BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the adoption of New Rule I pertaining to marijuana and marijuana products packaging and labeling application and approval process	)))))	AMENDED NOTICE OF PUBLIC HEARING ON PROPOSED ADOPTION

TO: All Concerned Persons

1. On February 25, 2022, the Department of Revenue (department) published MAR Notice No. 42-1048 pertaining to the public hearing on the proposed adoption of the above-stated rule at page 274 of the 2022 Montana Administrative Register, Issue Number 4. The department held the required public hearing on March 22, 2022, to consider the proposed adoption of the above-stated rule.

2. The department will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, please advise the department of the nature of the accommodation needed, no later than 5 p.m. on May 4, 2021. Please contact Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or todd.olson@mt.gov.

3. Upon review of the commentary and testimony provided at the March 22, 2022 public hearing, the department proposes revisions to the proposed text in New Rule I which are described in paragraph 4. The department has amended the statement of reasonable necessity for New Rule I, relative to the proposed rule revisions, and has amended the fiscal impact statement to provide additional detail (based on the proposed revised application fee structure in New Rule I(15)) and a correction to the number of affected licensees.

4. New Rule I is being amended from the original proposal notice, new matter underlined, deleted matter interlined:

NEW RULE I PACKAGING AND LABELING APPLICATIONS, ~~AND~~ FEES AND DEPARTMENT APPROVAL PROCESSES; EXIT PACKAGE APPROVAL; INITIAL REQUIREMENTS APPLICABLE TO ALL LICENSEES (1) remains as proposed.

(2) For purposes of this rule, a "unique marijuana product package" means~~:~~

~~(a) a prototype package for each of the marijuana product categories in (1); and~~

~~(b) within each of the marijuana product categories,~~ a custom package that contains variations in graphic or design elements including logos. For example, boxes used for pre-rolls with a graphic for "Grape Ape" and a different graphic for "Cherry Pie" are unique marijuana product packages.

(3) A unique marijuana product package does not mean a package with variations in language, such as product information or instructions, or a package that depicts flavor variation without an accompanying change in graphic or design, or a different ~~package~~ size, shape, or ~~package~~ color. For example, mylar bags used for marijuana flower with different colors for indica, sativa, or hybrid used in various sizes are not unique marijuana product packages.

(4) For purposes of this rule "generic package" or "generic packaging" means packaging without any graphic or design elements, including logo, whether preprinted on the package or affixed later with an adhesive, sticker, or by other means.

~~(4)~~ (5) All applicants, whether as an initial license applicant or existing licensee, must submit an application to the department~~, on a form provided by the department,~~ for approval of the labeling of each marijuana product category intended for sale to customers.

~~(a)~~ (6) An applicant must submit a separate application for each label~~.~~ - up to a maximum of eight total label applications - based on the applicant's sale of some or all of the following marijuana or marijuana product categories:

(a) adult-use flower;

(b) medical flower;

(c) adult-use ingestible marijuana-infused products;

(d) medical ingestible marijuana-infused products;

(e) adult-use non-ingestible marijuana-infused products;

(f) medical non-ingestible marijuana-infused products;

(g) adult-use marijuana concentrates and extracts; and

(h) medical marijuana concentrates and extracts.

(7) An applicant will be given the following labeling options for the product categories listed in (6):

(a) selecting and affirming its use of a pre-approved template label available for download from the department, at no cost to the applicant, as provided in (15); or

(b) use of a custom label design and pay the custom label application fee, as provided in (15).

~~(b)~~ (8) An applicant that elects to use its custom (i.e., non-department template) label design must submit only one template label for each marijuana product ~~type~~ category.

(9) Except as provided in ~~(c)~~ (10), a new label application is not required when the marijuana facts panel information changes for disclosures such as levels of total potential psychoactive THC, THC, THCa, CBD, or CBDa, date of harvest, strain name, or ingredients.

~~(c)~~ (10) An applicant that sells marijuana products to registered cardholders with THC levels in excess of the limits set in 16-12-224, MCA, must submit a separate application and label template for ~~those products~~ each of the marijuana product categories sold.

~~(5)~~ (11) ~~An applicant must apply~~ All applicants, whether as an initial license applicant or existing licensee, must submit an application to the department~~, on a form provided by the department,~~ for approval for the packaging of each ~~unique~~ marijuana product ~~package~~ category intended for sale to customers.

~~(a) An applicant must submit a separate application for each unique marijuana product package.~~

(12) An applicant will be given the following packaging options for the product categories listed in (6):

(a) selecting and affirming its use of generic packaging. The applicant shall identify on the application which marijuana or marijuana products will be placed in generic packaging; or

(b) use of custom packaging with graphic or design elements, including logo, whether preprinted on the package or affixed with an adhesive, a sticker, or by other means. In this case, ~~An~~ the applicant must provide a picture or accurate, detailed rendering ~~and a description of the product~~ of the packaging. Further, the applicant shall identify on the application which marijuana or marijuana products will ~~to~~ be placed in each unique marijuana product package.

~~(6)~~ (13) ~~An applicant~~ All applicants, whether as an initial license applicant or existing licensee, must submit an ~~separate~~ application to the department for approval for each exit package type it will use. If the applicant intends to use the same exit package type in multiple sizes, it may submit each size under ~~the same~~ one application.

(a) Exit packaging must comply with ARM 42.39.319(2).

(b) Exit packaging must comply with federal child-resistant packaging standards pursuant to 16-12-208(6), MCA.

~~(7)~~ (14) All applications and required attachments, such as photographs~~,~~ ~~product descriptions,~~ and renderings ~~of proposed labels, and proposed packaging~~ shall be submitted electronically to the department via its online portal.

~~(8)~~ (15) An applicant must submit the following fees to the department:

(a) no charge ($0.00) for label applications described in (7)(a) or packaging applications in (12)(a);

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

~~(b)~~ (c) $10 per package application described in (12)(b); and

(c) remains as proposed but is renumbered (d).

~~(9)~~ (16) The department shall review each application and shall notify an applicant, in writing, whether the packaging, label, or exit package has been approved or rejected.

~~(10)~~ (17) Whenever the department returns any application for correction ~~to the label or package~~, it shall notify an applicant, in writing, of the deficiencies or issues with the application or submitted ~~label or package~~ materials.

~~(11)~~ (18) An applicant ~~may resubmit a label or package once under the original application within ten days after the date of the department's first return for correction without paying another application fee. If the applicant fails to respond within ten days, the application shall be denied~~ will receive an invoice for all application fees upon the department's approval of the application(s). The applicant shall pay all invoiced application fees to the department within ten days of receipt. An applicant's failure to pay all invoiced application fees may result in the reversal of application approval and denial of the application.

~~(12) If the department returns a label or package application a second time, it shall notify an applicant, in writing, of the deficiencies or issues with the proposed package or label and that the application shall be denied.~~

~~(13)~~ (19) An applicant whose application is denied under ~~(11)~~ (5) or ~~(12)~~ (11) must reapply ~~and pay a new application fee~~.

~~(14)~~ (20) In order to fully implement the packaging and labeling requirements of the Act, all licensees must submit their packaging and label applications to the department by ~~July~~ August 1, 2022. Licensees may continue to use packaging and labeling that is compliant with the former Montana Medical Marijuana Act (Title 50, chapter 46, MCA) during the pendency of the department's approval(s), provided the licensee's applications were submitted by ~~July~~ August 1, 2022.

~~(15)~~ (21) A licensee that fails to submit applications for approval of packaging and labeling by ~~July~~ August 1, 2022 shall be subject to disciplinary proceedings.

(22) A licensee shall be subject to disciplinary proceedings when:

(a) it affirms to the department that it is using a pre-approved department template label but then uses any other label without submitting an application, applicable fees, and receiving department approval; or

(b) it affirms to the department that it is using generic packaging, but then uses any other product packaging, with graphic or design elements, including logo, whether preprinted on the package or affixed later with an adhesive, sticker, or by other means, without submitting an application, applicable fees, and receiving department approval.

(16) remains as proposed but is renumbered (23).

~~(17)~~ (24) A licensee must maintain approval letters for all product packaging, labels, and exit packages at the licensed premises and shall make those letters available to department inspectors upon request.

AUTH: 16-12-112, MCA
IMP: 16-12-112, 16-12-208, 16-12-215, 16-12-224, MCA

5. The statement of reasonable necessity is being amended as follows, new matter underlined, deleted matter interlined:

REASONABLE NECESSITY: The department proposes to adopt New Rule I which is necessary for the department to implement the provisions of 16-12-208(8), MCA, by providing an application and approval process for the packaging and labeling of the marijuana or marijuana products described in ARM 42.39.314 through 42.39.319. New Rule I also specifies the department's approval of a licensee's/license applicant's exit packaging, which is provided in 16-12-208(6), (8), and (9), MCA. The catchphrase for New Rule I informs licensees and license applicants of the applications, applicable fees, and initial requirements in the department's implementation of the authorizing statute.

Section 16-12-208(8), MCA, requires a licensee or license applicant to submit both a package and a label application, using forms prescribed by the department, for department review and approval. New Rule I implements this directive and outlines the process for the submission of package and label approvals.

The inclusion of (1) is necessary - for the limited purpose of this rule - to cross-reference the marijuana product categories in ARM 42.39.315 through 42.39.318 that require a separate label application and lessen potential confusion from the marijuana product categories (and subcategories) defined in statute and

ARM 42.39.102.

Sections (2) and (3) define what is, and what is not, a "unique marijuana product package" as guidance for when a product package requires an application and department approval. Sections (2) and (3) also provide examples, using specific products, to increase licensee understanding of what constitutes a unique marijuana product package.

Section (4) is proposed to define "generic package" or "generic packaging," which is a zero cost packaging alternative - provided in (15) - should a licensee opt for a more basic packaging format.

Section ~~(4)~~ (5) provides the general application submission requirement~~s~~ for a licensee or license applicant for the approval of a label. ~~Section (4) also clarifies that only one template label is required for each of the marijuana product categories in (1) unless the label will be used for marijuana or a marijuana product that exceeds the THC potency levels in 16-12-224, MCA. Because there are additional label requirements for medical marijuana products (see ARM 42.39.315(8)), applicants must also submit a separate label template for the medical marijuana products so that the department can ensure the label satisfies all of the marijuana laws.~~

Section (6) contains the department's proposed labeling application criteria. The department proposes a separate label application - up to a maximum of eight total label applications - based on the applicant's sale of some or all of the adult-use or medical marijuana or marijuana product categories. The department contends that all current lawful marijuana or marijuana product types can be categorized as one of the listed types. So an applicant who sells 50 individual marijuana or marijuana products, is only required to submit a maximum of eight label applications, depending on the category of the products sold.

Section (7) is proposed as the department's offer of product labeling options to label applicants. Subsection (7)(a) proposes a uniform, department-approved label that costs the applicant nothing for its approval and use, while (7)(b) describes a custom label design option for an applicant's products, which would carry an application fee to offset department costs in the label review for statutory compliance. The department believes the options in (7) meet industry's request for an option with minimal or no processing or cost while allowing for a custom labeling option. The department will develop and integrate the no-cost label option as a part of its work to implement the other portions of New Rule I.

Section (8) is proposed to clarify the requirement that an applicant must provide the department with a template (i.e., sample) label for each product category sold for review and approval.

Sections (9) and (10) are proposed to provide necessary clarity in product labeling compliance for marijuana facts panel information changes and for medical licensees who sell marijuana products with excess THC limits, as provided in statute.

Section ~~(5)~~ (11) sets forth ~~what is~~ the required application of a licensee~~, an applicant,~~ or license applicant ~~when it submits an application~~ for the approval of ~~a unique~~ marijuana product package~~s~~, as defined in (2) and (3).

Section (12), like proposed (7), provides product packaging options to applicants. Subsection (12)(a) proposes a generic package option that costs the applicant nothing for its approval and use, while (12)(b) describes a custom

packaging option for an applicant's products, which would carry an application fee to offset department costs in the package review for statutory compliance. The department believes the options in (12) meet industry's request for an option with minimal or no processing or cost, while allowing for a custom package option should an applicant desire it. The department will develop and integrate the no-cost package option as a part of its work to implement the other portions of New Rule I.

Section ~~(6)~~ (13) provides the process for the approval of exit packaging. Each exit packaging configuration requires a separate application, unless an applicant intends to use the same exit package configuration in multiple sizes, in which case it can submit the differing sizes under one package approval application.

Section ~~(7)~~ (14) sets forth how applicants may submit their applications. Pursuant to the authority in 16-12-208(8)(b), MCA, the department will require electronic applications and will only request a physical prototype, when necessary, to ensure that the label or package satisfies the marijuana laws.

Section ~~(8)~~ (15) is proposed to establish application fee requirements, including the no-fee options described in proposed (15)(a). The department is required by 16-12-208(8)(d)(i), MCA, to establish these fees, and guided by 16-12-112(1)(q), MCA, in establishing the amount. The department contends the fees proposed in (15)(b) through (d) are reasonable given the amount of review and processing of custom label and packaging applications and the related submissions.

Sections ~~(9)~~ (16) through ~~(13)~~ (19) further explain the general application approval/denial process, communications from the department of approvals or denials, and invoicing procedures - which includes no additional cost to an applicant should they need to resubmit an application under proposed (19). ~~submission process and also provides that an applicant may proceed under the initial application returned for correction and the conditions which require resubmittal of an application and payment of additional fees.~~

Section ~~(14)~~ (20) provides a deadline of August 1, 2022, by which all package and label applications must be submitted by for existing or known products. As new products are developed and new packaging is employed, applicants may submit approval for those products after this date.

Section ~~(15)~~ (21) makes clear that licensees that fail to submit the mandatory package and label applications risk disciplinary proceedings.

Section (22) is proposed to clarify and notify licensees that they are subject to adverse department action for failure to comply with the packaging and labeling requirements of 16-12-208, MCA, and New Rule I.

Section ~~(16)~~ (23) proposes to require a deadline for all licensees to submit their packaging and labeling applications for approval for all existing products in order to implement 16-12-208, MCA. The department is mindful of the challenges of converting labels and products for compliance under the marijuana laws. However, the Marijuana Regulation and Taxation Act became law in May 2021, and the department initiated its packaging and labeling rules (ARM 42.39.315 through 42.39.318) on October 22, 2021. The rules have been in effect since January 1, 2022, and licensees have been aware of program requirements.

Section ~~(17)~~ (24) requires licensees to maintain approval letters on site at their licensed premises to show to inspectors, if requested. This will assist inspectors in determining whether packaging and labeling is compliant and will help

shorten the length of time needed for an inspection by not requiring this determination be made on site.

~~FISCAL IMPACT: In accordance with 2-4-302(1)(c), MCA, the department is required to estimate the fiscal impact of New Rule I through the payment and collection of packaging and labeling application fees authorized under the Act and described in New Rule I(8), if known, and the number of persons affected. The fiscal impact of the application fees cannot be accurately measured for this rulemaking because the number of marijuana product packages, labels, and exit packages which require an application is not only dependent on the number of dispensary licensees but also on the variety of inventory sold by each licensee. As of February 15, 2022, there are 457 dispensaries who may be affected by proposed application fees in New Rule I.~~

FISCAL IMPACT: In accordance with 2-4-302(1)(c), MCA, the department is required to estimate the fiscal impact of New Rule I through the payment and collection of new packaging and labeling application fees authorized under the Act and described in New Rule I(15), if known, and the number of persons affected.

While the fiscal impact of the proposed rulemaking cannot be accurately estimated with a specific, dollar amount across all affected persons - due to the variety of marijuana and marijuana products sold by each dispensary licensee and the possible combinations of marijuana product packages, labels, and exit packages used by each licensee - the department provides non-exhaustive examples of estimated fiscal impact (below) and the incorporation of zero fee application options proposed in New Rule I(15)(a), which the department contends is more appropriate and relatable than a theoretical determination applied industry-wide.

The following assumptions are offered, relative to the number of persons affected by the fees in New Rule I or current industry conditions, as of the date of this notice:

1. There are 288 dispensary licensees that operate 453 locations in Montana. Of the 288 dispensary licensees, 82 are medical-only, and 206 are eligible for both adult-use and medical sales.

2. The minimum number of product categories for a dispensary licensee is one - a dispensary that sells only marijuana flower. The maximum is eight - a dispensary that sells all four product categories for both adult-use and medical.

3. All lawful products will fit into the eight categories described in proposed (6). For example, each marijuana strain does not require a custom label and application. The same analysis applies to packaging – a single approved package can come in many sizes and/or have different contents.

4. The department anticipates that few businesses will need or want labeling for all eight product categories; three to six product categories will be the most common.

5. Larger dispensary licensees will use mostly custom packages. Custom printed bags are in use on a large scale already.

6. While it is possible for licensees to use generic packaging and labeling exclusively, the department contends this unlikely. At a minimum, the licensee will want to incorporate a logo sticker on their otherwise inexpensive, commonly used

packaging like bags, jars, and medicine bottles, which would result in a unique marijuana product package, as defined in proposed (4).

Given the above-described assumptions, the department provides the following representative examples of estimated fiscal impact on licensees/license applicants:

A. Under the amended fee schedule in proposed (15), the minimum fiscal impact for an applicant is $10.00 total; based on a $10.00 exit package application with department label and generic packaging for all products that cost an applicant $0.00.

B. Under the amended fee schedule in proposed (15), an estimated fiscal impact for an applicant selling eight marijuana product categories is $750.00 total; based on the following example:

(i) exit packages: five at $10/per exit package = $50.00;

(ii) labels: eight x $25/per custom label = $200.00;

(iii) packages (five bag types, five jar types, five liquid containers, ten beverage containers, five medicine bottles, five pre-roll containers, five syringes, ten paper/foil candy wrappers) x $10 each = $500.00.

C. Under the amended fee schedule in proposed (15), an estimated average fiscal impact for a licensee is $60.00 total; based on the following example:

(i) exit package = $10.00;

(ii) department label = $0.00;

(iii) mix of generic and custom packaging (five customs: one bag type, two jar types, one liquid container, one pre-roll container) = $50.00.

In addition to the examples provided above, the department estimates many applicants will use generic labels ($0.00), basic exit packages ($10.00), and a mix of generic and custom packages (ranging $10 - 150.00). Smaller business applicants could easily opt for all generic packaging and labels and spend only $10.00 on the exit package application. Larger business applicants with diverse product offerings that come in a variety of package types who want custom labels may spend more than $300.00.

As discussed in the reasonable necessity statement for New Rule I(15), the department is required by 16-12-208(8)(d)(i), MCA, to establish these fees, and is guided by 16-12-112(1)(q), MCA, in establishing the amount. The department contends the fees proposed in (15)(b) through (d) are reasonable given the amount of review and processing of custom label and packaging applications and the related submissions.

6. No additional public hearing will be held to consider this amended proposal notice. The department is extending the comment period for this proposed rulemaking in accordance with 2-4-305, MCA, as described in paragraph 7.

7. Concerned persons may submit their data, views, or arguments, either orally or in writing. Written data, views, or arguments may also be submitted to: Todd Olson, Department of Revenue, Director's Office, P.O. Box 7701, Helena, Montana 59604-7701; telephone (406) 444-7905; fax (406) 444-3696; or e-mail todd.olson@mt.gov and must be received no later than 5:00 p.m., May 6, 2022.

/s/ Todd Olson
Todd Olson
Rule Reviewer

/s/ Brendan Beatty
Brendan Beatty
Director of Revenue

Certified to the Secretary of State April 19, 2022.