BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the adoption of New Rules I through XV, and the amendment of ARM 42.39.102 pertaining to the implementation of the Montana Marijuana Regulation and Taxation Act	))))))	NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On November 16, 2021, at 9:00 a.m., the Department of Revenue (department) will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption and amendment of the above-stated rules. The auditorium is most readily accessed by entering through the north (basement) doors of the building.

2. The department will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, please advise the department of the nature of the accommodation needed, no later than 5 p.m. on October 29, 2021. Please contact Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or todd.olson@mt.gov.

3. GENERAL STATEMENT OF REASONABLE NECESSITY The 67th Montana Legislature passed House Bill 701 (HB 701) which amends the Montana Marijuana Regulation and Taxation Act (Act), codified at 16-12-101, *et. seq.*, MCA. Among the stated purposes of the Act in 16-12-101, MCA, and the legislative intent of HB 701, is the authorization and provision of a regulatory framework for Montana's legal adult use cannabis industry and transfer of the Department of Public Health and Human Services' (DPHHS) medical marijuana program (MMP) to the department, which occurred effective July 1, 2021. The department's authority conferred to it by the legislature under 16-12-103, MCA, and the proposed rules under this rulemaking represent the department's initial steps to license and regulate the cultivation, manufacture, transport, and sale of marijuana as allowed by the Act while ensuring the safety of marijuana and marijuana products to the public and eliminating the illicit market for those products.

The department proposes to adopt New Rules I through XV and to amend ARM 42.39.102 to:

(a) adopt or amend definitions for new terminology established in, or as an extension of, the Act;

(b) provide department systems, forms, uniform application processes, and fee schedules through which marijuana businesses may apply to the department for

licensure, including applicable endorsements, in the areas of manufacturing, cultivating, dispensing, or transporting marijuana;

(c) provide department systems, forms, uniform application processes, and fee schedules for the limited cultivation and sale of medical marijuana to individuals with debilitating medical conditions (registered cardholders) under the MMP; and

(d) reorganize and incorporate existing MMP rule provisions, many of which have been in force since 2018, from ARM Title 42, chapter 39, into these proposed rules for administrative consistency between the MMP and the adult-use program.

While this general statement of reasonable necessity covers the basis for the following proposed rule adoptions, it is supplemented below, where necessary, to explain rule-specific proposals.

4. The rules as proposed to be adopted provide as follows:

NEW RULE I LICENSE, APPLICATION, AND RENEWAL FEES (1) Initial licensure and annual renewal fees for the following license types and endorsements are:

(a) 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.

(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.

(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.

FISCAL IMPACT: In accordance with 2-4-302(1)(c), MCA, the department is required to estimate the fiscal impact of New Rule I through the payment and collection of fees for the license types authorized under the Act and described in New Rule I, if known, and the number of persons affected.

Based on the final fiscal note prepared in support of HB 701 which contemplated current medical marijuana licensees and expected growth in the industry, license fee revenue to be collected by the department was estimated to be approximately $3.9 million for FY 2022, $4.3 million for FY 2023, $6.4 million for FY 2024, and $6.8 million for FY 2025.

The fiscal impact of the fee requirements stated in HB 701 with those proposed in New Rule I, and estimating the numbers of persons (i.e., licensees, registered cardholders, etc.) affected by the fees, cannot be accurately measured for this rulemaking because industry growth is volatile. As of September 2021, there were 296 providers, 434 dispensaries, 222 marijuana-infused products providers, five testing laboratory licensees, and 40,176 registered cardholders, who may be affected by proposed fees in New Rule I. The department directs interested persons to its reports dashboard at https://mtrevenue.gov/cannabis/mmp-reports-dashboard/#LicensesbyType for the most current licensee population information.

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.

(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; 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 material 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;

(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 noncannabinoid additive that would increase potency, toxicity, or addictive potential, or 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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes New Rule II to provide requirements for the licensure of marijuana manufacturer licensees.

Section (1) is necessary to specify what a marijuana manufacturer licensee is authorized to do because manufacturer activities are not described in the Act with a necessary level of detail.

Section (2) is necessary to state when the department is authorized to accept manufacturer license applications under 16-12-201, MCA, as amended by HB 701.

Section (3) is necessary to implement the provisions of 16-12-201(2)(a), MCA, and achieve the statutory goal of minimal amount of business disruption to former medical marijuana licensees.

Sections (4) and (5) are necessary because beginning January 1, 2022, marijuana-infused products provider (MIPP) licenses are no longer available under the Act. It is necessary for the department to include in rule the process by which MIPP licensees will be converted to the classification of marijuana manufacturer license.

Section (6) pertains to the local government approval process required for a former medical marijuana licensee in a "red county," defined in ARM 42.39.102. The department believes this rule section is a necessary reiteration of what the public may find difficult to locate in HB 701 or the Act, as amended.

Section (7) is proposed as a general requirement for all marijuana manufacturer licensees to establish reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-204, MCA.

Sections (8) through (11) are existing licensee requirements found in ARM 42.39.201 and are proposed for adoption into New Rule II as a part of the department's reorganization of the rules and for familiarity and administrative consistency regarding marijuana manufacturing.

Section (12) is proposed to restrict the "copycat" packaging of marijuana and marijuana products with packaging of commercial snack foods, candy, etc., such as those examples provided in the rule section. This restriction is necessary for public safety because the department observes that marijuana and marijuana products have been developed that appear very similar to mainstream food products and those could be misidentified by consumers, particularly children.

Sections (13) and (14) are proposed requirements because marijuana and marijuana products need to be shelf-stable products, and the introduction of variables like time-temperature control that could lead to spoilage or foodborne illness from consumption must be avoided. Section (14) provides for some food product handling through refrigeration or freezing when the manufacturer can maintain that state until the time of sale. Like other perishable food items, the department requires the manufacturer to provide the consumer with some food handling labeling.

Section (15) is a necessary restatement of public policy under the Act that is not permissible for a marijuana manufacturer licensee to alter, with additives, or fortify the potency of marijuana and marijuana products, or to increase the addictive potential of marijuana and marijuana products towards children.

Consistent with the proposed requirements in (7) through (11), proposed (16) includes requirements for a marijuana manufacturer licensee's written standard operating procedures and reflects the 16-12-204, MCA, requirement that marijuana manufacturer premises meet any applicable standards set by a local board of health for a retail food establishment, as defined in 50-50-102, MCA.

Section (17) is proposed for inclusion in the rule for ease of reference to the provision in the Act that permits marijuana manufacturer licensees, among others, to transport marijuana or marijuana products between other licensed premises without a transporter license so long as the transportation otherwise complies with the Act and the transporter rules of the department. The cross-reference to the transporter rule is also provided for necessary guidance to those requirements.

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.

(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.

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

(8) 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.

(9) 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.

(10) 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.

(11) 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.

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

(13) In accordance with Section 117, Ch. 576, L. 2021, a marijuana cultivator licensee must discontinue the use of hoop houses on or before October 1, 2023.

(14) 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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes New Rule III to provide certain requirements in the department's licensure of marijuana cultivators.

Section (1) is necessary to specify what a marijuana cultivator licensee is authorized to do because cultivator activities are not described in the Act with a necessary level of detail.

Section (2) is necessary to the rule to clarify when the department is authorized to accept marijuana cultivator applications under 16-12-201, MCA, as amended by HB 701.

Section (3) is necessary to implement the provisions of 16-12-201(2)(a), MCA, and achieve the statutory goal of minimal amount of business disruption to a marijuana cultivator licensee.

Section (4) pertains to the local government approval process required for a former medical marijuana licensee in a "red county," defined in ARM 42.39.102, and (5) reflects the allowance in 16-12-223, MCA. The department believes these rule sections are necessary reiterations of what the public may find difficult to locate in HB 701 or the Act, as amended.

Section (6) is a revision of existing licensee requirements found in ARM 42.39.111 and is proposed as a part of the department's reorganization of the rules and for familiarity and administrative consistency regarding cultivation, canopy measurement, and multiple canopy operations. Section (7) is proposed as necessary notification to a marijuana cultivator licensee that operating beyond canopy licensure levels may constitute a violation of the marijuana cultivator license.

Sections (8) through (11) represent minor revisions of existing licensee requirements found in ARM 42.39.111 and 42.39.310 and are proposed as a part of the department's reorganization of the rules and for familiarity and administrative consistency regarding a marijuana cultivator licensee's written standard operating procedures, material safety data sheets, logging pesticides, fertilizers, or other agricultural chemicals in the seed-to-sale tracking system, and describing required marijuana and marijuana products waste disposal protocols. The information may be used by the department and testing laboratories in the analysis of marijuana and marijuana products for pesticides, solvents, moisture levels, mold, mildew, and other contaminants.

Sections (12) and (13) are proposed for inclusion of license-specific requirements for marijuana cultivator licensees. Without this information in the rule, the department believes critical operational information for a marijuana cultivator licensee may be overlooked given the general construction of HB 701 and the amendments to the Act.

Lastly, the department proposes (14) for ease of reference to the provision in the Act that permits marijuana cultivator licensees, among others, to transport marijuana or marijuana products between other licensed premises without a transporter license so long as the transportation otherwise complies with the Act and the transporter rules of the department. The cross-reference to the transporter rule is also provided for necessary guidance to those requirements.

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.

(8) Marijuana dispensary customers must not handle marijuana or marijuana products outside of its packaging prior to purchase. Customers may not return marijuana or marijuana products unless the items are unopened and in their original packaging. 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 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 also includes the prohibition of selling cannabidiol products.

(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.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule IV to provide certain requirements in the department's licensure of a marijuana dispensary.

Section (1) is necessary to specify what a marijuana dispensary licensee is authorized to do because marijuana dispensary activities are not described in the Act with a necessary level of detail.

Section (2) is necessary to the rule to clarify when the department is authorized to accept marijuana dispensary applications under 16-12-201, MCA, as amended by HB 701.

Sections (3) and (4) are proposed to reference the local government approval process required for a former medical marijuana licensee in either a red county or green county, which are defined in ARM 42.39.102. The department believes these rule sections are necessary reiterations of what the public may find difficult to locate in HB 701 or the Act, as amended, and the designated terms of red county and green county are a more convenient reference.

Section (5) is a necessary clarification for a marijuana dispensary applicant or licensee regarding fee structures regardless of the customer base for the business.

Section (6) is proposed as a necessary restatement of general license restrictions in the Act against the sale of marijuana or marijuana products to persons obviously or apparently under the influence of drugs or alcohol.

Section (7) is proposed as guidance for a marijuana dispensary licensee that it is permissible to sell marijuana paraphernalia to registered cardholders 18 years of age and older.

Section (8) is proposed as a general product restriction which is necessary for inventory control and to ensure that the marijuana or marijuana products are not subject to contamination through direct customer contact. Section (8) also provides the option for a marijuana dispensary licensee to accept customer returns when product is unopened and in its original packaging or to deny marijuana or marijuana products returns.

Section (9) is a necessary restatement of the Act which prohibits a marijuana dispensary licensee or its employees from engaging in the unlicensed practice of medicine. The subsections provide guidance and examples of what constitutes the unlicensed practice of medicine. Complaints or allegations of engaging in the unlicensed practice of medicine may result in administrative action against a marijuana dispensary and its license.

Sections (10) and (11) represent minor revisions of existing marijuana dispensary licensee requirements found in ARM 42.39.203 and are proposed as a part of the department's reorganization of the rules and for familiarity and

administrative consistency regarding marijuana or marijuana products sales under the Act.

Similar to other retail sales restrictions provided in the Act and in these proposed rules, is proposed (12). This informs a marijuana dispensary licensee and its employees of purchaser identification requirements that must be confirmed prior to the sale of marijuana or marijuana products to the purchaser. Failure to adhere to these requirements is a violation and can subject a licensee to administrative action or other penalties for unauthorized sales to persons who are not registered cardholders or to minors.

Section (13) informs and clarifies for a marijuana dispensary licensee that the legislature enacted 16-12-208(7), MCA, to restrict marijuana dispensary licensees from selling hemp; and based on the definition of hemp, also includes the restriction of these licensees to sell cannabidiol products. Reiteration of this restriction in rule is necessary because there are several marijuana dispensary licensees who have, or are, engaged in the sale of cannabidiol products.

Section (14) represents a necessary reiteration of the statutory retail sales restriction for marijuana and marijuana products that exceed statutory THC levels and reserves the sale of those products to registered cardholders only.

Section (15) is proposed for inclusion in the rule for ease of reference to the provision in the Act that permits marijuana dispensary licensees, among others, to transport marijuana or marijuana products between other licensed premises without a transporter license so long as the transportation otherwise complies with the Act and the transporter rules of the department. The cross-reference to the transporter rule is also provided for necessary guidance to those requirements.

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) transport vehicle year, 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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule V to provide certain requirements in the department's licensure of a marijuana transporter.

Section (1) is necessary to specify what a marijuana transporter is authorized to do because marijuana transporter activities are not described in the Act with a necessary level of detail.

Section (2) is necessary to the rule for clarity of when the department is authorized to accept marijuana transporter applications under 16-12-222(1)(c), MCA. Section (3) is necessary to inform applicants of the required forms, supporting documents, and other necessary disclosures in order for the department to begin processing a marijuana transporter license application.

Sections (4) through (10), (11)(b), and (13) and (14) are revisions of existing marijuana transporter requirements found in ARM 42.39.114 and are proposed as a part of the department's reorganization of the rules and for familiarity and administrative consistency regarding the transport of marijuana and marijuana products. Section (4) describes the allowable vehicle types used for transport, to establish what are the designated departure and arrival locations and allowable transport time frame, and to require a description of what marijuana and marijuana products are subject to transport. Sections (5) through (7) provide guidance regarding transport manifest processing requirements. Sections (8) and (9) continue to describe from ARM 42.39.114 what must occur at the receiving licensee's premises to conclude the transport of the marijuana and marijuana products.

Section (10) continues the existing requirement of a marijuana transporter for minimal to no public visibility of marijuana and marijuana products (See 16-12-108, MCA).

Subsections (11)(a), (c), and (d) are proposed to require detailed information about the vehicle that is used in the transport of marijuana and marijuana products. These provisions are necessary since the transport is considered a licensed premises for inspection purposes, as described in (11)(a).

Section (12) provides necessary guidance to a marijuana transport licensee that the sale of marijuana and marijuana products from a marijuana transport vehicle is not allowed, nor is direct transport of marijuana and marijuana products to consumers.

Sections (13) and (14) are a revision of existing licensee requirements found in ARM 42.39.114 and are proposed as a part of the department's reorganization of the rules and for familiarity and administrative consistency regarding timely notification to the department involving the loss of product or if a transport vehicle is involved in an accident; and that transport manifests are subject to inspection by law enforcement or the department, if requested. The requirement in (13) is necessary to preserve evidence of an accident or to coordinate the loss of product in the seed-to-sale tracking system with the marijuana transport licensee. Inspection of

transport manifests in (14) is necessary for verification of compliance with the Act and these rules regarding the transport of marijuana and marijuana products.

Section (15) is proposed as an extension of the marijuana transporter requirements of the Act that require a marijuana transporter licensee to obtain a marijuana storage facility endorsement for any storage facilities, where applicable.

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.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule VI to provide procedural requirements and relevant cross references to regulatory authority pertaining to combined use licensees.

Section (1) is a necessary reiteration of the Act which provides the authorized activities associated with this license.

Section (2) is necessary for clarity of when the department is authorized to accept combined use license applications under HB 701.

Section (3) is proposed as guidance to a combined use licensee that this license type is subject to the marijuana laws.

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

(3) 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.

(4) 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)].

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule VII to provide licensing and compliance requirements for a marijuana testing laboratory.

Section (1) is necessary to specify what a marijuana testing laboratory is authorized to do because marijuana testing laboratory activities are not described in the Act with a necessary level of detail.

Section (2) is necessary to the rule for clarity of when the department is authorized to accept applications under 16-12-202, MCA, as amended by HB 701.

Section (3) is necessary to inform a marijuana testing laboratory licensee of the requirement in 16-12-202(2), MCA, that the marijuana testing laboratory must be endorsed by the state laboratory of the Department of Public Health and Human Services prior to applying to the department for licensure. The state laboratory's licensing and accreditation (i.e., endorsement) standards are established in ARM Title 37, chapter 107, subchapter 3.

Section (4) is proposed for inclusion in the rule for ease of reference to the provision in the Act that permits marijuana testing laboratories, among others, to transport marijuana or marijuana products between other licensed premises without a transporter license so long as the transportation otherwise complies with the Act and the transporter rules of the department. The cross-reference to the transporter rule is also provided for necessary guidance to those requirements.

NEW RULE VIII MARIJUANA STORAGE FACILITY ENDORSEMENT (1) A marijuana transporter or a marijuana testing laboratory may obtain a marijuana storage facility endorsement. 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. 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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule VIII because the Act authorizes a marijuana transporter licensee or a marijuana testing laboratory to obtain this endorsement but operational activities and general compliance matters are not described in the Act with a necessary level of detail.

Section (1) clarifies the classes of licensees that are eligible under the Act to obtain the endorsement. Sections (2) through (4) are necessary to establish the requirements that facilities associated under a marijuana storage facility

endorsement are temporary in nature, may not be used as a manufacturing facility under any circumstance, may not be shared with any other licensee, and are subject to the statutory local government approval process.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule IX to provide: procedural guidance as to who a marijuana worker is and the services they provide for a marijuana business, as specified in (1); the date the department will begin the issuance of the permits to marijuana workers in good standing, as provided in (2); the deadline specified in HB 701 for marijuana workers to undergo criminal background checks as described in (3); and consequences for a marijuana worker's failure to comply with the background check, provided in (4).

The department believes (1) through (4) are minimal, reasonable, and necessary requirements to ensure compliance with the Act and to fulfill the public policy goal that only reputable employees are involved in the marijuana industry.

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., flower, inhaled extract, edible or drinkable, topical, transdermal patch);

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

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

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

(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));

(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:

MARIJUANA

(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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule X to provide necessary requirements for marijuana dispensaries as general labeling requirements of marijuana and marijuana products.

Section 16-12-101, MCA, provides among other primary purposes of the Act, for legal possession and use of limited amounts of marijuana legal for adults 21 years of age or older and to ensure the safety of marijuana and marijuana-infused products. Section 16-12-112(1)(h), MCA, as an extension of the Act, specifically authorizes the department to adopt rules to implement " . . . labeling and packaging standards that protect public health by requiring the listing of pharmacologically active ingredients, including, but not limited to, tetrahydrocannabinol (THC), cannabidiol (CBD), and other cannabinoid content, the THC and other cannabinoid amount in milligrams per serving, the number of servings per package, and quantity limits per sale to comply with the allowable possession amount." Section 16-12-208, MCA, allows the department to establish standards for labeling.

Section (1) is proposed as a general statement of applicability that labeling requirements apply to dispensaries that sell marijuana or marijuana products to consumers.

Section (2) requires specific labeling information which the department contends is reasonably necessary under the purpose of 16-12-112(1)(h), MCA.

Sections (3) and (4), similar to (2), are proposed to inform the public or potential consumers of the contents, dosage, or serving sizes, of the marijuana or

marijuana products they are purchasing and include necessary warning statements about the product. The department contends that all of the labeling requirements in (3) and (4) are necessary and reasonable for the public's protection because without contents, measurements, serving sizes, warnings, etc., a consumer may misunderstand product contents or misuse the product to their own detriment. The addition of the QR code to link the product certificate of analysis will also help the consumer make informed decisions about the product such as about cannabinoid content. The department has also included a universal symbol to be applied to marijuana or marijuana products packaging in furtherance of protecting the public.

Section (5) is proposed as another reasonable and necessary requirement to protect the public from false and misleading statements about the product they are purchasing.

Section (6) is proposed as a necessary and reasonable product manufacturing disclosure requirement for those individuals with certain chemical sensitivities that could use chemically manufactured marijuana or marijuana products to their own detriment if this disclosure was not present.

Section (7) is necessary to provide for label review consideration which is authorized under 16-12-208, MCA, when the marijuana or marijuana product proposed for labeling has size constraints that would make traditional labeling impractical or impossible.

Section (8) provides that marijuana or marijuana products with excessive THC limits may only be sold to registered cardholders, which is an express restriction under 16-12-224(8)(c), MCA.

Section (9) clarifies general labeling requirements for marijuana fact panels for marijuana or marijuana products that do not require heat to administer or consume.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule XI to require distinct labeling for the marijuana flower sold to a consumer, in addition to the general labeling requirements, because this product category is consumed by

the purchaser. The addition of the percentage of concentration of total potential psychoactive THC is necessary to have a more accurate measure of THC content because this product typically requires heat to administer or consume. The department contends this is a reasonable and necessary extension of its consumer product safety obligations provided in the Act.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule XII

to require distinct labeling for ingestible marijuana-infused products sold to a consumer, in addition to the general labeling requirements, because this product category is consumed by the purchaser. Requirements for ingredients and possible food allergen reactions for consumers in proposed (1)(a) and (b), respectively, are authorized under 16-12-112, MCA, and protect the public. Requirements in (1)(c), such as those for THC dosage and servings per package, are required by the Act. Section (2) is a proposed requirement to protect the public because the department is aware of circumstances where product claims of "total THC" levels have been misleading. Section (3) is proposed as product guidance for licensees and is information that the department anticipates will be included in the QR code. The department contends the requirements in New Rule XII are a reasonable and necessary extension of its consumer product safety obligations provided in the Act.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule XIII to require distinct labeling for non-ingestible marijuana-infused products sold to a consumer, in addition to the general labeling requirements. Requirements for ingredients in proposed (1)(a) are authorized under 16-12-112, MCA, and protect the public. Requirements in (1)(b), such as those for THC dosage and servings per package, are also required by the Act. Section (2) is a proposed requirement to protect the public because the department is aware of circumstances where product claims of "total THC" levels have been misleading. Section (3) is proposed as product guidance for licensees and is information that the department anticipates will be included in the QR code. The department contends the requirements in New Rule XIII are a reasonable and necessary extension of its consumer product safety obligations provided in the Act.

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;

(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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule XIV to require distinct labeling for marijuana concentrates and extracts sold to a consumer, in addition to the general labeling requirements, because this product category is consumable by the purchaser. Requirements for ingredients and possible food allergen reactions for consumers in proposed (1)(a) and (b), respectively, are authorized under 16-12-112, MCA, and protect the public. Requirements in (1)(c), such as those for THC dosage and servings per package, are required by the Act. Section (2) is a proposed requirement to protect the public because the department is aware of circumstances where product claims of "total THC" levels have been misleading. Section (3) is proposed as product guidance for licensees and is information that the department anticipates will be included in the QR code. The department contends the requirements in New Rule XIV are a reasonable and necessary extension of its consumer product safety obligations provided in the Act.

<u>NEW RULE XV 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.

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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule XV to implement the product packaging requirements expressly provided in the Act or to carry out the department's consumer product safety obligations provided in the Act.

Subsection (1)(a) is proposed as a requirement that most immediately impacts the consumer: packaging that prevents contamination or spoilage of the product. Subsections (1)(b) through (d) are proposed and authorized under 16-12-208(5), MCA, and are intended to prevent marijuana product food packaging from being a copycat of non-marijuana product food packaging which could be mistaken by a child.

Section (2) implements 16-12-208(6), MCA, and is intended to provide additional guidance for exit packaging.

Section (3) is proposed and necessary as another general public protection mechanism so that consumers are aware of what constitutes a single serving of the licensees' drinkable marijuana product when the products are sold in larger volume sizes.

Section (4) is proposed for ease of licensee reference to the statutory restriction regarding exit packaging information and designs.

5. The rule as proposed to be amended provides as follows, new matter underlined, deleted matter interlined:

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

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

(1) through (4) remain the same but are renumbered (2) through (5).

<u>(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.</u>

(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.

(5) remains the same but is renumbered (8).

(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.

(6) remains the same but is renumbered (10).

(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.

(7) through (10) remain the same but are renumbered (15) through (18).

(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.

~~(11) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72 hour period at the same location, and cured under uniform conditions. A harvest lot may contain multiple strains.~~

(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.

(12) and (13) remain the same but are renumbered (23) and (24).

(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.

(14) remains the same but is renumbered (26).

(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.

(15) remains the same but is renumbered (30).

(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).

(16) remains the same but is renumbered (40).

~~(17) "Process lot" means:~~

~~(a) any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures, and test batches from the same or different harvest lots; or~~

~~(b) any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures, and test batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.~~

(18) and (19) remain the same but are renumbered (41) and (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) "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.

(20) and (21) remain the same but are renumbered (45) and (46).

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

(48) "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.

(22) through (24) remain the same but are renumbered (49) through (51).

(52) "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.

(53) "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 psychoactive THC = (THCa x .877) + THC.

(54) "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.

(55) "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

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.102 to add necessary definitions for new terminology relating to the department's implementation of the Act and to provide concise terminology for concepts that were utilized in the drafting of HB 701. The use of concise terminology is beneficial for all stakeholders and the department, such as using the term "red county" to describe " . . . a county in which the majority of voters voted not to approve Initiative Measure No. 190 in the November 3, 2020 general election." Similarly, a "green county" is proposed to describe " . . . a county in which the majority of voters voted to approve Initiative Measure No. 190 in the November 3, 2020 general election."

The department also proposes to remove the definitions of "harvest lot" and "process lot." These definitions were transferred to the department from DPHHS and are unnecessary and are most often referenced in the testing laboratory rules that remain with DPHHS. The department will evaluate the necessity for cross-referencing these definitions upon DPHHS adopting its testing laboratory rules definitions and as the department continues to implement HB 701.

6. Concerned persons may submit their data, views, or arguments, either orally or in writing, at the hearing. Written data, views, or arguments may also be submitted to: Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696;

or e-mail todd.olson@mt.gov and must be received no later than 5:00 p.m., November 29, 2021.

7. Todd Olson, Department of Revenue, Director's Office, has been designated to preside over and conduct the hearing.

8. The Department of Revenue maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request, which includes the name and e-mail or mailing address of the person to receive notices and specifies that the person wishes to receive notice regarding particular subject matter or matters. Notices will be sent by e-mail unless a mailing preference is noted in the request. A written request may be mailed or delivered to the person in number 6 above or faxed to the office at (406) 444-3696, or may be made by completing a request form at any rules hearing held by the Department of Revenue.

9. An electronic copy of this notice is available on the department's web site at www.mtrevenue.gov, or through the Secretary of State's web site at sosmt.gov/ARM/register.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor, Representative Hopkins, was contacted by e-mail on October 5, 2021.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption and amendment of the above-referenced rules may significantly and directly impact small businesses, but any significant or direct small business impact is attributable to the department through the implementation of the statutory requirements of HB 701 and the Act.

/s/ Todd Olson
Todd Olson
Rule Reviewer

/s/ Brendan Beatty
Brendan Beatty
Director of Revenue

Certified to the Secretary of State October 12, 2021.