BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

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| In the matter of the adoption of NEW RULES I through III and the amendment of ARM 42.39.104, 42.39.115, 42.39.401, 42.39.405, 42.39.409, 42.39.413, and 42.39.415 pertaining to implementation of House Bills 128, 903, and 948 (2023), and revising requirements applicable to chemical, infused product, and mechanical manufacturers of marijuana | ) ) ) ) ) ) ) ) ) ) ) | NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION AND AMENDMENT |

TO: All Concerned Persons

1. On January 18, 2024, at 10:00 a.m., the Department of Revenue 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.

2. The Department of Revenue 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 December 29, 2023. 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 68th Montana Legislature enacted several pieces of legislation that revised the Legislature's interpretation and implementation of the Montana Marijuana Regulation and Taxation Act (MMRTA) from 2021 and included House Bills (HB) 128, 903, and 948.

For purposes relative to this rulemaking, and among other enactments, HB 128 provided for the general revision of marijuana laws; clarified limitations of the MMRTA; removed outdated dates; removed background check requirements for certain individuals; extended the moratorium for new marijuana licenses; transferred authority over marijuana testing laboratories from the Department of Public Health and Human Services to the department; clarified legislative intent on a cultivator's ability to increase tiers; revised requirements for a combined-use license; and extended the department's rulemaking authority.

HB 903 notably revised the definition for "former medical marijuana licensee" in 16-12-102, MCA, to those cultivators, manufacturers, and dispensaries licensed or having an application for licensure pending on April 27, 2021, instead of November

3, 2020. This change expanded licensure to those applicants and licensees not accounted for under House Bill 701 (2021) (HB 701).

Based on the above-described legislative changes, this rulemaking is necessary to align ARM 42.39.104, 42.39.115, 42.39.401, 42.39.405, 42.39.409, 42.39.413, 42.39.415 with the statutes amended by HB 128 and HB 903.

The department also proposes to adopt NEW RULES I through III which involves the transfer of content from ARM 42.39.401 (*see* current (9), (10), and (12) through (15) of the rule) to the respective new rules to clarify requirements applicable to marijuana manufacturers who are engaged in chemical, infused product, and mechanical manufacturing of marijuana and marijuana products. The department contends NEW RULES I through III are necessary for the department to carry out its statutory duty to protect Montana consumers and are based on the evolution of the manufacturing processes employed by licensees to render the expansive varieties of marijuana products that are available in the marketplace.

Lastly, the department proposes amendments to the above-described rules to simplify and clarify department procedures and licensee requirements, which are both department goals under the Governor's Executive Order 2021-01, "Red Tape Relief Initiative."

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

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

NEW RULE I MARIJUANA MANUFACTURER LICENSE – CHEMICAL MANUFACTURING (1) A marijuana manufacturer licensee that applies to engage in chemical manufacturing must indicate that type of manufacturing activity on its initial license or license renewal application. There is no additional cost for a marijuana manufacturer licensee who elects a chemical manufacturing designation on its initial license or license renewal application.

(2) 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 (3)(a);

(b) only use food grade nonhydrocarbon-based solvents, such as water, vegetable glycerin, vegetable oils, or animal fats;

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

(d) have processing equipment approved for use by the fire code official with jurisdiction over the licensed premises;

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

(f) have all applicable safety data sheets readily available at the licensed premises; and

(g) have a current, written standard operating procedure available for inspection at the licensed premises that details employee training on closed-loop

extraction system operation and proper handling of solvents and gasses used in processing or stored on the licensed premises.

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

(a) 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

(b) 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 600 pounds per square inch.

(4) A marijuana manufacturer licensee that engages in chemical manufacturing may not use 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.

AUTH: 16-12-104, 16-12-112, 16-12-221, MCA
IMP: 16-12-104, 16-12-109, 16-12-112, 16-12-201, 16-12-203, 16-12-207, 16-12-208, 16-12-210, 16-12-221, 16-12-301, MCA

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt NEW RULE I to provide specific licensure requirements for a marijuana manufacturer licensee engaged in chemical manufacturing.

Proposed (1) is necessary to notify applicants for marijuana manufacturer licenses engaged in chemical manufacturing of the requirement to notify the department of its election to engage in chemical manufacturing. The rule section also clarifies there is no additional cost for the designation on an initial license or license renewal application.

Proposed (2) and (3) are a transfer and general restatement of current ARM 42.39.401(9) and (10) for all marijuana manufacturer licensees to establish reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-221, MCA.

Section (4) proposes to transfer the existing requirement from ARM 42.39.401(11)(a) to continue specific guidance for this manufacturing method regarding the prohibition of class 1 solvents through the department's inclusion of the reference named in the rule section.

NEW RULE II MARIJUANA MANUFACTURER LICENSEE – INFUSED PRODUCTS (1) A marijuana manufacturer licensee that applies to engage in marijuana-infused product manufacturing must indicate that type of manufacturing activity on its initial license or license renewal application. There is no additional cost for a marijuana manufacturer licensee who elects an infused product manufacturing designation on its initial license or license renewal application.

(2) A marijuana manufacturer licensee that engages in marijuana-infused product manufacturing must store all products that require refrigeration or freezing in a refrigerator or freezer until the time of sale and affix these foods with a label that indicates the product must be kept refrigerated or frozen, as appropriate.

(3) A marijuana manufacturer licensee that engages in marijuana-infused product manufacturing may not:

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

(b) 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;

(c) infuse raw or cooked meat; or

(d) infuse root vegetables, including but not limited to garlic and onion, in oil.

(4) A marijuana manufacturer licensee that produces marijuana-infused products must have current, written SOPs at the licensed premises available for inspection that detail the following:

(a) an employee illness policy that requires employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food; and

(b) procedures for monitoring and maintaining refrigeration and cold holding equipment, if applicable.

AUTH: 16-12-104, 16-12-112, 16-12-221, MCA
IMP: 16-12-104, 16-12-109, 16-12-112, 16-12-201, 16-12-203, 16-12-207, 16-12-208, 16-12-210, 16-12-221, 16-12-301, MCA

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt NEW RULE II to provide specific licensure requirements for marijuana manufacturer licensees engaged in marijuana-infused product manufacturing.

Proposed (1) is necessary to notify applicants for a marijuana manufacturer license engaged in marijuana-infused product manufacturing of the requirement to notify the department of its election to engage in marijuana-infused product manufacturing. The rule section also clarifies there is no additional cost for the designation on an initial license or license renewal application.

Proposed (2) and (3) are a transfer and reorganization of current ARM 42.39.401(12) through (14) which require marijuana and marijuana products to be shelf-stable products under time-temperature controls to avoid spoilage or foodborne illness. The sections require basic food product handling through refrigeration or freezing until the time of product sale to the consumer, and like other perishable food items, the department requires the manufacturer to provide the consumer with some food handling labeling. Proposed (3) also continues to restrict "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.

Consistent with the requirements in ARM 42.39.401, proposed (4) includes requirements for written standard operating procedures and requires all marijuana manufacturer licensees to establish reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-221, MCA.

NEW RULE III MARIJUANA MANUFACTURING LICENSE – MECHANICAL MANUFACTURING (1) A marijuana manufacturer licensee that applies to engage in mechanical manufacturing must indicate that type of manufacturing activity on its initial license or license renewal application. There is no additional cost for a marijuana manufacturer licensee who elects a mechanical manufacturing designation on its initial license or license renewal application.

(2) A marijuana manufacturer licensee must have current, written SOPs at the licensed premises available for inspection that details the procedures for the safe handling, maintenance, and storage of a hydraulic press.

AUTH: 16-12-104, 16-12-112, 16-12-221, MCA
IMP: 16-12-104, 16-12-109, 16-12-112, 16-12-201, 16-12-203, 16-12-207, 16-12-208, 16-12-210, 16-12-221, 16-12-301, MCA

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to adopt New Rule III to provide more specific licensure requirements for marijuana manufacturer licensees applying to engage in mechanical manufacturing than what is currently found in ARM 42.39.401(10).

Proposed (1) is necessary to notify marijuana manufacturer licensees of the new requirement to designate the type of manufacturing processes, which include chemical, infused, or mechanical, that the department is authorizing on application or renewal. The rule section also clarifies there is no additional cost for the designation on an initial license or license renewal application.

Consistent with the requirements in ARM 42.39.401, proposed (2) includes requirements for written standard operating procedures and requires all marijuana manufacturer licensees to establish reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-221, MCA.

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

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

(a) through (c) remain the same.

~~(d) Marijuana dispensary license: $5,000 per licensed premises.~~

(e) remains the same but is renumbered (d).

~~(f)~~(e) Manufacturer license:

(i) remains the same.

(ii) $10,000 for each manufacturing facility that produces, on a monthly basis, between ten ~~pounds of concentrate~~ and 15 pounds of concentrate;

(iii) $20,000 for each manufacturing facility that produces, on a monthly basis, between 15 ~~pounds~~ and 20 pounds of concentrate; ~~and~~

(iv) ~~any manufacturing licensee that produces, on a monthly basis, more than 15 pounds of concentrate, shall pay an additional $1,000 per pound.~~ $30,000 for each manufacturing facility that produces, on a monthly basis, between 20 and 30 pounds of concentrate;

(v) $40,000 for each manufacturing facility that produces, on a monthly basis, between 30 and 40 pounds of concentrate;

(vi) $50,000 for each manufacturing facility that produces, on a monthly basis, between 40 and 50 pounds of concentrate;

(vii) $60,000 for each manufacturing facility that produces, on a monthly basis, over 50 pounds of concentrate.

(g) remains the same but is renumbered (f).

(g) The application fee to change location of a licensed premises: $2,500.

(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 applicable license fee identified in (1). The department will not begin processing an application until it receives all processing fees. A licensee shall pay the department the remaining 80 percent of the license fee upon department notification of 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 registry identification card: ~~is~~ $10.

(5) Application to change or update controlling beneficial owners, financial interest holders, sources of funding, or other business organization: $1,000, which is nonrefundable and must be paid in full before the department will begin processing the application.

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

~~(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,~~ 16-12-221,16-12-222, 16-12-226, 16-12-508, 16-12-533, MCA

IMP: 16-12-112, ~~16-12-204,~~ 16-12-221, 16-12-222, 16-12-226, 16-12-508, 16-12-533, MCA.

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes amendments to proposed ARM 42.39.104(1)(e) to create an administratively less burdensome and more predictable license fee structure for manufacturing licenses. The department is also transferring the fee in current (6) to proposed (1)(g) for improved organization. Further the department proposes the addition of a new fee for

applying to change the ownership and other business organization related transactions. The application fee is necessary because of the increase in these types of applications that the existing fee structure did not contemplate and reflects the amount of time and expense associated with processing those applications.

FISCAL IMPACT: In accordance with 2-4-302(1)(c), MCA, the department is required to estimate the fiscal impact of the payment of the license fees listed in proposed ARM 42.39.104(1)(e)(iii) through (vii), if known, the application fees described in proposed ARM 42.39.104(5), if known, and the number of persons affected.

The department cannot accurately estimate the fiscal impact of the proposed manufacturing license fees because what production tier a manufacturing licensee selects for its operation is an independent business decision based on the needs of each licensee and its business model. But based on the department's concentrate production data analysis since adoption of the rule in 2022, the department believes that many manufacturing licensees will realize a net benefit from its new tier, compared to the existing tier, before the license renewal cycle commences.

The department also cannot accurately estimate the fiscal impact of the proposed application fees because the estimate would range from a low of $1,000, based on only one applicant's fee, to a theoretical maximum of $1,000 multiplied by every licensee in Montana that opts to change its organizational structure or underlying beneficial owners, financial interest holders, or sources of funding.
As of December 4, 2023, there are:

1. 185 cultivator licensees operating 362 cultivator sites;
2. 170 dispensary licensees operating 435 dispensary sites;
3. 108 manufacturing licensees operating 169 manufacturing sites; and
4. Three testing laboratory licensees.

42.39.115 WORKER PERMITS; ADDITIONAL TESTING LABORATORY WORKER REQUIREMENT (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 or testing laboratory.

~~(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.~~

(2) An applicant applying to work in a marijuana testing laboratory must undergo a criminal background check and pay the background check fee provided in ARM 42.39.104 before the department will begin processing the application.

~~(6)~~ (3) Applicants must pay the fee provided in ARM 42.39.104 within ten days of ~~submitting an application~~ applying. Failure to pay the fee within the 10-day period will result in denial of the application.

(7) remains the same but is renumbered (4).

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 amend ARM 42.39.115 to include a previously overlooked requirement that all testing laboratory workers undergo background checks pursuant to 16-12-206(3), MCA. In connection with the background check requirement for testing laboratory workers, the department proposes a companion requirement that testing laboratory workers must obtain a marijuana worker permit to align with other industry workers.

Lastly, the department proposes amendments to remove current (2) through (5) which is necessary to reflect HB 128's amendments to 16-12-129, MCA, which removed background checks for marijuana business workers. The department's first proposed amendment reflects the requirement in the catchphrase of the rule.

42.39.401 MARIJUANA MANUFACTURER LICENSES – GENERAL PROVISIONS (1) remains the same.

(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~~ 2025.

~~(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)~~ (3) Licensees will elect their tier level at their next renewal date and pay the fee provided in ARM ~~42.39.102~~ 42.39.104.

(5) and (6) remain the same but are renumbered (4) and (5).

~~(7)~~ (6) A marijuana manufacturer licensee must take all reasonable measures and precautions to ensure the following:

(a) remains the same.

(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; and

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

(d) remains the same but is renumbered (c).

~~(8)~~ (7) A marijuana manufacturer licensee must:

(a) remains the same.

(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.~~ manufacturing;

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

(e) provide hand-washing facilities designed to ensure that employee hands are not a source of contamination of marijuana-infused products, contact surfaces, or packaging materials used for marijuana-infused products.

~~(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)~~ (8) 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) and (c) remain the same but are renumbered (a) and (b).

~~(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)~~ (9) 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~~ manufacture, process, or offer for sale a synthetic marijuana product as defined in 16-12-102, MCA.

~~(16)~~ (10) A marijuana manufacturer licensee must have current, written ~~standard operating procedures~~ SOPs at the licensed premises and available for inspection for the following:

(a) ~~each category and type of marijuana that it produces~~ for each final form product, the equipment, ingredients, and manufacturing process used, which shall be kept confidential by the department;

(b) ~~cleaning~~ how all equipment, counters, and surfaces are thoroughly cleaned;

(c) remains the same.

(d) proper disposal of any waste produced during processing in accordance with ARM 42.39.310; ~~and~~

~~(e) training employees on how to use the closed-loop system and handle and store the solvents and gasses safely.~~

(e) how employees are trained in the use of all emergency equipment such as eye-wash stations, fire extinguishers, chemical spill kits, or any applicable safety concern; and

(f) precautions to ensure that employees with illnesses or open lesions be excluded from any operations which may be expected to result in contamination of marijuana products until their condition is corrected.

~~(17)~~ (11) A marijuana manufacturer licensee and an employee of a marijuana manufacturer licensee may only transport ~~their~~ marijuana and marijuana products that are in the licensee's seed-to-sale tracking system inventory in accordance with 16-12-222(4), MCA, and ARM 42.39.413~~(4)~~ (3) through ~~(15)~~ (18) ~~but~~ and 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,~~ 16-12-221, 16-12-222, MCA

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.401 primarily to effectuate the transfer of content in current (9), (10), and (12) through (15) to NEW RULES I through III. The department also proposes to amend the catchphrase of the rule to add "General Provisions" which is necessary to clarify the scope of the rule.

The department's proposed amendments to current (2) and removal of current (3) are necessary to align with HB 128 amendments to statute. Proposed (3) through (6) reflect renumbering of rule sections except the text in proposed (6)(c)

has been relocated to proposed (7)(d). Similar to the department's proposals in NEW RULES I through III, proposed (7)(e) establishes reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-221, MCA, and is necessary for general consistency of marijuana manufacturing regardless of the method(s) employed.

Proposed (8) reflects a necessary revision of the rule section that removes requirements for chemical manufacturing (moved to NEW RULE II) but keeps the section's applicable general manufacturing requirements.

Proposed (9) has been amended to cross-reference HB 948's prohibition of synthetic marijuana product, as defined in 16-12-102, MCA.

Similar to other amendment proposals in this rulemaking, proposed (10) seeks to establish requirements for written standard operating procedures and requires all marijuana manufacturer licensees to establish reasonable measures to ensure a clean, safe manufacturing area and equipment, pursuant to 16-12-112 and 16-12-221, MCA.

Finally, proposed (11) contains amendments which reflect areas of concern raised by stakeholders and are necessary to clarify and specify the conditions for the lawful transport of marijuana and marijuana products by a marijuana manufacturer licensee.

42.39.405 MARIJUANA CULTIVATOR LICENSES (1) remains the same.

(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~~ 2025.

~~(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) and (5) remain the same but are renumbered (3) and (4).

~~(6)~~ (5) For purposes of determining the appropriate canopy license tier:

(a) an existing outdoor cultivation space counts as a cultivation facility as used in ~~(5)~~ (4) and its square footage counts toward the total allowable square footage under each tier;

(b) and (c) remain the same.

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

~~(8)~~ (7) A marijuana cultivator licensee must create and maintain a manual of written ~~standard operating procedures~~ SOPs 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) through (c) remain the same.

~~(9)~~ (8) If a marijuana cultivator licensee makes a material change to the ~~standard operating procedures~~ SOPs, it must document the change and revise the written ~~standard operating procedures~~ SOPs manual accordingly.

(10) remains the same but is renumbered (9).

~~(11)~~ (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, which must be updated weekly. The log shall be kept confidential by the department.

(12) remains the same but is renumbered (11).

~~(13)~~ (12) A marijuana cultivator licensee and an employee of a marijuana cultivator licensee may only transport ~~their own~~ marijuana and marijuana products that are in the licensee's seed-to-sale tracking system inventory in accordance with 16-12-222(4), MCA, and ARM 42.39.413~~(4)~~ (3) through ~~(15)~~ (18) ~~but~~ and 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, 16-12-221, 16-12-222, 16-12-223, MCA

REASONABLE NECESSITY: In addition to the department's general statement of reasonable necessity, the department proposes to amend ARM 42.39.405. The department's proposed amendments to current (2) and removal of current (3) are necessary to align with HB 128 amendments to statute. Proposed (3) through proposed (9) reflect the necessary renumbering of rule sections based on the removal of current (3).

Proposed amendments to (7) and (8) which adopt the acronym of SOP for standard operating procedures reflect a proposed definition of "SOP" in ARM 42.39.102 which is proposed in MAR Notice No. 42-1073, filed concurrently with this rulemaking.

Proposed (10) seeks to amend a licensee's agricultural chemical log requirement to be updated on a weekly basis to provide clarity of this reconciliation requirement which is different from a licensee's reconciliation of marijuana item inventories in the seed-to-sale tracking system at the close of business each day.

Proposed (11) contains amendments which reflect areas of concern raised by stakeholders and are necessary to clarify and specify the conditions for the lawful transport of marijuana and marijuana products.

Proposed (12) improves clarity for cultivator licensees regarding what marijuana and marijuana products they are able to transport under the license.

42.39.409 MARIJUANA DISPENSARY LICENSES (1) remains the same.

(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~~ 2025.

~~(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) through (7) remain the same but are renumbered (3) through (6).

(7) A marijuana dispensary licensee may not sell a branded, commercially manufactured food product (e.g., Chex Mix, Nerds Ropes) as a marijuana-infused product except when commercially manufactured food products are used as ingredients in a marijuana-infused product in a way that renders them unrecognizable as the commercial food product in the final marijuana-infused

product and the licensee does not state or advertise to the consumer that the final marijuana-infused product contains the commercially manufactured food product.

(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) through (11) remain the same.

(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, including any state or territory that has authorized digital driver's licenses;

(b) through (d) remain the same.

(e) a passport or passport card 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) remains the same.

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

(13) 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.

(14) remains the same.

(15) A marijuana dispensary licensee that offers retail deli-style sales must maintain and make available for inspection a SOP detailing sterile handling techniques to handle marijuana flower.

~~(15)~~ (16) A marijuana dispensary licensee and an employee of a marijuana dispensary licensee may only transport marijuana and marijuana products that are in the licensee's seed-to-sale tracking system inventory in accordance with 16-12-222(4), MCA, and ARM 42.39.413~~(4)~~ (3) through ~~(15)~~ (18) ~~but~~ and may not transport marijuana or marijuana products of other licensees without a marijuana transporter license.

(16) remains the same but is renumbered (17).

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

(18) A marijuana dispensary must not maintain or make available for sale any marijuana product that has not received a "test passed" status from a licensed marijuana testing laboratory.

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 amend ARM 42.39.409. The department's proposed amendments to current (2) and removal of current (3) are necessary to align with HB 128 amendments to statute. Like proposed New Rule II(3), proposed (7) in this rule continues to restrict "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.

The department proposes amendments to (8) to reflect the removal of the requirement for a licensee to enter destruction of product into the seed-to-sale tracking system to alleviate an administrative burden for licensees for product that is no longer in their seed-to-sale tracking system.

The department's amendments to (12) are proposed to reflect that state governments have authorized digital versions of driver licenses and the rules acknowledge alternate forms of authorized identification.

Current (13) is proposed for removal because HB 948 amended 16-12-208, MCA, to clarify that only hemp flower and hemp plants are restricted for dispensaries and the rule section is now obsolete.

Proposed (13) is consistent with other licensee requirements for marijuana and marijuana products to be shelf-stable products under time-temperature controls to avoid spoilage or foodborne illness. The sections require basic food product handling through refrigeration or freezing until the time of product sale to the consumer, and like other perishable food items, the department requires the manufacturer to provide the consumer with some food handling labeling.

Proposed (15) seeks to establish requirements for standard operating procedures and requires all licensees offering deli-style sales establish sterile handling techniques which is necessary to ensure product safety for consumers. Similarly, the department proposes (18) which the department believes is necessary guidance for licensees to ensure product safety for consumers.

As has been discussed in other proposals above, proposed (16) in this rule contains necessary amendments to clarify and specify the conditions for the lawful transport of marijuana and marijuana products.

Finally, current (17) is proposed for removal because it is an obsolete provision adopted to aid in the transition of the industry under HB 701.

42.39.413 TRANSPORTATION OF MARIJUANA AND MARIJUANA PRODUCTS; MARIJUANA TRANSPORTER LICENSES (1) remains the same.

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

(3) remains the same but is renumbered (2).

~~(4)~~ (3) All distribution and delivery of marijuana and marijuana products must:

(a) remains the same.

(b) depart from a licensed premises and be delivered to a licensed premises or to a registered cardholder's address, in which case the registered cardholder must

provide a valid registry identification card to the transporter prior to the transporter completing the transport;

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

(i) and (ii) remain the same

(iii) the most direct route to be traveled to complete the transport;

~~(iii)~~ (iv) actual date and estimated time of departure;

~~(iv)~~ (v) actual date and estimated time of arrival;

(v) remains the same but is renumbered (vi).

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

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

(A) remains the same.

(B) accurate amount of product being transported verified by count or with a weighing device pursuant to 30-12-203, MCA, and ARM 24.351.101; and

(C) remains the same.

(d) be accomplished within ~~48~~ 72 hours from the date and time of departure.

(4) If the transport requires an overnight stay during the planned direct route to complete the transfer, the transporting licensee must:

(a) identify the stay on the transport manifest prior to transport;

(b) accept the in-transit product into the storage facility's inventory or other licensed premises; and

(c) store the in-transit product in the licensee's licensed premises.

(5) The transporter of the marijuana or marijuana product must record in the seed-to-sale tracking system:

(i) the actual time of departure from the originating license; and

(ii) the actual time of arrival at the destination.

(5) through (7) remain the same but are renumbered (6) through (8).

(9) A receiving licensed premises may not accept any marijuana or marijuana products from a transporter that does not match the description and/or quantity shipped on the transport manifest.

(10) Upon receipt, the receiving licensed premises shall ensure that the product received is as described in the transport manifest, verified by count or with a weighing device pursuant to 30-12-203, MCA, and ARM 24.351.101. A receiving licensed premises must immediately record receipt of the transported inventory.

(11) 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.

(12) Except as provided in (b), a receiving licensed premises must reject a transport that contains marijuana or marijuana products that do not match the description and/or quantity shipped on the transport manifest.

(a) Transport manifest discrepancies must be reconciled by the originating licensee at the originating licensed premises prior to transport.

(b) A receiving licensed premises may accept packages on a transfer manifest with a +/- of 0.9 grams per pound for scale variance and -5 to -7 grams per pound for drying.

~~(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) through (15) remain the same but are renumbered (13) through (18).

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 amend ARM 42.39.413. The department's proposed removal of current (2) is necessary to align with HB 128 amendments to statute.

The department proposes several minor, yet necessary, amendments to proposed (3) to add additional clarity to the requirements for every marijuana transport transaction whether it occurs licensee-to-licensee or licensed-to-registered cardholder.

New (4) and (5) are proposed to reflect changes that are occurring in the seed-to-sale tracking system and adding a transfer hub, which includes more detailed information for reporting and transport. The sections also provide necessary guidance and compliance to ensure marijuana products are stored in a licensed premises when an overnight stay is involved in transport. Section (5) is proposed for better tracking and to clarify whether a transporting or receiving licensee failed to timely record transport and receipt.

Current (5) through (7) are renumbered as (6) through (8).

Proposed (9) through (12) are necessary additions to the rule, or are relocations of text from current (8) and (9), because the transport of marijuana products is increasing in frequency and involves complex logistics for its smooth operation. Stakeholders have requested the department provide guidance regarding the exchange of transported product because the marijuana laws involve strict liability and compliance issues involve different licensees at different times.

Current (10) through (15) are renumbered as (13) through (18).

42.39.415 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~~ license and one marijuana dispensary ~~on the same licensed premises~~ license.

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

~~(3)~~ (2) 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

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., January 22, 2024.

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 of HB 128, Representative Kassmier, was contacted by email on June 5, 2023 and on December 7, 2023. The primary bill sponsor of HB 903, Representative Hopkins, was contacted by email on August 11, 2023 and on December 7, 2023. The primary bill sponsor of HB 948, Representative Galloway, was contacted by email on August 11, 2023 and on December 7, 2023.

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. While the extent of any potential impact is fact-dependent on the circumstances of each licensee, the department notes the impactful changes correlate to the fiscal impact of application fees discussed above.

/s/ Todd Olson
Todd Olson
Rule Reviewer

/s/ Scott Mendenhall
Scott Mendenhall
Deputy Director of Revenue

Certified to the Secretary of State December 12, 2023.