BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the adoption of NEW RULES I and II and the amendment of ARM 42.39.102, 42.39.123, 42.39.314, 42.39.315, 42.39.316, 42.39.317, 42.39.318, 42.39.319, 42.39.320 pertaining to packaging and labeling of marijuana, marijuana wholesaling, and marijuana advertising	))))))))))	NOTICE OF ADOPTION AND AMENDMENT

TO: All Concerned Persons

1. On December 22, 2023, the Department of Revenue (department) published MAR Notice No. 42-1073 pertaining to the public hearing on the proposed adoption and amendment of the above-stated rules at page 1834 of the 2023 Montana Administrative Register, Issue Number 24.

2. On January 19, 2024, the department held a public hearing to consider the proposed adoption and amendment. The following commenters appeared and provided oral testimony to the proposed rulemaking: Brandon Madland, Montana Cannabis Industry Association (MTCIA); Pepper Petersen, Montana Cannabis Guild (Guild); Joanna Barney, Sacred Sun Farms; Sahil Mehta, Euphoria Wellness; Adam Arnold, Collective Elevation; and Elliot Lindsey, Grizzly Pine. The department received written comments from Chris Gatten; Rebecca Rozar, Sacred Sun Farms; Anthony Saur, The Green Bee; Jen Hensley, Hensley & Associates; and Kate Cholewa, MTCIA.

3. The department has amended ARM 42.39.102 and 42.39.315 as proposed.

4. The department has withdrawn the proposed amendments to ARM 42.39.319 from consideration.

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

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

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

(b) net weight or number of individual seeds or number of plants, as applicable;

~~(c) number or plants;~~

(d) and (e) remain as proposed but are renumbered (c) and (d).

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

NEW RULE II (42.39.321) WHOLESALE PACKAGE AND LABEL APPLICATIONS (1) through (3) remain as proposed.

(4) A marijuana wholesaler must apply and receive department approval to use all wholesale packaging and labels before distributing any packaged and labeled wholesale products for final sale to customers. Package and label approval is not required for wholesale products that will receive additional processing or will be repackaged and relabeled by another licensee.

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

42.39.123 ADVERTISING (1) remains as proposed.

(2) "Advertise or advertising" means the publication, dissemination, solicitation, or circulation of visual, oral, or written communication to directly induce any person to purchase or consume marijuana or marijuana products. Advertising includes the promotion of special pricing, ~~events,~~ sales, or discounts on marijuana and marijuana products. Advertising does not include branding, marketing, or packaging and labeling of marijuana and marijuana products or information regarding special pricing, sales, or discounts on display within a licensed premises.

(3) through (11) remain as proposed.

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

(13) remains as proposed.

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

42.39.314 GENERAL LABELING REQUIREMENTS (1) Labeling requirements apply to marijuana and marijuana products sold from a dispensary to customers and wholesale products intended for final sale to customers from one licensee to another.

(2) remains as proposed.

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

(a) and (b) remain as proposed.

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

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

(4) through (9) remain as proposed.

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

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

(a) remains as proposed.

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

(c) through (3) remain as proposed.

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

42.39.317 LABELING OF NON-INGESTIBLE MARIJUANA-INFUSED PRODUCTS (1) In addition to the general labeling requirements set forth in ARM 42.39.314, each packaging of non-ingestible marijuana-infused products shall be labeled with the following information:

(a) remains as proposed.

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

(c) through (3) remain as proposed.

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

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

(a) remains as proposed.

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

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

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

(A) remains as proposed.

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

(ii) through (3) remain as proposed.

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

42.39.320 PACKAGING AND LABELING APPLICATIONS, FEES AND DEPARTMENT APPROVAL PROCESSES; EXIT PACKAGE APPROVAL; INITIAL REQUIREMENTS APPLICABLE TO ALL LICENSEES (1) through (16) remain as proposed.

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

(a) remains as proposed.

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

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

(18) through (22) remain as proposed.

AUTH: 16-12-112, MCA
IMP: 16-12-112, 16-12-208, 16-12-215, 16-12-224, 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: Commenters expressed concern with the proposal in NEW RULE I(1)(a) which would require label information to include a licensee's name and license number. This is a departure from information that is made available pursuant to statute, and the commenters requested the removal of license number from the rule.

RESPONSE 1: The department understands the commenters' concerns and upon adoption has stricken the license number from NEW RULE I(1)(a) and has also removed license number from general label requirements in ARM 42.39.314(3)(c) for consistency within the rules.

COMMENT 2: Mr. Saur commented to NEW RULE I that the rule seems redundant, does not significantly contribute to public health and safety, and dispensaries already provide strain information and potential potency expectations. This additional labeling requirement creates unnecessary work for both businesses and inspectors without clear benefits.

RESPONSE 2: The department disagrees that NEW RULE I is redundant to ARM 42.39.314, because that rule does not currently address packaging and labeling for the sale or transfer of marijuana seeds or plants at all. The department directs Mr. Saur to the statement of reasonable necessity provided for NEW RULE I which is reiterated for the purposes of this response.

COMMENT 3: Ms. Barney requested the department clarify what constitutes a seed that would require labeling to comply with NEW RULE I. Ms. Barney and other commenters requested that the department provide a grace period – of some undescribed period of length – for licensees to obtain labeling that is compliant with

the rule so they may continue, or initiate, the sale of seeds or plants. Ms. Barney notes that many licensees obtain labels in bulk, often from foreign markets, and new labeling requirements take time to order, process, and incorporate into a licensee's business.

Ms. Barney also noted a typographical error in NEW RULE I(1)(c).

RESPONSE 3: The department responds that the definition of a "seed" is unnecessary for labeling because the rule intends to provide a basic requirement for labeling of all marijuana seeds or plants if they are packaged for ultimate sale to the public.

The department also understands that new or revised labeling requirements may necessitate changes in business processes or require additional procurement for licensees, but ensuring accurate marijuana labeling is part of the department's role in public health and safety of the industry and its products.

The department declines to delay implementation of NEW RULE I because it is a business decision when a licensee obtains packaging and labeling from out-of-country vendors versus domestic sources or the licensee purchases labels in such bulk quantities that any change in labeling regulations requires extended amounts of time to transition.

The department appreciates Ms. Barney's observation of the unintended typographical error and (1)(c) has been corrected upon adoption.

COMMENT 4: The department received several comments from multiple commenters who expressed support for NEW RULE II and the general revision of packaging and labeling requirements when applied to wholesale marijuana products.

RESPONSE 4: The department appreciates the comments and thanks the commenters for their feedback.

COMMENT 5: Mr. Petersen provided extensive commentary at the public hearing regarding his ongoing objection to the department's prior adoption of wholesale package and label application requirements in ARM 42.39.320, which preceded the proposal of NEW RULE II.

RESPONSE 5: Mr. Petersen's commentary is outside the scope of the rulemaking.

Further, the Legislature delegated the duty to the department to establish wholesale marijuana packaging and labeling requirements that comply with 16-12-208(8), MCA. Since industry wholesale packaging and labeling practices have normalized since the adoption of ARM 42.39.320, the appropriate response is the adoption of NEW RULE II on the justification provided in the proposal notice.

COMMENT 6: Both Ms. Barney and Mr. Lindsey asked the department to clarify the impact of NEW RULE II on the wholesale sale of bulk marijuana flower/buds versus product that is retail-ready or bulk product which is then sold to a dispensary license for "deli-style" sales to customers.

Ms. Barney questions how transfers between wholesalers in METRC would be impacted by NEW RULE II(4). She also suggested that wholesale transactions would be better served by allowing the product's certificate of analysis to follow the product in a wholesale transaction instead of a wholesale package or label.

RESPONSE 6: Based on the comments and recommendations of Mr. Lindsey and Ms. Barney, the department has amended NEW RULE II(4) upon adoption to provide the increased clarity the commenters seek, and which covers the bulk sale of marijuana on a wholesale basis to a dispensary for "deli-style" sale.

As to Ms. Barney's question about product transfers between wholesalers and suggestion to use a certificate of analysis to follow wholesale product, the department responds that NEW RULE II is not a product tracking rule and the last sentence of NEW RULE II(4), as adopted, provides that package and label approval is not required for wholesale products that will receive additional processing or will be repackaged and relabeled by another licensee.

COMMENT 7: Mr. Madland and Ms. Barney commented about the department's addition of tincture to ARM 42.39.102(12) for edible marijuana-infused product. They requested the department clarify the addition of the product type to the definition was merely for classification and that tincture potency remains governed by statute.

RESPONSE 7: Tincture potency remains governed by 16-12-224, MCA, but the inclusion of tincture as an example of edible marijuana-infused product clarifies tinctures statutory potency variation allowance enacted under HB 229 amendments to 16-12-224, MCA.

COMMENT 8: Ms. Barney commented that the department should revise its proposed amendment to ARM 42.39.102(22) because an analytic label contains more detail than a customer label and would not be generally beneficial when directed for final sale to a customer.

RESPONSE 8: The department appreciates Ms. Barney's suggestion but disagrees to adopt the suggestion on the basis that the amendment causes confusion or is substantively duplicative since the definition supports the analytical labeling requirements found in ARM 42.39.314.

COMMENT 9: Ms. Barney commented her support for the additional definitions proposed in ARM 42.39.102 because definitions add clarity to the regulations and how the department will implement them.

RESPONSE 9: The department appreciates the comments and thanks Ms. Barney for her feedback.

COMMENT 10: Several commenters expressed concern or objection to the department's proposed amendments to ARM 42.39.123 – Advertising.

Mr. Madland and the MTCIA requested clarification that the amended definition of "advertising" in (2) applies to external communication with the public because absent that clarification, the amended definition is overbroad. Ms. Cholewa commented that the regulation of advertising is broken, that the amendments in this rulemaking are not helpful for either the department or licensees, and that a "redo" of the underlying statute is necessary.

Mr. Petersen provided commentary about ARM 42.39.123 that is outside the scope of rulemaking. The commentary was political and asserted that the department's rulemaking is being influenced by legislators desiring the elimination of all advertising for marijuana licensees. Mr. Petersen employed hyperbole to state that the department is "re-defining advertising in an Orwellian fashion" and provided examples of failed legislation relating to advertising as being dispositive of legal insufficiency of advertising regulation.

Similar to the comments of MTCIA, Ms. Barney believes the proposed amendment to (2) lacks necessary clarity because it is too open to interpretation and suggested its removal. Ms. Barney also requested the justification for the removal of only one colloquial term for marijuana from proposed (7) while others remain. Ms. Barney also requested clarification on the amendment of proposed (12) which indicates that possession of marijuana at a trade conference would not be allowable for a registered cardholder.

Mr. Mehta commented objection to the amendments to (2) and stated his position that vague definitions lead to lawsuits. Mr. Mehta continued his commentary outside the scope of the rulemaking and indicated his willingness to engage in litigation to resolve his issues with rulemaking through litigation because". . . .[w]e have lots of attorneys, you only have one."

RESPONSE 10: The department responds to the ARM 42.39.123 comments as follows:

- To Mr. Madland, the MTCIA, Ms. Barney, and Mr. Mehta the restriction in ARM 42.39.123(2) applies to external communications with the public. However, based on the comments, the department has amended (2) upon adoption to improve clarity.
- As to Ms. Cholewa's/MTCIA's opinion about the legal sufficiency or public policy provided in 16-12-211, MCA, the department responds that comments are outside the scope of the rulemaking. The department implements the Legislature's directive in the statute and the amendments to the rule reflect identified issues and improve guidance to licensees about what is allowable, or prohibited, under the law. Should the Legislature change the law, the department will, likewise, implement the revised law as directed.
- To Mr. Petersen, the Legislature provided in 16-12-211(4), MCA, "[T]he department shall adopt rules to clearly identify the activities that constitute advertising that are prohibited under this section." The department also directs Mr. Petersen to the preceding paragraph to Ms. Cholewa's/MTCIA's comments as a partial response. As to the remainder of Mr. Petersen's commentary, the department declines to

respond because the comments are baseless, inflammatory, and outside the scope of rulemaking.

- Ms. Barney is correct that the department removed one colloquial term for marijuana from the list of prohibited vernaculars. The reason for the removal was based on the fact that "ganja" is actually not a colloquial term for marijuana and the department agreed to the removal based on research and a legal opinion from department counsel.
- To Mr. Mehta, the department provided its response (above) to address his concerns about clarity in the amendments to ARM 42.39.123(2). As to the remainder of Mr. Mehta's comments about threatened litigation, the department responds that all of its rulemaking is conducted in compliance with the Montana Administrative Procedure Act (MAPA). If Mr. Mehta believes that any rulemaking was not adopted in substantial compliance with MAPA, then he has recourse in the court system to pursue his complaint, and where the department will assert its defense.

COMMENT 11: Similar to his comments regarding NEW RULE II, Mr. Lindsey commented his belief that general labeling requirements in ARM 42.39.314 do not effectively address the sequence and timing of processing of some product categories and requested the department provide additional clarity. Mr. Lindsey provided examples where edible marijuana product must be labeled because it is "retail ready," but bulk flower sold for deli-style sale does not have the same labeling requirement.

RESPONSE 11: The department refers Mr. Lindsey to the adoption of NEW RULE II, as adopted, and to Response 6 which the department believes satisfies the request for additional clarity being sought.

As for Mr. Lindsey's comments about labeling that addresses the sequence and timing of processing of some product categories, the department responds that ARM 42.39.314 is a general labeling requirements rule. Just as the department proposed and adopted NEW RULES I and II to address those rules' specific labeling requirements, it may be necessary for the department to propose additional labeling guidelines through future rulemaking. If Mr. Lindsey has specific suggestions, the department encourages him to provide them, in writing, for consideration.

COMMENT 12: Ms. Barney commented to the proposed amendment in ARM 42.39.314(3)(d) that the requirement of inclusion of a product's final form testing results is unclear and is redundant to the information accessible through a label's QR code.

RESPONSE 12: The department disagrees that the requirement for final form testing results is unclear and the product's QR code is sufficient since several distinct products may be derived from a given METRC batch and each product may have gone through additional processing which altered its potency or classification.

The disclosure of a final form product's testing results is required in the interest of public health and safety for the buying public.

The department also directs Ms. Barney to the statement of reasonable necessity for the changes to ARM 42.39.314 which is to align the rule with quality assurance testing and sampling requirements found in ARM Title 42, chapter 39, subchapter 6, and the referenced authorities. The department believes that any perceived lack of clarity in the general labeling rule for final form testing result disclosure is reconciled in the testing and sampling requirements.

COMMENT 13: Mr. Madland, the MTCIA, and Ms. Hensley commented their support for the amendments to ARM 42.39.316 requiring actual serving size or dosage and actual milligram package sizes; however, they each requested use of the phrase "to the accuracy required by statute."

Ms. Hensley furthered her comments noting that "actual" is not defined. If left to interpretation, one might say that "actual" meant the accuracy required by statute, but if a scientist were reading it, they may interpret it as down to the molecule. Which one is appropriate? Ms. Hensley implies that the department appears to be interpreting "actual" without the HB 229 prescribed variance, is beyond what the Legislature allows, and is unduly burdensome.

RESPONSE 13: A dispensary licensee must not sell marijuana products that exceed the single package THC concentration limits provided in 16-12-224(8), MCA. While the department agrees with the commenters that House Bill 229 (2023) created an allowable deviation in THC concentration for single packages of +/- 10% when the Legislature amended 16-12-224, MCA, the department disagrees with Mr. Madland and the MTCIA that the suggested phrase is a substantive improvement over the term "actual" and disagrees with Mr. Hensley that "actual" is somehow unclear.

Single package deviation applies to a product's concentration, not to the accuracy of labeling of the product. Actual dosage and actual milligram package sizes are transparent and more informative for the end customer - in the interest of public health and safety – and is not any more burdensome for labeling than ensuring a package falls within the allowable deviation.

Based on this rationale, the department declines to adopt the suggestions into the final rule.

COMMENT 14: Similar to the comments made to NEW RULE I, Mr. Madland, Ms. Barney, and Mr. Gatten commented on the amendments to ARM 42.39.317 that the department provide a grace period for licensees to obtain labeling that is compliant with the rule and also to allow licensees to deplete their existing stock of labels after the rule change. Mr. Gatten asked for a year or more to implement packaging changes outside of potency listings that change from batch to batch.

Mr. Gatten also extended his labeling commentary to include opinions about the impacts of rulemaking on smaller local businesses versus "Mega-cannabis companies."

RESPONSE 14: The department declines to permit licensees to use non-compliant labeling after the adoption of these rules on the same basis as provided in the second and third paragraphs of Response 3.

The department declines an attempt to respond to Mr. Gatten's commentary on "Mega cannabis companies" as they are outside the scope of the rulemaking.

COMMENT 15: Mr. Madland and Ms. Barney commented that the department's proposed addition of allergen statement(s) in the package and labeling rules is confusing because it requires affirmation to the absence of something (i.e., an allergen) and they requested the words' removal from the rule(s).

RESPONSE 15: Based on the comments received, the department has removed the words "or absence" from all allergen statement requirements.

COMMENT 16: Ms. Barney commented that the proposed amendment to ARM 42.39.318(1)(c)(i)(B) to include vapes and other smokable marijuana products required clarification because it does not adequately address whether certain product sub-types (e.g., rosin that is in a dabable form) should be included.

Mr. Saur commented appreciation for the removal of vapes and smokeable products from the requirement, but it is unclear if businesses must reapply for label approval solely to remove this information. Since this is the only change, reapplying seems an unnecessary burden. Can the department provide language that allows for the removal of information that is no longer required without having to reapply for a new approval letter?

RESPONSE 16: Based on Ms. Barney's comments, the department is revising ARM 42.39.318(1)(c)(i) upon adoption to remove (B) on the basis that (1)(c)(i) provides sufficient guidance for fact panel requirements for marijuana concentrates that require the application of heat before they are administered or consumed. The department responds to Mr. Saur that product labels may, and often do, include more information than what is required under rule. Additional label approval to remove previously required information, as a general rule, is not necessary and applies in this instance. However, the department declines a universal statement to that effect because the impact of removing required label information is a fact-dependent analysis that may require proposed rulemaking whether initiated by the department or in response to legislation.

COMMENT 17: The department received several comments, questions, and objections to the proposed amendments to ARM 42.39.319 regarding exit packaging, advertising, and the cost to licensees to comply with the proposed requirements.

RESPONSE 17: Based on the commentary received, and as indicated under paragraph 4 of this notice, the department has withdrawn the proposed amendments to ARM 42.39.319 from consideration; the current form of the rule remains intact.

COMMENT 18: The department received several comments regarding the proposed amendments to ARM 42.39.320, especially the proposed fee structure for wholesale license applications. Mr. Madland and the MTCIA commented that the proposed fees would adversely impact package and label costs despite arguable increases in efficiency for the department. Mr. Petersen echoed these sentiments and questioned why the cost to applicants is increasing. Mr. Mehta commented his belief that the proposed wholesale package and label fees show a disrespect for industry.

Ms. Barney questioned whether the department would require a new application form for wholesale packaging and labeling and also commented that the application costs would be burdensome to licensees. Mr. Saur also questions whether businesses will need to reapply for current labels due to these changes, which could result in further financial burdens.

Mr. Saur questions about how businesses should track wholesale product approvals, especially when they are not directly involved in the application process. Mr. Saur requests guidance on how individual dispensaries can verify the validity of these approvals and a method to track them in a store.

RESPONSE 18: Based on the comments received, the department has reevaluated its wholesale packaging and labeling application process and determined that a reduction in the new wholesale packaging and labeling application fees is warranted. The department has revised ARM 42.39.320(17) upon adoption to reflect new application fee amounts.

The department responds to Ms. Barney that it does not contemplate the need for a separate wholesale packaging and labeling applications form at this time. The department anticipates only a modification to the existing application for an applicant to disclose whether the packaging and labeling is intended for wholesale purposes under NEW RULE II.

The department responds to Mr. Saur that it is a dispensary licensee's business decision through which wholesaler it procures its inventory, and it is likewise a business decision whether a dispensary licensee adequately vets it vendors and products. But potential compliance issues for non-compliant retail product are the responsibility of the retailer. The department also informs Mr. Saur that any wholesaler is able to verify and document through METRC which product packages and labels have received department approval should any such proof be requested by third parties (e.g., retailers) for compliance or wholesale inventory tracking purposes.

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

Certified to the Secretary of State March 12, 2024.