana-infused product that contains at least one skin-permeation-enhancing 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.

(53) "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: 50-46-344, MCA

IMP: 50-46-303, 50-46-307, 50-46-308, 50-46-310, 50-46-318, 50-46-344,

MCA