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 ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On October 22, 2021, the Department of Revenue (department) published MAR Notice No. 42-1033 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 1369 of the 2021 Montana Administrative Register, Issue Number 20.

2. On November 16, 2021, the department held a public hearing to consider the proposed adoption and amendment. There were no commenters present to provide testimony or commentary in support of the rulemaking. The following commenters appeared and provided oral testimony in opposition to the proposed rulemaking: Casey Palmer, Sugar Leaves; David Hiller, Yellowstone Buds; Christopher Young, Young Law Office; Katrina Farnum, Garden Mother; Nathan Kosted, Stillwater Laboratories; Susan Stanley, Sensicare; Shelley Sink, Evergreen 406; Mariah Bond, Euphoria Wellness; Sam Belanger, Montana Hemp Farmer's Cooperative/Green Ridge; Kate Cholewa, Montana Cannabis Industry Association (MTCIA); Jason Smith, Montana Advanced Caregivers; Jon Speare, White Buffalo Laboratories; Karen Roellich; Josh Vandewetering, Lionheart Caregiving Dispensary; Billie Rhoades, Lionheart Caregiving Dispensary; Erica Sciate; Joanna Barney, Sacred Sun Farms; and Richard Abromeit, Montana Advanced Caregivers. The department received written comments from interested persons in support of the proposed rules and also received written comments submitted by interested persons in opposition.

3. The department has adopted New Rules IX (42.39.115), XI (42.39.315), XII (42.39.316), and XV (42.39.319) as proposed.

4. The department has adopted the following new rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I (42.39.109) LICENSE, APPLICATION, AND RENEWAL FEES

(1) Initial licensure and ~~annual~~ renewal fees for the following license types and endorsements are:

(a) Two-year ~~M~~marijuana transporter license: $10,000.

(b) through (e) remain as proposed.

(f) Manufacturer license:

(i) remains as proposed.

(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~~.~~; 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.

(g) remains as proposed.

(2) At the time of the initial application and at renewal, an applicant shall pay the department a nonrefundable processing fee equal to 20 percent of the license fee identified in (1). The department will not begin processing an application until it receives all processing fees. A licensee shall pay the department the remaining 80 percent of the license fee upon department notification of approval of its application or renewal.

(3) through (6) remain as proposed.

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 (42.39.401) MARIJUANA MANUFACTURER LICENSES

(1) through (4) remain as proposed.

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

(6) and (7) remain as proposed.

(8) A marijuana manufacturer licensee must:

(a) remains as proposed.

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

(c) remains as proposed.

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

(a) through (f) remain as proposed.

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

(10) remains as proposed.

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

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

(b) through (14) remain as proposed.

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

(16) and (17) remain as proposed.

AUTH: 16-12-112, MCA
IMP: 16-12-204, 16-12-222, MCA

NEW RULE III (42.39.405) MARIJUANA CULTIVATOR LICENSES (1) A marijuana cultivator license allows a marijuana cultivator to plant, cultivate, grow, dry, package, and label marijuana and sell marijuana to licensed marijuana manufacturers, licensed dispensaries, and to other licensed marijuana cultivators, and to sell marijuana products to licensed dispensaries. Marijuana cultivator licensees may not sell marijuana flower to other marijuana cultivator licensees.

(2) through (12) remain as proposed.

~~(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) remains as proposed but is renumbered (13).

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

NEW RULE IV (42.39.409) MARIJUANA DISPENSARY LICENSES

(1) through (6) remain as proposed.

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

(8) Marijuana dispensary customers must not handle marijuana or marijuana products outside of its packaging prior to purchase. Customers may ~~not~~ return marijuana or marijuana products ~~unless the items are unopened and in their original packaging~~ 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) and (10) remain as proposed.

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

(12) remains as proposed.

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

(14) and (15) remain as proposed.

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

(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.

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

NEW RULE V (42.39.413) MARIJUANA TRANSPORTER LICENSES

(1) through (3) remain as proposed.

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

(a) remains as proposed.

(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;

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

(i) through (iv) remain as proposed.

(v) transporter's driver's license number, vehicle ~~year,~~ make, model, and license plate number;

(vi) through (15) remain as proposed.

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

NEW RULE VI (42.39.415) COMBINED USE LICENSES (1) and (2) remain as proposed.

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

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

NEW RULE VII (42.39.417) MARIJUANA TESTING LABORATORY LICENSES (1) remains as proposed.

(2) A current marijuana testing laboratory licensee may continue to operate under its existing license and shall pay the annual license renewal fee provided for in [NEW RULE I] at its next renewal date.

~~(2)~~ (3) The department shall begin accepting applications for new marijuana testing laboratories on January 1, 2022.

(3) and (4) remain as proposed but are renumbered (4) and (5).

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

(7) A marijuana testing laboratory licensee must obtain and maintain a $25,000 surety bond which names the department as loss payee in the event the laboratory licensee fails to adhere to the security plan approved by the department, or it otherwise operates the facility in a manner that allows for, or results in theft,

loss, or diversion of marijuana items. A copy of the bond must be submitted to the department as a part of the license application process.

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

NEW RULE VIII (42.39.420) MARIJUANA STORAGE FACILITY ENDORSEMENT (1) A marijuana transporter or a marijuana testing laboratory ~~may~~ shall obtain a marijuana storage facility endorsement for any overnight storage of marijuana or marijuana products. A marijuana storage facility endorsement allows a marijuana transporter or marijuana testing laboratory to maintain a separate, off-site storage facility.

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

(3) and (4) remain as proposed.

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

NEW RULE X (42.39.314) GENERAL LABELING REQUIREMENTS

(1) and (2) remain as proposed.

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

(a) strain name;

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

(b) through (h) remain as proposed but are renumbered (c) through (i).

(4) through (9) remain as proposed.

AUTH: 16-12-112, MCA
IMP: 16-1-101, 16-12-112, 16-12-208, 16-12-224, MCA

NEW RULE XIII (42.39.317) 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) remains as proposed.

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

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

(A) through (D) remain as proposed.

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

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

(A) through (3) remain as proposed.

AUTH: 16-12-112, MCA

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

NEW RULE XIV (42.39.318) 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) and (b) remain as proposed.

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

(i) remains as proposed.

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

(A) remains as proposed.

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

(d) through (3) remain as proposed.

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

5. The department has amended the following rule as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

42.39.102 DEFINITIONS The following definitions apply to this chapter:

(1) through (9) remain as proposed.

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

(11) through (40) remain as proposed.

~~(41) "Proof of residency" means a readable photocopy of a current Montana driver's license, Montana state-issued identification card, or tribal identification card.~~

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

(43) and (44) remain as proposed but are renumbered (42) and (43).

~~(45)~~ (44) "Registered premises" ~~means the premises specified in an application for a license that is owned or in possession of the licensee and where the licensee is authorized to cultivate, manufacture, dispense, store, transport, or test medical marijuana.~~ has the same meaning as "licensed premises."

(46) through (52) remain as proposed but are renumbered (45) through (51).

~~(53)~~ (52) "Total potential psychoactive THC" means the highest theoretical concentration of psychoactive THC available in a marijuana item achievable only through the complete conversion of THCa to THC with the application of heat during administration/consumption. Total potential psychoactive THC is the sum of THC and THCa calculated using the following equation: Total potential psychoactive THC = (THCa x 0.877) + THC.

(54) and (55) remain as proposed but are renumbered (53) and (54).

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

6. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT 1: The department received several comments on New Rule IV(13), both in writing and at the public hearing, that could be summarized as a general objection to the rule's interpretation of the statutory prohibition of a marijuana dispensary licensee selling hemp to include cannabidiol (CBD) products, which included objection from Mr. Belanger's Cooperative. Many commenters contend that the department misconstrued this portion of the legislative intent of House Bill 701 (HB 701).

Mr. Vandewetering provided observational commentary about Montana's advances of legitimizing the industry and thanked the department for its part in that. He also commented his belief that the department "over-interpreted" the definition of hemp and suggests that the legislature really intended to regulate the flower portion and not that marijuana dispensaries could not sell CBD products when retail gas stations could.

The department also received direct feedback from the legislature, through its Revenue Interim Committee and Economic Affairs Interim Committee meetings, held on November 9 and November 17, 2021, respectively. Both committees voiced that the legislature did not intend HB 701 to contain a dispensary restriction on the sale of hemp-derived CBD products and that the department would be fulfilling legislative intent by amending the rule to permit the sale of CBD at licensed dispensaries.

RESPONSE 1: The department thanks all commenters and the interim legislative committees for their comments. Based on the commentary and testimony received, the department has amended New Rule IV upon adoption to refine the hemp restriction to hemp flower and hemp plants and not CBD products.

COMMENT 2: The department received written commentary and testimony at the public hearing that certain proposed fees in New Rule I are excessive, such as general license fees, transporter license fee, testing laboratory license fees, change of location fee, and fingerprint fees.

There was general commentary that questioned whether the 20 percent amount in (2) is in addition to the license fee. Ms. Cholewa and Mr. Young commented their understanding that the 20 percent payment in (2) is a non-refundable down payment of the license fee. Mr. Young also commented about the need for fingerprint fees in (5). Ms. Barney wanted clarification that the 20 percent amount only applied to license fees, not to the miscellaneous fees (e.g., background check).

The department received commentary that the fees charged by the department to licensees will pass through and inflate the costs of marijuana and

marijuana products which will influence the purchasing public to opt for the illicit market at lower prices.

The department also received commentary regarding the amounts charged to a licensee for testing marijuana and marijuana products and the commenters advocated for additional testing laboratories to foster lower testing fees through increased competition.

Mr. Speare and Ron Brost, Director of Stillwater Laboratories, questioned the necessity for the department's proposed fee for marijuana testing laboratories of $5,000 and that the fee is excessive compared with the current fee of $2,000. Mr. Speare requested a "phased in" increase if any increase was made at all.

Ms. Cholewa requested clarification of the department's overproduction penalty assessment procedures since license fees for manufacturers are based on the volume of concentrate and production is annual.

RESPONSE 2: The legislature authorized the department to designate certain fees sufficient to administer and enforce the Montana Marijuana Regulation and Taxation Act (Act) (See 16-12-112(1)(q), MCA). New Rule I is a fee schedule rule that includes several statutory fees as well as those fees that in the department's estimation satisfy the needs and requirements of 16-12-112(1)(q), MCA.

The transporter license is a two-year license so that fee is for that extended license period and the department contends is commensurate in scale to the other license fees for the industry such as a dispensary, tier one manufacturer, or testing laboratory. The department understands that clarity of the length of the license period could be improved, so the department has amended (1)(a) upon adoption.

The department acknowledges to Messrs. Speare, Kosted, and Brost that the annual license fee for testing laboratories of $5,000 does represent an increase from the current amount that was adopted by the Department of Public Health and Human Services (DPHHS) in 2018 under ARM 37.107.117. And without speculating why DPHHS set the license fee at the prior amount it did (an arbitrary mid-range between $1,000 and $5,000, which DPHHS stated in its rulemaking), the department contends the testing laboratory fee in New Rule I is now commensurate with the other license types and is necessary to administer and enforce the Act under the expanded marketplace. Moreover, the testing laboratories testified and have provided previous testimony to the department and the interim committees about the amount of capital improvements they are making - or have made - in preparation of the expanding marketplace. But when increased license fees are included in this context, their contentions of an undue burden are not sustained.

The department appreciates the comments regarding the location change fee in New Rule I(6), but a change of business location is a substantial transaction and requires more than a plan or application review; there is a substantial amount of department time and resources to process the change. Multiple premises inspections are required (wrapping up one location, approving the other) and determining premises suitability under the marijuana laws. The department believes the fee is appropriate and declines to change it at this time.

As to the 20 percent non-refundable fee comments, the department responds that additional guidance has been provided in (2) which clarifies the license fee and that the balance of it is due and payable upon approval of the application or renewal.

The $30 charge per background check in (5) is a "hard cost" that the department pays to process criminal background checks which is passed on to the person submitting the background check. The department cannot lessen the fee and effectively administer applicant licensing; and as the department's background check costs increase over time, the cost to the applicant/licensee will likely increase as well.

In response to the comments that processing, license, or ancillary fees in the rule are excessive and will inflate the costs of product which will lead customers to purchase through the illicit market, the department is sensitive to the concerns raised although they are speculative. The industry is not a new one in Montana and the department has weighed legislative intent regarding fee structures with the costs and benefits of the expanding marketplace. The department believes the fees are appropriate, reasonable, and declines to change the fee amounts at this time.

The department understands the comments regarding marijuana and marijuana products testing costs but declines to respond as they are outside the scope of this rulemaking.

To answer Ms. Cholewa's overproduction penalty comment, 16-12-221, MCA, provides that manufacturer license fees are based on concentrate produced each month. The department intends to reconcile manufacturing overproduction with a licensee annually and has amended New Rule II(5) accordingly.

COMMENT 3: Ms. Cholewa commented that manufacturing license fees do not make sense for those who manufacture cannabis-infused goods but do not produce concentrate because they are paying the same license fee ($5,000) as those manufacturers who are producing concentrate. Ms. Cholewa advocated for a flexible fee solution for those who do not produce concentrate.

RESPONSE 3: Ms. Cholewa is correct that manufacturing license fees begin at $5,000 even for manufacturers who produce less than one pound of concentrate, or none. See 16-12-221(6)(a)(i), MCA. While the department may create additional fee levels as necessary under 16-12-221(6)(b), MCA, the department believes the request falls outside the scope of this initial rulemaking, but the department is amenable to future rulemaking if there is necessity.

COMMENT 4: Mr. Palmer and Ms. Barney made comments related to exit packages and whether it was redundant to require two sealed bags.

RESPONSE 4: Section 16-12-208(9), MCA, defines exit packaging as " . . . . a sealed, child-resistant certified receptacle into which marijuana or marijuana products already within a container are placed at the retail point of sale." This is reflected in the department's definition in ARM 42.39.102 and the implementation of exit packaging in New Rule XV (ARM 42.39.319).

Based on the comments provided, the department concludes that a marijuana dispensary licensee may opt to have only one exit package as long as the package

complies with the child resistant package requirements and is limited to the design elements and language limitations of 16-12-208(6), MCA.

COMMENT 5: Messrs. Hiller, Smith, Abromeit, and Ms. Rhodes commented that outdoor cultivators should be permitted to tier-up an existing location, but that is not provided in New Rule III.

Ms. Rhoades also asked the department to clarify if a cultivator could tier-up its license and transfer locations and if the $2,500 change of location fee would apply to cultivators.

RESPONSE 5: The department directs Messrs. Hiller, Smith, Abromeit, and Ms. Rhodes to Comment and Response No. 40 (below).

In response to Ms. Rhode's questions about a cultivator transferring locations, the department has yet to determine whether these types of transfers are authorized under the Act or what kind of administrative rules would be necessary.

COMMENT 6: Mr. Hiller and others provided commentary or asked the department to clarify which license types are permitted to transport their own marijuana and marijuana products without the need for a transporter license.

RESPONSE 6: Section 16-12-222(4), MCA, provides, in pertinent part, that ". . . a person who obtains a cultivator license, manufacturer license, adult-use dispensary license, medical marijuana dispensary license, or testing laboratory license or is an employee of one of those licensees, may. . . . [t]ransport marijuana or marijuana products between other licensed premises without a transporter license." The department contends no additional clarification is necessary.

COMMENT 7: Mr. Young commented that New Rule II(8)(b) requires licensees to maintain and provide to the department detailed manufacturing instructions, which may be considered to be "trade secrets" and the department should keep this information confidential.

Ms. Barney also provided commentary that concurs with Mr. Young.

RESPONSE 7: The department understands Mr. Young's and Ms. Barney's concerns and has amended the rule to reflect that any licensee manufacturing information or processes that are reviewed by or provided to the department will be treated as confidential and proprietary.

COMMENT 8: Mr. Young provided commentary about the transporter provisions in New Rule II(17) and attempted to correlate the transport provisions to multi-party transactions and contracts governed by the Uniform Commercial Code.

RESPONSE 8: The department declines to respond to Mr. Young's comments because they fall outside the scope of the rulemaking and were presented to the public hearing audience more as a solicitation for legal representation than comments to the rulemaking.

COMMENT 9: Mr. Young commented on New Rule IV(6), and questioned whether Montana's DRAM shop law applies to a marijuana dispensary licensee selling marijuana or marijuana products to any person obviously or apparently under the influence of drugs or alcohol.

Other commenters also questioned the retail sales restriction against selling marijuana or marijuana products to any person obviously or apparently under the influence of drugs or alcohol. Ms. Farnum offered related commentary that medical patients come to her dispensary to purchase marijuana and marijuana products in order to transition from prescription drugs and those customers may be under some influence of lawful drugs at the time of purchase.

RESPONSE 9: The department declines to respond to Mr. Young's DRAM shop comments because they fall outside the scope of the rulemaking, are speculative and request the department to render a legal opinion, and were presented to the public hearing audience more as a solicitation for legal representation than comments to the rulemaking.

The department responds to the other commenters that retail sales restrictions of marijuana and marijuana products to include any person obviously or apparently under the influence of drugs or alcohol are identical to those for alcoholic beverages sales, are generally directed at the adult use/recreational market, and are consistent with the intent of the Montana Marijuana Regulation and Taxation Act. The department will be coordinating training on identifying signs of intoxication in the near future. Until such time as the training is developed and the industry receives the training, the department requests licensees and their employees exercise discretion when considering a marijuana or marijuana product sale to any person obviously or apparently under the influence of drugs or alcohol.

COMMENT 10: Mr. Young asked whether the department would allow a business which uses independent contractors as marijuana workers solely for the purpose of supplying workers to the industry - in other words, a staffing agency.

RESPONSE 10: Based on the cursory information provided, the department responds that the requested activity is a fair reading of the rules and appears allowable.

COMMENT 11: Ms. Farnum questioned how the department will assess fees for a two-license, single location into another single location - would the change of location fee be charged twice?

RESPONSE 11: When moving two licenses that operate out of one location into a new single location only one $2,500 fee is charged.

COMMENT 12: Ms. Farnum asked about the manufacturing restriction against noncannabinoid additives increasing the potency of marijuana or marijuana products and whether that applies to additives like ginger or caffeine.

RESPONSE 12: The department understands the scope of the question and to improve clarity, the department has amended New Rule II(15) to reflect synthetic cannabinoids - including Delta-8 tetrahydrocannabinol - are subject to the manufacturing restriction.

COMMENT 13: The department received comments regarding canopy measurement methodologies and why the department does not include vertical measurement of the canopy space. Ms. Cholewa advocates Montana adopt a more precise definition like that in California.

RESPONSE 13: The department is currently working with its seed-to-sale tracking vendor to implement a "harvest scheduler" that the department believes will ease concerns over canopy measurement. The harvest scheduler is a tool that the department plans to use to schedule the measurement of canopy sizes at consistent times based on the development of the cultivator's crop which will improve accuracy of canopy measurement. The department will communicate the status of these system improvements as they become available.

COMMENT 14: Commenters have asked the department about the reasoning behind phasing out hoop houses by October 1, 2023, as reflected in New Rule III(13).

RESPONSE 14: The department did not independently propose this determination. Section 117, HB 701, requires the discontinuation of hoop houses by the stated date. If commenters are inclined to pursue the reversal of this requirement, it will require an act of the legislature. Even so, and based on the comments the department has removed New Rule III(13) as it is unnecessarily redundant to the Act.

COMMENT 15: Ms. Farnum and other commenters questioned the restriction of customer returns of marijuana or marijuana products found in New Rule IV(8). The commenters advocated for an optional return policy that would track the product return and destruction through the seed-to-sale tracking system.

RESPONSE 15: The department agrees and based on the comments has amended New Rule IV(8) upon adoption.

COMMENT 16: Ms. Farnum presented commentary regarding the marijuana transporter rule, New Rule V. She is concerned about the amount of business asset or location information that is open and public on transport manifests and whether any of that information can be kept off the manifests and unique license identifications can be used instead.

Ms. Farnum also asked for clarification of (9) and what is "immediately" when reporting product transport discrepancies, about vehicle security system required in (11)(b).

Ms. Farnum also asked the following questions:

1. whether standardized procedures for testing laboratories could be implemented;

2. what "temporary" means for storage facilities;

3. if background check results used for other purposes can be used for marijuana worker permits and how long employees can use their badges; and

4. whether a grace period could be a part of the new labeling requirements and if the word "cannabis" may be used for labeling.

Ms. Farnum last commented that packaging restrictions against products that look like other commercially available foods impacts many of her products.

RESPONSE 16: The department has made initial inquiries with the seed-to-sale tracking system vendor about system changes for tracking manifests. There is no definite information as of the filing of this adoption notice, but the department will notify licensees of any substantive developments.

The department interprets "immediately" to mean that the timing of the reporting to the department should occur upon the discovery of any actual product discrepancy.

As to the vehicle system requirements, the department believes that a security system is a necessary requirement for a vehicle involved in the transport business and personal or employee vehicles should not be used if they cannot meet the minimal security requirements.

The department responds that test batch size issues are outside the scope of this rulemaking and should be directed to the Department of Public Health and Human Services. As for standardized testing procedures, the department agrees that implementing such procedures would be beneficial to the industry, but national standardized instrument methodology is impossible at present because marijuana remains federally illegal. This means that federal regulating bodies like the EPA, FDA, and USDA, which regulate and provide standard methods for all other lab types will not provide guidance or standards for consideration.

The department agrees that "temporary" storage could be clarified and the department has amended the rule upon adoption to mean a 48-hour period.

The department responds to the worker permit questions that (2) and (3) of the rule are clear, and further that a marijuana worker may not use background check results used for other purposes. HB 701 directed the department to conduct all worker background checks and protected criminal justice information generally cannot be used nor relied upon for secondary purposes.

The department understands the questions and concerns regarding labeling and responds that the department is developing labeling and packaging procedural rules and it is the department's goal to have that proposal rules notice finalized in the near future, but it will occur after the adoption of the other pending division rules. As stated in the Cannabis Control Division's December newsletter, " . . . as long as you are compliant with medical rules and laws for packaging and labeling requirements, you will be in compliance until formal guidance is published."

At its December 9, 2021 meeting, the Economic Affairs Interim Committee expressed concerns with the department's proposed allowance of the word "cannabis" in the packaging and labeling rules (New Rule X, and New Rules XII

through XIV). Based on the Economic Affairs Interim Committee's express direction, the department must decline Ms. Farnum's request.

Regarding Ms. Farnum's food packaging question concerning New Rule II(12), the department observes that many other states have adopted similar "copycat" packaging restrictions and the rule restrictions are necessary and clear as a means to avoid potential product confusion - especially for children - between the commercially manufactured food product and the copycat marijuana product. While the department declines to amend the rule, the department is willing to explore the placement of picture samples or other helpful guidance on the requirements through the Cannabis Control Division's communications or webpage.

COMMENT 17: Ms. Stanley commented that New Rules II, III, and IV all state that existing manufacturers, cultivators, and dispensaries can continue to operate under their current licenses in the adult use market but do not specifically state that existing licensees may participate in the wholesale market, only that they continue to operate under their current licenses. Her recommendation would be for the department to clarify those activities each licensee is able to do.

RESPONSE 17: The department believes that the statutes and new rules are clear and they are not meant as restrictions as what a licensee may do under their existing license and under HB 701. While the department declines to make the suggested rule amendments, it does see benefit in developing some educational or informational guidance for licensees that opt to remain in the medical-only market.

COMMENT 18: Ms. Stanley requested amendments to the cultivator license activity description in New Rule III(1) to add more distinction between cultivators and manufacturers.

RESPONSE 18: The department directs Ms. Stanley to Comment and Response No. 39 (below).

COMMENT 19: Ms. Stanley requested the department clarify New Rule IV(1) because " . . . dispensaries are not allowed to function as wholesalers and it conflicts with cultivators and manufacturers. It seemed the intent of HB 701 was to allow cultivators and manufacturers to be the wholesalers, so I would suggest deleting other licensed dispensaries from (1) unless it was the intent that dispensaries are to become wholesalers."

Related to Ms. Stanley's dispensary activity comment, Ms. Cholewa commented her observation that there is an unregulated wholesaling business model that requires the department's attention and there are no administrative rules to address it.

RESPONSE 19: Similar to Response 18, statute permits the activity to which Ms. Stanley refers. Section 16-12-102(1), MCA, provides an adult-use dispensary ". . . . means a licensed premises from which a person licensed by the department may (a) obtain marijuana or marijuana products from a licensed cultivator, manufacturer, dispensary, or other licensee approved under this chapter . . ."

To answer Ms. Cholewa's comment, the department understands and appreciates the comments but they fall outside the scope of this rulemaking and would require independent development and dialogue with the affected stakeholders before such a proposal could be introduced.

COMMENT 20: Ms. Stanley requested the department clarify the paraphernalia sales parameters in New Rule IV(7) because it only appears to address paraphernalia sales to registered cardholders.

RESPONSE 20: The department thanks Ms. Stanley for the observation and the department has amended the rule section as recommended.

COMMENT 21: Ms. Stanley and Ms. Cholewa both commented their belief that New Rule IV(11) requires an amendment to clarify that a dispensary licensee may still sell marijuana and marijuana products to a registered cardholder who does not possess their card but the sale will be made as an adult-use market sale at the applicable tax rate.

RESPONSE 21: The department thanks Ms. Stanley and Ms. Cholewa for the comments and the rule has been amended as suggested.

COMMENT 22: Ms. Stanley commented on New Rule XIII(1)(b)(i) through (iii) and suggested striking the term "serving size" from (i) and (ii) and deleting (ii) entirely since non-ingestible items are not going to be eaten and are not sold in multi-serving packages.

RESPONSE 22: The department thanks Ms. Stanley for the comments and the rule has been amended upon adoption.

COMMENT 23: Ms. Stanley commented to the department's proposed amendments to the definitions in ARM 42.39.102 that there is some internal inconsistency because of the expansion of the application of the definitions to the adult-use market. Ms. Stanley provided some suggested amendments.

RESPONSE 23: The department thanks Ms. Stanley for the comments and some of the ARM 42.39.102 definitions have been amended as suggested.

COMMENT 24: Ms. Cholewa commented her opinion regarding the department's labeling and packaging requirements in New Rules X through XV: (1) that licensees cannot be ready by January 1 with the requirements; (2) labels are expensive and are subject to the same supply chain delays many other products are currently experiencing; (3) there should be a timeline for review once labels have been submitted for approval; (4) the department needs to provide additional clarity regarding minor changes to labels, such as an approved label and packaging for a chocolate chip cookie that also applies to a vanilla cookie; and (5) labels and packaging that meet the requirements under the former rules should be permitted until June 30, 2022.

A handful of others also commented similarly or concurred with (1), (2), (3), and (5) of Ms. Cholewa's comments.

RESPONSE 24: The department understands the questions and concerns regarding labeling, and refers the commenters to the seventh paragraph at the bottom of Response 16.

COMMENT 25: Ms. Cholewa questioned licensee transportation activity and questioned if it is lawful for licensees to transport their own product. Ms. Cholewa also questioned whether transporters will be transporting cash between people. Why would a cultivator buy product from a manufacturer? The department should address this conduct in the rules.

RESPONSE 25: The department directs Ms. Cholewa to Response 6 to answer her first question and adds that any rules changes to limit this ability exceed the scope of this rulemaking and should be independently developed with appropriate legislative and stakeholder input.

As for the transport of money, the department acknowledges this activity is likely but involves private business relationships between licensees, and substantive concerns are speculative at this time.

The department's answer to Ms. Cholewa's final question is that the Act provides for it; whether the legislature intended it or the author of Initiative Measure No. 190. The department acknowledges business activities like this in its implementation of the Act, and will monitor the need to develop and implement rules.

COMMENT 26: Mr. Smith commented on New Rule II(9)(a) that he understands the department's concern regarding the unlicensed practice of medicine, but that it is common for one person (i.e., a dispensary employee) to tell another person (i.e., a customer) their experiences or results using specific products for the treatment of various ailments. Mr. Smith contends this is not medical advice and asks the department to clarify whether this is permissible.

RESPONSE 26: The department believes that New Rule II(9)(a) is clear and does not prohibit licensee employees from anecdotal product discussions.

COMMENT 27: In addition to the fees comments made at the public hearing and in writing, Mr. Speare also provided the following comments:

27.1 - New Rule II(9)(g) and New Rule III(10)(a) use the term "material data safety sheets" but the federal standards under OSHA changed to refer to them as "safety data sheets"; the references should be changed in rule.

27.2 - New Rule II(11)(a) uses the term "class 1 solvents." Mr. Speare recommends adding more specificity to "class 1" and provided text and data from the federal Food and Drug Administration.

27.3 - New Rule III(11) contains a potentially helpful requirement for testing labs to have access to agricultural chemical (i.e., pesticides) logs when applicable (e.g., for customers who have submitted applicable testing samples that was subsequently found to be non-conforming to the required action level for a

pesticide). It would be prudent to ensure that the seed-to-sale tracking system has the capability for cultivators to log pesticides, fertilizers, or other agricultural chemicals as well as make that information viewable to testing labs prior to approving this rule.

27.4 - New Rule V(4)(c)(v) lists requirements for information on transport manifests including vehicle year. METRC currently does not specify entry of year of vehicle when entering information for transfer manifests. Mr. Speare recommends changing this requirement to include state driver's license number.

27.5 - New Rule VII(2) - Mr. Speare comments and opines that the existing marijuana industry - and marijuana testing laboratories - should be granted the same moratorium from new laboratories - until July 1, 2023 - that HB 701 clearly granted to cultivators, manufacturers, and dispensaries. Mr. Speare attributes the lack of provision for marijuana testing laboratories in HB 701 to a drafting error in the legislation.

27.6 - New Rule VIII(1) and (3) - Testing labs were not mentioned in HB 701 for the requirement for storage facilities. If testing labs will have this requirement, there should be more clarity as to how that is applied. Also, it is Mr. Speare's understanding this requirement has been under review by the DPHHS as unnecessary given the bonded status of labs and usual practice regarding laboratory samples.

27.7 - New Rules XI, XII, XIII, and XIV (Labeling Requirements) - "Total potential psychoactive THC" (TPPT) is required on product labels [New Rules XI (2)(a), and XIV (1)(c)(i)(A)(I) and New Rules XII(2), XIII(2), XIV(2)]. TPPT is a new definition (ARM 42.39.102(53)). It is understandable to include this distinction for the sake of customer understanding and safety, but it creates internal confusion within the proposed rules as well as with DPHHS' rules which already use "Total THC" for the same meaning. Mr. Speare's recommendation is to replace all uses of TPPT with "Total THC" and remove the definition in ARM 42.39.102(53).

Alternatively, if the department decides to keep the usage of TPPT, Mr. Speare recommends allowing the use of "Total THC" on applicable product labels, adding language to the effect that "Total THC" and "Total potential psychoactive THC" are equivalent/synonymous.

RESPONSE 27: The department thanks Mr. Speare for his time and the detailed comments. The department responds as follows (utilizing the same numbering convention in Comment 27):

27.1 - The department has amended the rule to correct the safety data sheet references.

27.2 - The department has amended the rule to include the expanded solvent reference.

27.3 - The department understands the nature of the comment that this information could be useful to chemists to determine if any anomalies in lab data can be investigated by what is found in a pesticide log. However, testing labs are capable of determining pesticides results without the use of a log as well. Based on this conclusion, the department declines to make additional amendments at this time.

27.4 - The department has amended the rule to include the additional transport manifest information and to remove vehicle "year."

27.5 - The department directs Mr. Speare to Response No. 37 which constitutes the department's response to all marijuana testing laboratory moratorium comments.

27.6 - The department declines to remove any requirement and has amended the rule to provide improved clarity. While the department cannot respond to DPHHS' past practice or to the accuracy of Mr. Speare's communications with DPHHS, the department did receive comment from DPHHS that the bonding requirements for marijuana testing laboratories which were in rule, had not been omitted from New Rule VII. Based on the comments received, the department has included the bonding requirements as New Rule VII(6) and (7).

27.7 - The department disagrees that any potential confusion outweighs the benefits of correctly labeling the product. TPPT is only for labeling purposes and Total THC is only for the lab certificate of analysis (CofA). The intent with this rule is to prevent labeling products with misleading THC results, which is an issue in the industry. Total THC is not in the department's rule and TPPT is not in DPHHS lab rules. Because the department's rules are centered on heated/unheated products applicable to the customers upon ingestion, application, this designation is important on labels. Based on this discussion, the definition in ARM 42.39.102(53) and any reference to TPPT will remain as proposed, but the department is willing to revisit the issue with stakeholders and DPHHS in the future.

As an extension of the analysis, the department has corrected the TPPT equation in the definition.

COMMENT 28: Ms. Barney asked on New Rule X regarding labeling, whether a booklet may be used, like a peel away wrap label that can be found like on an over-the-counter medicine bottle where you peel it and there is more information on the back--is that allowable?

RESPONSE 28: The department responds that New Rule X is clear and agrees that a booklet can be used in labeling.

COMMENT 29: Ms. Barney asked about the unique identification number required in New Rule X(3)(c) and whether the department could consider this to be the "mother package" since the package number and all of the historical data is in the system?

RESPONSE 29: The department responds that there is no singular "mother package" as that designation changes from the source package to the tested package and on through to individual end packages. For labeling compliance under the rule, the unique identification number to be used is the number that corresponds to the current package.

COMMENT 30: In addition to the comments made at the public hearing by Mr. Kosted and the comments of Mr. Brost regarding fees, Stillwater Laboratories, Inc. (Brost or Stillwater) also provided extensive written comments as follows:

30.1 - HB701, Section 109 includes specific warning language to be included in labels. We propose additions to New Rule X(3).

30.2 - HB701, Section 5(8)(b)(iv) includes information regarding dosages that is not in MAR Notice No. 42-1033 and should be added.

30.3 - For clarity, include a certificate number, lab test date, and lab name and ID for product traceability in New Rule X(3).

30.4 - Revise New Rule X(3)(a) regarding the common name description from "flower, inhaled extract, edible or drinkable, topical, transdermal patch" to the more commonly used "strain name, concentrate type, edible name, topical name, etc."

30.5 - Revise New Rule X(3)(a)(i) to include the product type from the title of New Rules XI through XIV (marijuana flower, ingestible marijuana concentrate, non-ingestible marijuana concentrate, ingestible marijuana infused product, noningestible marijuana infused product).

30.6 - Revise New Rule X(3)(e)(iv) for the servings label language from the unit of production (cf. "cookies" to "servings") on the rationale that a serving may be more (or less) than a unit of production.

30.7 - Recommends the department include a warning for product handling of perishables.

30.8 - Recommends the department require boldface type in marijuana products warnings to keep out of the reach of children and pets. The rationale being that this would be consistent with prior DPHHS direction.

30.9 - Recommends the department strike New Rule X(7) on the basis that reduction of the font size will greatly reduce readability of a product label but will not necessarily result in a significantly smaller label size.

30.10 - In New Rule VIII, it may be interpreted that transportation of marijuana by testing laboratories requires a storage endorsement if lay-overs are included in a lab-to-lab run. Stillwater opines that this requirement does not apply to marijuana testing laboratories under the Act, but in the event the department disagrees, clarification of conditions is necessary.

30.11 - New Rule X(3)(h) - Stillwater advocates for the department to change the marijuana symbol from a color-based symbol to black and white.

30.12 - Stillwater provided the department with a mock-up table of specifications and a sample label in the font sizes required under the Act and the department's rules. The department assumes the information was provided to assist the department in its final determination of labeling requirements because no specific commentary was provided.

30.13 - New Rule VII(2) - Stillwater comments and opines that the existing marijuana industry - and marijuana testing laboratories - should be granted the same moratorium from new laboratories - until July 1, 2023 - that HB 701 clearly granted to cultivators, manufacturers, and dispensaries.

RESPONSE 30: The department thanks Mr. Brost, Stillwater, and its employees for their time and the detailed comments. The department responds as follows (utilizing the same numbering convention in Comment 30):

30.1 - Because these required warnings are provided in HB 701/the Act, as codified, the department declines to add the content into rule, which could be viewed

as being unnecessarily redundant in contravention of 2-4-305(2), MCA, of the Montana Administrative Procedure Act (MAPA).

30.2 - See Response 30.1, generally, regarding MAPA.

30.3 - The department contends that while the information suggestion may be useful for marijuana testing laboratories, it is not as useful for consumers. Based on this justification, the department declines to make the requested change.

30.4 - Based on the comments, the department has amended the rule to include the additional information.

30.5 - Based on the comments, the department has amended the rule to include the additional information.

30.6 - Based on the comments, the department has amended the rule as suggested.

30.7 - The department declines to make the suggested revision because a variation of the proposed language is in New Rule II(14).

30.8 - The department declines to make the suggested revision because all required warnings are important and boldface type does not create a level of import for this warning over any other.

30.9 - The department respectfully declines to make the suggested revision at this time, but acknowledges product labeling revisions are likely for inclusion in future rulemaking.

30.10 - The department appreciates the comments, but it falls within the department's rulemaking authority to implement requirements to reasonably administer the Act. Given that the state of Montana is large, geographically, the department affirms the necessity that marijuana testing laboratories shall obtain a storage facility endorsement when a laboratory transports marijuana or marijuana products and the transportation includes overnight storage of the products.

Based on these comments, the department has amended New Rule VIII(1) to clarify the conditions for the imposition of the requirement and has also amended (2) to provide the maximum amount of time for the use of a temporary storage facility.

30.11 - The department received comment from the co-designer of the International Intoxicating Cannabis Product Symbol (IICPS), Dr. David Nathan, which the department is using. According to Dr. Nathan, who commented to this rulemaking, IICPS is the only cannabis product symbol to conform to existing consensus standards for warning signs, as defined by ISO 3864 and ANSI Z535. The consensus standards organization, ASTM, is entering its second and final round of balloting on approval of the IICPS through ASTM WK75247, *Specification for an International Symbol for Identifying Consumer Products Containing Intoxicating Cannabinoids*. Passage will make the IICPS the only cannabis product symbol in the world to be designated as a consensus standard in its own right. For the foregoing reasons, the department respectfully declines to make the suggested revision.

30.12 - Because there was no specific request or comment relative to the label specifications and mockup, no response from the department is necessary.

30.13 - The department directs Stillwater to Response No. 37 which constitutes the department's response to all marijuana testing laboratory moratorium comments.

COMMENT 31: The department received several comments to the proposed rulemaking which, in practicality, are comments to industry restrictions that are present in the Act and are outside the scope of rulemaking. Examples of the objections are that: (a) dispensaries must have a single, secured entrance for patrons; (b) licensees shall bear the responsibility and cost for procuring unique identification tracking tags to facilitate the tracking of marijuana and marijuana products; and (c) a person under 21 years of age is not permitted inside a marijuana business unless the person is a registered cardholder.

RESPONSE 31: The department understands the challenges that licensees face in a new or more-strictly regulated industry and directs the commenters to the following portions of the Montana Code Annotated as representative of the requirements examples to which they commented: for item (a) see 16-12-207(9), MCA; for item (b) see 16-12-105(1)(c), MCA; for item (c) see 16-12-207(12), MCA.

COMMENT 32: Pepper Peterson, CEO of the Montana Cannabis Guild (Guild), provided the following written comments:

32.1 - Transporter fees are appropriate at $10,000 as this keeps a reasonable floor in place to ensure delivery companies are reputable and capable.

32.2 - Fees to conduct background checks are too high and can be done for much cheaper. Further, it is the opinion of the Guild that HB 701 requires only licensees to submit to fingerprint background checks while Marijuana Worker Permit holders should be able to use the cheaper and easier non-fingerprint required checks. The intent of the legislature was never to put the onerous fingerprint requirement on workers, rather only licensees.

32.3 - Mr. Peterson questions the need for the department's change of location fee.

32.4 - Mr. Peterson commented to the trade secret concerns raised by Mr. Young and Ms. Barney in Comment No. 7.

32.5 - Mr. Peterson commented that New Rule IV(7) says we may not serve registered cardholders under 18. What about those cardholders who are under 18? There are some and their guardians generally pick their product up for them--is this considered serving?

32.6 - Mr. Peterson commented his opinion that there should be an insurance and bonding requirement for transporters; there should be a requirement for onboard video cameras for transport vehicles; and a requirement for GPS tracking for all delivery vehicles.

RESPONSE 32: The department responds as follows (utilizing the same numbering convention in Comment 32):

32.1 - Mr. Peterson's comments require no response.

32.2 - The Department of Justice charges $50 for a fingerprint background check and $30 for name based – so the department contends that a flat $30 is reasonable. As to the requirement for workers, workers only have to submit their background check once, and $30 is not onerous.

32.3 - The department directs Mr. Peterson to the fourth paragraph of Response No. 2.

32.4 - The department directs Mr. Peterson to Response No. 7.

32.5 - Mr. Peterson reads the rule incorrectly. This provision says licensees cannot sell paraphernalia to those under 18. The department also directs Mr. Peterson to Comment and Response No. 20 for additional information.

32.6 - The department responds that minimum insurance is already required by state law. As for the requirements for onboard video cameras and GPS tracking for transporters, the department declines these requirements as they would likely be determined to be unduly burdensome to these licenses.

COMMENT 33: The department received a written comment from Jeff Schmidt, OneLife Organics, that expresses his concerns after the moratorium expires that new cultivators need to start at the bottom of the canopy tiers and work their way up like existing cultivators have had to do. Mr. Schmidt believes the regulations and these new rules need to protect the local businesses from larger companies that can buy a 100,000 square foot building and immediately enjoy the benefits of the industry's hard work.

RESPONSE 33: Unfortunately, Mr. Schmidt misunderstands the post-July 2023 cultivator licensing restrictions of HB 701. Section 4(1)(f), HB 701, codified as 16-12-223(1)(f), MCA, specifically provides that "a marijuana business that has not been issued a license before July 1, 2023, must be initially licensed at a tier 2 canopy license or lower."

COMMENT 34: The State Laboratory believes language should be added to the proposed rules that addresses the $1,000,000 insurance and $25,000 bonding requirements for testing laboratories. These requirements were formally covered in ARM 37.107.302(21) and (22) promulgated by the State Laboratory. However, with passage of HB 701, it appears rulemaking relating to insurance and bonding requirements more appropriately lies with the Department of Revenue. See 16-12-112(1)(a), MCA (authority to adopt rules governing the manner in which applications for testing laboratory licenses will be considered), and 16-12-206(4)(b)(iii), MCA (qualification for licensure requires testing laboratories to meet insurance and bond requirements established by rule).

In the course of evaluating a testing laboratory applicant's qualification for endorsement, the State Laboratory intends to include in its rules criteria to ensure insurance and bond requirements established by DOR are met.

RESPONSE 34: The department agrees and based on the comments has amended New Rule VII to add (6) and (7) upon adoption.

COMMENT 35: As alluded to in Response No. 30.11, the department received written comment from Dr. David L. Nathan, M.D., DFAPA, of Doctors for Cannabis Regulation, who lauded the department's efforts to adopt the IICPS product symbol, which is the only cannabis product symbol to conform to existing consensus standards for warning signs, as defined by ISO 3864 and ANSI Z535.

RESPONSE 35: The department appreciates Dr. Nathan's expertise and thanks him for the helpful commentary and support.

COMMENT 36: The department received the following commentary from two individuals who are involved in, or advocate for, Substance Abuse and Mental Health Services Administration (SAMHSA) evidence-based recommendations on marijuana prevention strategies:

36.1 - New Rule II(15) - banning flavored marijuana products is one public health strategy to reduce youth use.

36.2 - New Rule V(4)(b) - states transporters may be delivering to a registered cardholder's address while (12) says they may NOT transport directly to consumers. Please clarify.

36.3 - There is much in New Rule V describing all the protocols in place for delivery to licensed premises, but not for delivery to a registered cardholder.

36.4 - How is the state of Montana ensuring that deliveries are only received by the registered cardholder and not by underage youth who are not cardholders?

36.5 - New Rule X(3) - The required graphic indicating that the package contains marijuana is only .33". This is barely visible/legible, but may be the only indication a child has that a product is not candy or food.

36.6 - New Rule X(4) – Excellent warnings!

36.7 - New Rule X - could be strengthened to include: (i) depicts a person under age 21; (ii) portrays objects, images, human, or cartoon figures, or any other animate creature including, without limitation, an insect, toy, fruit, vehicle, or robot; (iii) contains text referring to a cartoon, or any other animate creature including, without limitation, an insect, toy, fruit, vehicle or robot; (iv) contains any images, characters, or phrases that closely resemble images, characters, or phrases commonly used to advertise to children.

36.8 - Commentary included statements that represent a differing approach about public policy recommendations that are outside the scope of the department's rulemaking authority.

RESPONSE 36: The department thanks the commenters and responds as follows (utilizing the same numbering convention in Comment 36):

36.1 - The department declines to make these suggested changes because they are too broad. Flavor is added for reasons other than for making the product more appealing to children.

36.2 - Cardholders and consumers are different. The department directs the commenters to the definitions provide in the Act and in ARM 42.39.102.

36.3 - Transporters may deliver to registered cardholders or between licensed premises.

36.4 - The department has added New Rule IV(16) and amended New Rule V(4)(b), which will improve the sale and transport concerns expressed.

36.5 - The department directs the commenters to Response Nos. 30.11 and 34, which the department believes adequately address the comments.

36.6 - The department appreciates the comments and support.

36.7 - The department appreciates the comments and contends these are covered by our current language, depending on how they are depicted; except for

"fruit," but fruit does not primarily appeal to children. The department will be reviewing all packages for this content.

36.8 - The department is responsible under the Act for its implementation. While the department's rules do impact public policy, it is not the role of the department to establish public policy goals; that is an act of the legislature.

COMMENT 37: In addition to the comments received from Mr. Kosted at the public hearing and those from Mr. Speare and Mr. Brost described in Comments 27.5 and 30.13, the department also received written comments from Andre Umansky at Fidelity Diagnostics Laboratory and other written comments objecting to the "start date" for the department's acceptance of new marijuana testing laboratory applications, which is reflected in New Rule VII(2). The department also received feedback from the Economic Affairs Interim Committee during its November 17, 2021 meeting.

As alluded to in Comments 27.5 and 30.13, the commenters request that the marijuana testing laboratory portion of the industry be granted the same moratorium - until July 1, 2023 - as existing marijuana cultivators, dispensaries, and manufacturers. Many of the commenters attribute the lack of a specific moratorium provision for marijuana testing laboratories to a drafting error in HB 701.

RESPONSE 37: Imposing a moratorium on marijuana testing laboratories via administrative rule violates the applicable statutes' plain language and 2-4-305, MCA, of the Montana Administrative Procedure Act (MAPA). The licensing moratorium is derived from 16-12-201, MCA, which provides, in relevant part:

> 16-12-201. Licensing of cultivators, manufacturers, and dispensaries.
> (1)(a) Between January 1, 2022 and June 30, 2023, the department may only accept applications from and issue licenses to former medical marijuana licensees that were licensed by or had an application pending with the department of public health and human services on November 3, 2020 and are in good standing with the department and any applicable local regulations or ordinances as of the [January 1, 2022].
> (b) *The department shall begin accepting applications from and issuing licenses to cultivate, manufacture, or sell marijuana or marijuana products to applicants who are not former medical marijuana licensees under subsection (1)(a) on or after July 1, 2023.*" (emphasis added).

Former medical marijuana licensees are defined to mean "a person that was licensed by or had an application for licensure pending with the department of public health and human services to provide marijuana to individuals with debilitating medical conditions on November 3, 2020." 16-12-102(14), MCA. Marijuana testing laboratories are clearly not included in this definition and, therefore, 16-12-201, MCA, does not impose a licensing moratorium on marijuana testing laboratories.

The limitation on only accepting applications from, and issuing licenses to former medical marijuana licensees, is specific to cultivators, manufacturers, and dispensaries, evidenced both by the definition of former medical marijuana licensee and by the title of 16-12-201, MCA. Further, the language in (1)(b) expressly lifts the

moratorium on cultivators, manufacturers, and dispensaries on July 1, 2023, meaning it was only applied to these license types in the first instance.

And assuming that the department was inclined to adopt an administrative rule which would grant the licensed marijuana testing laboratory industry a moratorium from competition, that rule would likely violate 2-4-305(3), MCA, which provides:". . . [e]ach proposed and adopted rule must include a citation to the specific section or sections in the Montana Code Annotated that the rule purports to implement." Without a specific implementing statute, the department cannot purport that it is in compliance with MAPA and legislative intent absent a foundational component for such a rule.

Should the legislature express that the marijuana testing laboratory moratorium omission was an error, the department still cannot effectuate that change through this rulemaking because the department lacks implementing authority any amendments would exceed the scope of the rulemaking, as provided in 2-4-305(6), MCA, and the department received specific public comment during this rulemaking that marijuana testing laboratories should not receive any moratorium through rule.

Lastly, the department notes for the record that it received approximately 40 identical "template" comments on this issue from persons who are, or appear to be, related to Stillwater Laboratories - all of which arrived after the close of the comment period at 5:00 p.m. on November 29, 2021. Notwithstanding the untimely receipt of the comments, the department reviewed the comments in the ordinary course of this rulemaking and concluded no new data or arguments were present in the comments from those described by Mr. Kosted at the public hearing, in Comments 27.5 and 30.13 regarding Messrs. Speare and Brost, or from Mr. Umansky, and these comments do not impact the department's responses.

COMMENT 38: At its December 9, 2021 meeting, the Economic Affairs Interim Committee (committee) objected to the fee structure for manufacturer licensees in New Rule I in that it does not adequately capture licensing fees for manufacturers that produce 15 pounds or more of concentrate per month, and requested the amendment to New Rule I since 16-12-204, MCA, allows the department to create additional fee levels, as necessary, for marijuana manufacturers.

RESPONSE 38: Based on the committee's request, and to resolve this objection, the department has amended New Rule I to include new (1)(f)(iv).

COMMENT 39: At its December 9, 2021 meeting, the Economic Affairs Interim Committee objected to the department's interpretation of permissible license activity in New Rule III which the committee purports will permit cultivator licensees to become brokers of marijuana. The committee expressed that while it does not object to cultivators selling marijuana seeds or marijuana plants to other cultivator licensees, it was not the legislative intent to allow cultivators to sell marijuana flower to other licensees.

RESPONSE 39: Based on the committee's request, and to resolve this objection, the department has amended New Rule III(1) to clarify the restriction.

RESPONSE 40: At its December 9, 2021 meeting, the Economic Affairs Interim Committee objected to the department's proposed reinstatement, based on public comment, of a cultivator licensee's ability to "tier up" its outdoor cultivation. Section 16-12-223(6) is silent on the issue, but the committee stated that it was legislative intent to prohibit outdoor cultivators from tiering up.

RESPONSE 40: Based on the committee's request, and to resolve this objection, the department has retained the restriction in New Rule III(5).

COMMENT 41: At its December 9, 2021 meeting, the Economic Affairs Interim Committee objected the department's interpretation of the restriction for cultivation activity for New Rule VI, Combined Licenses.

RESPONSE 41: Based on the committee's request, and to resolve this objection, the department has amended New Rule VI(3) to clarify this license type is also subject to the cultivator license activity provided in 16-12-223, MCA.

7. The effective date of the department's adoptions and amendments is January 1, 2022.

/s/ Todd Olson	/s/ Brendan Beatty
Todd Olson	Brendan Beatty
Rule Reviewer	Director of Revenue

Certified to the Secretary of State December 14, 2021.