

MARIJUANA PACKAGING, LABELING, AND PRODUCT DESIGN GUIDE

Section for Compliance and Enforcement April 2025

Table of Contents

Introduction	3
Protect Public Health; Not Attractive to Children	3
False or Misleading Products	3
Product and Packaging Designs	4
Prohibited Designs and Shapes	4
Commercially-Similar Branding	5
Packaging/Container Specifications	6
Food Contact Substances	7
Marijuana Product Packaging Design	7
Colors and Logos	7
Product Name	9
Side and Behavioral Effects	9
Label	10
QR Code	10
Applicable requirements	10
Labeling	11
Word "Marijuana" and Universal Symbol	11
Product Testing Label	12
Marijuana Seeds and Plants Packaging Labeling	18
Limited Information	18
Pre-Approval Process	19
Submission	19
Complete Submission	19
Submission Approved	19
Final Marijuana Product Packaged and Labeled	20
Amounts of Marijuana Product Allowed in Packages	20
Packaging Elements May Not Be Easily Removed or Separated	21
Product Compliance Team	21
Appendix A	22
Appendix B	23
Appendix C	25
Appendix D	27

Introduction

Article XIV of the Missouri Constitution and department rules emphasize the importance of public health and safety of final marijuana product, including product design, packaging design and labeling design to assist in the safe use of marijuana product.

This guide is not a replacement for reading the rules. It is to answer frequently asked questions from licensees about product, packaging, and labeling requirements. This guide is meant to assist licensees by giving examples of how the department interprets the rules to frequently encountered situations. The information in this guide is for general purposes only and does not, and is not intended to, constitute legal advice or replace the need for department approval, where applicable.

All licensees are responsible for understanding and complying with the final marijuana product packaging, labeling and product design requirements outlined in Article XIV, 19 CSR 100-1 and §195.805 RSMo.

Licensees may find additional information and references at the links below:

- Article XIV, Section 1
- Article XIV, Section 2
- 19 CSR 100-1
- §195.805 RSMo
- Facility Communications and Guidance Webpage

Pursuant to 19 CSR 100-1.120(6), any violation of 19 CSR 100-1.120 shall be punishable by an appropriate and proportional department sanction, up to and including an administrative penalty of five thousand (\$5,000) dollars for each product/packaging category, identified by approval number, in which a requirement is violated.

Protect Public Health; Not Attractive to Children 19 CSR 100-1.120(1)

"All marijuana product shall be produced, packaged, and labeled in a manner that protects public health and is not attractive to children."

Licensees are responsible for producing final marijuana products in a manner that ensures the protection of public health throughout marijuana product lifecycle.

For example, it would likely be a violation of rule for a licensee to:

- Use ingredients not intended for human consumption or human use.
- Use ingredients not as intended by the ingredient's manufacturer.

False or Misleading Products 19 CSR 100-1.120(1)(A)

"No marijuana product may be manufactured, packaged or labeled in a false or misleading manner, such as by inaccurately representing product ingredients." Licensees shall not create and/or sell misrepresented marijuana product to another licensee or consumers/individual ID cardholders.

For example, it would likely be a violation of rule for a licensee to:

- Represent a marijuana product as "live" that was produced using dried and cured marijuana plant material.
- Change a marijuana product's strain name to a different strain name.
- Represent a marijuana product as "strain-specific" when a botanical or synthetic terpene blend was added to mimic a specific strain.
- Represent a marijuana product as "strain-specific" when it was produced or manufactured using multiple strains.
- Combine multiple strains in a single container and call it a "new" strain.

Product and Packaging Designs 19 CSR 100-1.120(1)(B)

Applies to all marijuana product, including seeds and plants, and all marijuana packaging used in the final marijuana product provided for retail sale.

Prohibited Designs and Shapes 19 CSR 100-1.120(1)(B)1

"No marijuana product or packaging may be designed using the shape or any part of the shape of a human, animal or fruit, including realistic, artistic, caricature or cartoon renderings."

The marijuana product itself, the container(s) and/or any design including a logo, on the container(s) or product shall not be shaped as a human, animal or fruit or any part of a human, animal or fruit.

In addition to 19 CSR 100-1, this requirement is outlined for edible marijuana product, packaging, or logo in §195.805 RSMo.

For example, it would likely **<u>NOT</u>** be a violation of rule for a licensee to:

- Use a design with an object or objects that do not resemble, represent, or have attributes of an animal, fruit, or human.
- Use marijuana-infused fruit products made of and still in the form of real fruit, such as dehydrated fruit.

For example, it would likely be a violation of rule for a licensee to:

- Use a design that resembles, represents or has attributes of an animal, fruit or human. For example,
 - A silhouette or shadow.
 - A letter having fruit, animal or human characteristics, like the letter "S" having characteristics of a snake.
 - An object that combines human, animal and/or fruit characteristics or shapes to create new fictional characters, such as a unicorn or other mythical creature.
- Use a design that features a part of an animal, fruit or human, such as an animal head or horns, feathers, slice of fruit or a human mouth, eye or hand.
- Use marijuana product shaped or stamped with any part of an animal, fruit or human.
- Use marijuana product, brand, company logos, images, patterns, packaging or containers shaped in a manner that may be appealing to children.

Commercially-Similar Branding 19 CSR 100-1.120(1)(B)2

"No marijuana product or packaging may be designed in such a way as to cause confusion between a marijuana product and any product not containing marijuana, such as where marijuana products or packaging are visually similar to any commercially similar product that does not contain marijuana."

Final marijuana product itself, its container and/or any design on the container and/or final marijuana product cannot resemble the product, container or designs of a local, state, national or international brand's product of a commercially-similar product that does not normally contain marijuana.

For example, it would likely **<u>NOT</u>** be a violation of rule for a licensee to:

- Collaborate with a local, state, national or international brand and use the brand and/or logo on a vape cartridge flavored like or inspired by a particular product produced by the manufacturer if the products are not commercially similar.
- Collaborate with a brand manufacturer and use the brand logo on a new marijuanainfused edible, as long as the marijuana-infused edible or packaging design does not look like a commercially similar product.
- Make and brand their own marijuana-infused product such as chocolate and peanut butter edible; provided that the marijuana-infused product design or package is not visually similar to a commercially similar chocolate and peanut butter product that does not contain marijuana.

For example, it would likely be a violation of rule for a licensee to:

- Collaborate with a local, state, national or international brand to make a visually similar marijuana-infused version of the collaborating brand's product.
- Design a product or package with similar product design or similar branding and imagery as a local, state, national or international brand.

Packaging/Container Specifications 19 CSR 100-1.120(1)(B)3

"All marijuana product packaging, with the exception of marijuana seeds and plants, shall be resealable, opaque and certified as child resistant. Where marijuana product is packaged in a series of containers, the container closest to the product, excluding methods of administration or wrappers, must be compliant with this requirement."

Product packaging holding the marijuana product cannot contain any translucent areas, must be resealable and must be certified child resistant. If product is wrapped in individual servings or doses, the individual wrappers are not required to be re-sealable, opaque or child-resistant, but the packaging containing all of the wrapped servings or doses must comply with these requirements. Methods of administration are not required to be re-sealable, opaque or child-resistant, but the packaging containing the method of administration must comply with these requirements if the method of administration contains marijuana product.

Child-resistant packaging includes packaging that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly. Licensees may refer to 16 CFR part 1700 or the Consumer Product Safety Commission for childresistant packaging descriptions. One way to confirm whether packaging is child resistant is to request a child-resistant certificate from the manufacturer.

For example, it would likely be a violation of rule for a licensee to:

- Use a single serving container that is not resealable, such as a pop-top aluminum can.
- Use a multi-pack that is not resealable.
- Use a clear glass container where the product within the container can be seen from the outside of the package.
- Use a container that is not certified as child resistant.
- Use a container that is no longer child resistant after opening.

Food Contact Substances 19 CSR 100-1.120(1)(B)4

"All marijuana product packaging, with the exception of marijuana seeds and plants, shall be constructed from FDA-approved food contact substances. Where marijuana product is packaged in a series of containers, the container closest to the product, including methods of administration or wrappers, must be compliant with this requirement, unless the department approves application of this rule to a different container in the series."

For example, it would likely be a violation of rule for a licensee to:

- Use preroll paper that is not made from food-grade material for consumable marijuana product.
- Use a method of administration that is not made of FDA-approved food contact substances material that touches marijuana product.
- Use a wrapper, that touches the marijuana product, that is not made of FDAapproved food contact material.

Marijuana Product Packaging Design 19 CSR 100-1.120(1)(B)5

*"All marijuana product packaging design, including that for exit packaging*¹*, may only utilize—"*

Unless otherwise required by rule, licensees are allowed, but not required to include information listed in 19 CSR 100-1.120(1)(B)5.A-E.

Colors and Logos 19 CSR 100-1.120(1)(B)5.A

"Limited colors, including a primary color as well as up to two (2) logos or symbols of a different color or colors, whether images or text, including brand, licensee or company logos, provided that the widest part of a logo or symbol is no wider than the length or height, whichever is greater, of the word "Marijuana" on the packaging."



¹ Exit packaging is not reviewed through the item approval process prior to use but is required to comply with 19 CSR 100-1.120 where applicable.

Limited colors

The entire package and all packages in series of containers, including the interior of the packaging, must be limited to one solid color².

For example, it would likely **<u>not</u>** be a violation of rule for a licensee to:

• Use a packaging design adhered to a container that does not match the standard color of the container such as a black label on a silver aluminum can or white label on a black mylar bag. The standard color of the container does not serve as the primary color.

For example, it would likely be a violation of rule for a licensee to:

- Use more than one color on the packaging³.
- Use a packaging design adhered to a container that does not match a customized⁴ color of a container such as a green label on a purple aluminum can or a yellow label on a blue mylar bag.
- Use patterns or shades/gradients of the packaging's primary color.

Logos

Logos and symbols are designs adopted by an organization to identify its products. A package may not have more than two logos or symbols. The logos are not limited in color.

For example, it would likely **NOT** be a violation of rule for a licensee to:

- Use the same two logos or symbols on multiple layers of packaging.
- Use a logo that consist of images or symbols.
- Use a logo that includes words or a slogan.
- Use a logo that includes an image of the marijuana product.
- Use a logo to designate product as sativa, hybrid, or indica.

For example, it would likely be a violation of rule for a licensee to:

- Use a logo larger (either taller or wider) than the word "Marijuana".⁵
- Include multiple symbols and/or multiple independent statements to put extra information or advertising on the packaging under the guise of a logo.

² Not limited to use of traditional primary colors of red, yellow, or blue.

³ Excluding the logos or symbols.

⁴ Not standard color.

⁵ Logos cannot be larger (length or height) than widest part of logo or symbol, whichever is greater.

Word "Marijuana"

The word "Marijuana" is to be clear and conspicuous in black or white font on the package including all packages in series of containers.

See 19 CSR 100-1.120(1)(C)1 for additional information.

Product Name 19 CSR 100-1.120(1)(B)5.B

"A product name."

The common or usual name of the product. The product name should closely resemble the item name used in Metrc. The product name must be in black or white font.

For example, it would likely **<u>NOT</u>** be a violation of rule for a licensee to:

- Include strain or flavoring.
- Include sativa, hybrid or indica in the name.
- Use as part of a logo to stylize or have in color.

For example, it would likely be a violation of rule for a licensee to:

- Use name that does not relate to product identity.
- Use colored font when not included as part of a logo.

Side and Behavioral Effects 19 CSR 100-1.120(1)(B)5.C

"Text indicating side effects and behavioral effects of usage."6

Text clearly communicates the side effects and behavioral effects of the product such as "sleepy," "relaxed" or "hungry". Text must be in black or white font.

For example, it would likely **<u>NOT</u>** be a violation of rule for a licensee to:

• Use as part of logo to stylize or have in color.

For example, it would likely be a violation of rule for a licensee to:

- Make unfounded nutritional, health, structure/function and/or implied claims.
- Include statement of aspirational or ambiguous meaning.
- Designate product as sativa, hybrid or indica.

⁶ Licensees are not required to include text indicating side effects and behavioral effects of usage.

Label 19 CSR 100-1.120(1)(B)5.D

"A label required by this rule."

The label that complies with the requirements in 19 CSR 100-1.120(1)(C)2. The label, including text, must be legible and in black and white. See 19 CSR 100-1.120(1)(C) below for additional information.

QR Code 19 CSR 100-1.120(1)(B)5.E

"A QR code linking to a website where a purchaser can learn more about the product."

For example, it would likely **NOT** be a violation of rule for a licensee to:

• Use a QR code in the primary color of the packaging.

For example, it would likely be a violation of rule for a licensee to:

- Include a logo or image as part of the QR code unless it is a logo\symbol.
- Include additional wording such as "scan here".
- Use a QR code that does not link to a website featuring more information about the product.

Applicable requirements 19 CSR 100-1.120(1)(B)6

"Marijuana product packaging must be in compliance with applicable local, state and federal requirements."

Licensees are responsible for understanding and adhering to all local, state and federal product packaging requirements for final marijuana product SKUs created in their licensed facility. Marijuana product items may contain additional information to be compliant with this requirement through 19 CSR 100-1.120(1)(C)4. The Item Approval process reviews items for compliance with 19 CSR 100-1.120. Approval of a final marijuana product through the Item Approval process does not confirm compliance with applicable local, state, and federal requirements and is only specific to compliance with DCR rule requirements within 19 CSR 100-1.120.

Labeling 19 CSR 100-1.120(1)(C)

*"Except as specifically identified herein, labeling requirements apply to containers, wrappers*⁷, packages and methods of administration that contain marijuana product, except seeds or plants. The labels required herein are not required on the paper for prerolls."

To promote safe use of marijuana product, all layers of marijuana product containers and packaging must be labeled with the word "Marijuana" and universal symbol, and the container closest to the product must be labeled with a product testing label, unless there is a specific exception.

See 19 CSR 100-1.120(1)(C)3 referenced below for labeling requirements for marijuana seeds and plants.

Word "Marijuana" and Universal Symbol 19 CSR 100-1.120(1)(C)1

"Unless alternative placement of "Marijuana" or the universal symbol has been approved by the department, all marijuana product shall be clearly and conspicuously labeled with "Marijuana" printed at least as large as any other words used, as well as a prominently displayed universal symbol in red and white print that consists of the following: A. A diamond containing the letters "THC"; B. The letter "M" located under the "THC" within the diamond; and C. For infused products, the number of milligrams of THC in the package, placed directly under the diamond."

Both the word "Marijuana" and the universal symbol must be easily seen and readable on every layer of marijuana product packaging.

Edible marijuana-infused products must comply with 195.805.2, RSMo., which requires the universal symbol to be placed on the <u>front of the package</u> in <u>red and white print</u> and <u>measure one-half inch by one-half inch from point to point</u>.

For infused products, licensees are required to indicate the number of milligrams of THC in the package, placed directly under the diamond in the universal symbol. DCR will allow licensees to indicate the intended or approximate milligrams. If an approximate milligram amount is displayed on the packaging, the licensee must ensure only a reasonable deviation exists between the approximate amount of THC and the final tested amount. A reasonable deviation is less than 10% above or below the amount listed on the product testing label. Marijuana products that fall outside of the 10% deviation are required to be relabeled.

For example, it would likely **<u>NOT</u>** be a violation of rule for a licensee to:

• Exclude the word "Marijuana" and the universal symbol from a preroll with no crutch or visible filter.

⁷ "Wrapper" is a covering for an individual serving and/or dose of a final marijuana product separating it from other individual servings and/or doses of final marijuana product items in the final marijuana product packaging. An example of a wrapper is a single-serving pouch.

For example, it would likely be a violation of rule for a licensee to:

- Exclude the word "Marijuana" or the universal symbol from a preroll crutch or visible • filter or other small container.
- Place the word "Marijuana" or the universal symbol on or over a logo. •
- Use illegible text or stylize the word "Marijuana". •
- Place the word "Marijuana" on multiple lines of text. •
- Include "Marijuana" in the logo design. •
- Partially cover the word "Marijuana" or integrate it into the logo.
- Span the word "Marijuana" across multiple panels.

Product Testing Label 19 CSR 100-1.120(1)(C)2

"Unless alternative placement of a label has been" approved by the department, the marijuana product container closest to the product shall bear a label displaying only the following information, in the following order, from top to bottom and left to right:"

Information covered below is required to be displayed on the label in the order listed and the label shall not include any other information. Variances to allow additional information on the testing label are noted below.

Ingredients 19 CSR 100-1.120(1)(C)2.A

"All active and other ingredients, which shall not include groupings of ingredients that obscure the actual ingredients, such as 'natural flavors' or 'botanically derived terpenes' and shall include solvents used in the manufacturing process."

All ingredients used to make the final marijuana product, except for components of natural and

ACTIVE AND OTHER INGREDIENTS

Water, sugar, corn syrup, fruit pectin, citric acid, sodium citrate, cannabis resin (butane), natural [XXXXX] color (sorbitol, water, natural glycerin [variable based on flavor]), sunflower lecithin

MARIJUANA PRODUCT INFORMATION Servings/Doses per package: # Best If Used By: MM/DD/YYYY Produced By: LIC000### Tested By: TES000### Testing Tag: 1A40C01000001110000##### *Source Tag: 1A40C01000001110000##### *Standard Barcode Placeholder Product Weight: # unit

CANNABINOID PROFILE Δ9-THC: ## mg/serving-dose; *##%

Δ9-THCa: ## mg/serving-dose; *##% CBD: ## mg/serving-dose; *##% CBDa: ## mg/serving-dose; *##%

*Total Δ9-THC ## mg/serving-dose; ##% *Total CBD ## mg/serving-dose; ##%

****TERPENE PROFILE** beta-Myrcene: ##% Linalool: ##% alpha-Pinene: ##% Caryophyllene: ##% beta-Pinene: ##% a-Humulene: ##% d-Limonene: ##% a-Bisabolol: ##%

CBN: ## mg/serving-dose; *##% THCV: ## mg/serving-dose; *##% CBDV: ## mg/serving-dose; *##%

Δ8-THC: ## mg/serving-dose; *##%

INSTRUCTIONS AND LENGTH OF EFFECT Eat 1 gummy, Effects typically last 1-4 hours MARIJUANA PRODUCT APPROVAL NUMBER MOOOOXXXXXXX

*STRAIN/FLAVOR: [FLAVOR]

WARNING

Cognitive and physical impairment may result from the use of marijuana. Keep out of reach of children

Additional information that may be included by licensees. *Additional information required if included in mandatory testing.

artificial flavoring for ingestible marijuana products, must be listed on the product testing label including solvents used in the manufacturing process, if applicable.

Ingredients may be list in descending order, alphabetical order, or other order. The strain name may be listed within the ingredients if the product is strain-specific. Allergen information may be included within the ingredients list.

For example, it would likely be a violation of rule for a licensee to:

- Exclude ingredients used to make final marijuana product, such as food coloring or dyes.
- Group flavoring additives for marijuana-infused products administered by smoking or vaporizing.
- List strain name if non-specific product or combine multiple strains and identify it as a new strain.

For ingestible marijuana-infused products, DCR has granted a department-initiated variance modifying the rule language to: *"All active and other ingredients, which shall not include groupings of ingredients that obscure the actual ingredients and shall include solvents used in the manufacturing process. Components of natural and artificial flavorings for ingestible marijuana products may be grouped, such as 'lime flavoring', 'natural banana flavoring', or 'artificial strawberry flavoring'."* See **Appendix B** for variance from 19 CSR 100-1.120(1)(C)2 dated February 5, 2024.

Servings and Doses Per Package 19 CSR 100-1.120(1)(C)2.B

"Servings and doses per package for marijuana licensees or doses per package for medical licensees."

Marijuana products produced by comprehensive or microbusiness licensees shall be labeled with both the number of servings and the number of doses per package. Marijuana products produced by medical licensees shall be labeled with doses only. Serving and dose amounts should match Metrc and be identical if both are required on the label.

For example, it would likely be a violation of rule for a licensee to:

• Include "puffs", "grams", "prerolls", or other descriptors. Such information may be included in the instructions for use, required lower on the label.

Best If Used By 19 CSR 100-1.120(1)(C)2.C

"A 'best if used by' date."

After the date, the product will no longer be at its peak quality and flavor. The date must include month, day and year.

Licensee Producing Final Marijuana Product 19 CSR 100-1.120(1)(C)2.D

"The license number of the licensed entity from which the final marijuana product originated."

The license number is the 9-character license number for the cultivation, manufacturing, wholesale or dispensary licensee that produced the <u>final</u> marijuana product for sale.

For example, it would likely be a violation of rule for a licensee to:

- Include the licensee's name.
- Use a license number for a licensee that did not produce the final marijuana product, even if that licensee is dispensing the final marijuana product or if that licensee had a role in the production of the product.
- Use a partial license number.

Testing Licensee Completing Mandatory Testing 19 CSR 100-1.120(1)(C)2.E

"The testing licensee where the final marijuana product passed mandatory testing."

Licensees should only indicate the 9-character license number of the testing licensee that completed mandatory testing of the final marijuana product and should not include the name of the testing licensee.

For example, it would likely be a violation of rule for a licensee to:

- Include the licensee's name.
- Use the license number for a licensee that did not complete the mandatory testing of the final marijuana product.
- Use a partial licensee number.

Statewide Track and Trace System Tag Number 19 CSR 100-1.120(1)(C)2.F

"The state-wide track and trace system tag number associated with the mandatory testing results for the final marijuana product."

Each sample collected for mandatory testing will be assigned a unique identifier (24-digit ID number) by the statewide track and trace system (Metrc) to be used for the package tag. This package tag number is visible to all downstream licensees in Metrc.

DCR has granted department-initiated variances to allow a licensee to include the final marijuana product source package tag number and standard barcode if done so in the manner described below.

"The licensee may display the final marijuana product source package tag number directly under the tag number associated with the mandatory testing results for the final marijuana product required by 19 CSR 100-1.120(1)(C)2.F if a licensee chooses to include this additional information." See **Appendix A** for variance from 19 CSR 100-1.120(1)(C)2 dated August 18, 2023. "The licensee may display a standard barcode associated with the package tag number. The barcode must be directly next to, or under the required statewide track and trace system tag number associated with the mandatory testing results for the final marijuana product as required by 19 CSR 100-1.120(1)(C)2.F; or directly next to, or under the final marijuana product source package tag number allowed through the August 18, 2023 variance, if a licensee chooses to include this information." See **Appendix C** for variance from 19 CSR 100-1.120(1)(C)2 dated May 29, 2024.

"Dispensary licensees receiving final marijuana product without a standard barcode or designated space for a barcode on their label may add a standard barcode to the packaging outside of the label. The standard barcode shall not cover any information required by 19 CSR 100-1.120, nor add any additional information." See **Appendix D** for variance for product packaging design dated October 18, 2024.

In general, a standard barcode is a machine-readable image that identifies a product and is used to track inventory and pricing. It generally consists of bars and spaces such as a UPC or a square pattern of black and white squares such as a QR code.

For example, it would likely be a violation of rule for a licensee to:

- Include a logo or image as part of the standard barcode.
- Include additional wording such as "scan here".

Dispensary licensees may add a standard barcode directly to the packaging for the purpose of inventory, tracking and sales as allowed in the variance on October 18, 2024. If there is a designated space on the label for a barcode, the dispensary licensee must add the standard barcode in the designated space. If there is already a barcode on the label, a dispensary licensee is not allowed to include an additional standard barcode and must utilize the standard barcode provided.

Total Weight of Marijuana 19 CSR 100-1.120(1)(C)2.G

"The exact total weight of the marijuana included in the package—(I) For dried, unprocessed marijuana, concentrates, prerolls, and infused prerolls, weight shall be listed in grams; (II) For infused products other than infused prerolls, weight shall be listed by milligrams of delta 9 tetrahydrocannabinol."

The weight should not include the weight of the package or method of administration.

Cannabinoid Potency 19 CSR 100-1.120(1)(C)2.H

"The exact delta-9-tetrahydrocannabinol (Δ 9-THC), delta-9-tetrahydrocannabinolic acid (Δ 9-THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), and delta 8 tetrahydrocannabinol (Δ 8-THC) per serving/dose, listed in milligrams."

The exact potency, in terms of milligrams per serving-dose (mg/serving-dose), for each cannabinoid listed, as determined by mandatory testing must be listed on the product testing label.

It is the responsibility of the licensee providing the final marijuana product to determine the final marijuana product's serving or dosage size. It is the testing licensee's responsibility to capture serving size at the time of sampling final marijuana product for mandatory testing to ensure cannabinoid mg/serving-dose values can be calculated based on the dosage or serving size determined by the licensee submitting the final marijuana product for testing.

For example, it would likely be a violation of rule for a licensee to:

• List potency in milligrams per gram (mg/g)

According to the variance from 19 CSR 100-1.120(1)(C)2 dated May 29, 2024, licensees may include the cannabinoid percent per package (%), including Total Δ 9-THC and Total CBD, on the final marijuana product label if:

- The reported percent and total calculations were made for the representative sample collected by the testing licensee for mandatory testing. Licensees may request this calculation by selecting "Additional Mandatory Cannabinoid % and Totals" in addition to the product's appropriate "Mandatory" testing category.
- Cannabinoid % results are placed directly after the milligrams per serving/dose, as determined by mandatory testing, on the final marijuana product label. Cannabinoid % results must be listed for each required cannabinoid in 19 CSR 100-1.120(1)(C)2.H.

See **Appendix C** for variance dated May 29, 2024.

Terpene Analysis 19 CSR 100-1.120(1)(C)2.I

"Results of terpene analysis, if tested during mandatory testing."

If a terpene analysis is conducted along with mandatory testing, all terpene results, with the exception of non-detects or zeros, must be included on the product testing label.

Terpene results listed on the product label must match the mandatory test results uploaded in the statewide track and trace system and the certificate of analysis (COA) provided by the testing licensee.

Instructions 19 CSR 100-1.120(1)(C)2.J

"Instructions for use."

Language must clearly declare how a patient or consumer should administer the final marijuana product, including the amount of product per serving or dose.

For example, it would likely be a violation of rule for a licensee to:

• Include additional text not directly related to instructions.

Length of Time of Effects 19 CSR 100-1.120(1)(C)2.K

"Estimated length of time the serving or dosage will have an effect."

For example, it would likely not be a violation of rule for a licensee to:

• Express the length of time in a range.

Packaging Approval Number 19 CSR 100-1.120(1)(C)2.L

"The department-issued product packaging approval number."

The unique identifier (M0000XXXXXX approval number) is automatically assigned to the final marijuana product when it is approved through the Item Approval process in the statewide track and trace system after DCR reviews the item for compliance with 19 CSR 100-1.120(1).

For example, it would likely be a violation of rule for a licensee to:

- Include a partial approval number.
- Include an approval number not tied to a specific marijuana product.

According to the variance from 19 CSR 100-1.120(1)(C)2 dated August 18, 2023, a licensee may display the marijuana product strain or flavor on the label. If a licensee chooses to include this information, the strain or flavor is required to be listed directly above the required warning in 19 CSR 100-1.120(1)(C)2.M. See **Appendix A** for variance dated August 18, 2023.

For example, it would likely be a violation of rule for a licensee to:

- Include the product name in this section.
- Include a strain name when the marijuana product is not strain specific.

Warning 19 CSR 100-1.120(1)(C)2.M

"The following warning: 'Cognitive and physical impairment may result from the use of marijuana. Keep out of reach of children."

A label is compliant only if this exact warning language is included on the product testing label.

Marijuana Seeds and Plants Packaging Labeling 19 CSR 100-1.120(1)(C)3

"Marijuana seeds and plants shall be clearly and conspicuously labeled with "Marijuana" printed at least as large as any other words used on the packaging and a universal symbol designed as described in this rule."

The word "Marijuana" and the universal symbol must be easily seen and readable on the packaging.

Marijuana seeds and plants are not required to include the label identified in 19 CSR 100-1.120(1)(C)2.

Marijuana Seeds Labeling 19 CSR 100-1.120(1)(C)3.A

"Marijuana seed packaging must bear a label with the strain information."

Marijuana Plants Labeling 19 CSR 100-1.120(1)(C)3.B

"Marijuana plant packaging must bear a label with the strain information and propagation date."

Marijuana plant packaging must have a label listing the plant strain name and the propagation date. The date must include month, day and year.

Limited Information 19 CSR 100-1.120(1)(C)4

"Marijuana product packaging may not contain any information other than that specifically required by this subsection, except information to be in compliance with applicable local, state, and federal requirements."

Approval of a final marijuana product through the Item Approval process only confirms marijuana products packaged for retail sale have been reviewed for compliance with DCR rule requirements within 19 CSR 100-1.120 and does not indicate compliance with applicable local, state, and federal requirements.

For example, it would likely **NOT** be a violation of rule for a licensee to:

• Use containers that have instructions advising consumers how to open the child resistant container, such as threaded cap that states "Push Down and Turn" if they are part of the packaging and the licensee does not have the option to remove them.

For example, it would likely be a violation of rule for a licensee to:

- Add instructions to a container if not included in container manufacturing.
- Include non-marijuana product, such as a lighter or other promotional item.

Pre-Approval Process

19 CSR 100-1.120(2)

"Prior to use, all marijuana product designs, packaging designs and label designs must be submitted to the department for review of compliance with section (1) of this rule."

Each final marijuana product SKU produced by each individual licensee, including the packaging, labeling and product design must be submitted to DCR for a compliance review with 19 CSR 100-1.120(1) prior to use.

Submission 19 CSR 100-1.120(2)(A)

"Submission must be made through a department provided, web-based system by the licensee that is responsible for ensuring compliant packaging and labeling, pursuant to section (3) of this rule."

The creation of a new item in the "Final Packaging" categories in the statewide track and trace system will cause automatic submission of the item for compliance review. In addition to the information required in Metrc, licensees will be required to provide supporting documentation via email on the same day as submission in Metrc.

Complete Submission 19 CSR 100-1.120(2)(B)

"Within thirty (30) days of submission, the department will communicate in writing to the licensee whether the submission is complete. 1. If deemed incomplete, the department will identify reasons why it determined the submission is incomplete and will deny the application. 2. If deemed complete, the submission will be approved or denied within sixty (60) days of the original submission."

Submission Approved 19 CSR 100-1.120(2)(C)

"Once a design has been approved, the licensee will receive an approval number for the marijuana product, packaging and label design, as a whole."

The approval number is used on the label for compliance with 19 CSR 100-1.120(1)(C)2.L. The marijuana product, packaging and labeling for the item approved must be identical to the information provided within the submission.

Final Marijuana Product Packaged and Labeled 19 CSR 100-1.120(3)

"All marijuana product shall be compliantly packaged and labeled by the cultivation, manufacturing, or microbusiness wholesale facility providing the final marijuana product for sale except where cultivation or microbusiness wholesale facilities are providing dried, unprocessed marijuana to dispensary licensees for use in creating prerolls or for dispensing directly to consumers or qualifying patients in custom amounts. In such a case, the dispensary facility is responsible for ensuring the product is compliantly packaged and labeled prior to sale."

Cultivation and manufacturing licensees that produce the final marijuana product are required to submit marijuana product, packaging and labeling designs for pre-approval for marijuana products produced by the licensee. The licensee is then required to package and label the marijuana product using the approved packaging and labeling prior to transferring for retail sale.

When ground marijuana product is sent to dispensary licensees to create prerolls, the dispensary licensee is required to submit the marijuana product (preroll) design, packaging and labeling for preapproval.

When bulk marijuana flower that has been mandatory tested is being sent to dispensary licensees to dispense directly to patients and consumers (often referred to as deli-style), the dispensary licensee is required to submit the marijuana product design, packaging and labeling for preapproval.

Dispensary licensees shall only receive final marijuana product whose product, packaging and label designs have been approved by DCR (with the exception of ground marijuana product for use in creating prerolls and dispensing deli style). DCR-approved final marijuana product can be identified as follows:

- In Metrc:
 - o Items will be listed in a "final packaging" item category.
 - Item names will be identified with an approval number immediately before the item name.
- Physical packaging:
 - An approval number will be included on the compliance label and match the approval number before the item name in Metrc.

Amounts of Marijuana Product Allowed in Packages 19 CSR 100-1.120(4)

"Final marijuana product shall not be packaged in a manner that exceeds three (3) ounces of dried, unprocessed marijuana, or its equivalent."

Per 19 CSR 100-1.010(26), one ounce of dried unprocessed marijuana is equivalent to 8 grams of marijuana concentrate or 800 milligrams of THC in infused products.

Packaging Elements May Not Be Easily Removed or Separated 19 CSR 100-1.120(5)

"Product packaging may not be designed in a manner such that the required elements for packaging and labeling are easily removed or separated from the package, such as placing required information on part of the package that must be removed in order to access the product."

The word "Marijuana", the universal symbol and required label must be affixed to the packaging holding the marijuana product itself in such a way that would make it difficult for a patient or consumer to remove.

For example, it would likely be a violation of rule for a licensee to:

- Affix a sticker for required elements for packaging and labeling that is easily removable or does not adhere to the package completely.
- Place the required elements in a location that must be torn or removed to access the product. For example, the word marijuana or the universal symbol may not be over the tear line on a mylar bag, straddle the jar body and lid or as part of a tamper-evident seal.

Product Compliance Team

For questions or feedback regarding packaging, labeling and product design compliance or the Item Approval process, email <u>CannabisProductCompliance@health.mo.gov</u>.

Licensees can find additional information on our website: <u>https://health.mo.gov/safety/cannabis/facility-comms-guidance.php</u>.

Appendix A



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 | Phone: 573-751-6400 | FAX: 573-751-6010 RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711



Paula F. Nickelson

Michael L. Parson Governor

August 18, 2023

Missouri Facility Licensees

RE: Variance from 19 CSR 100-1.120(1)(C)2

Licensees,

Pursuant to 19 CSR 100-1.020(1)(A), the Division of Cannabis Regulation is granting a variance from 19 CSR 100-1.120(1)(C)2, modifying the provision of the aforementioned rule regarding the requirement for only the information outlined in paragraph 2, A through M to be displayed on the label. DCR will grant a variance as follows:

- The licensee may display the marijuana product strain or flavor on the label. Specifically, the strain or flavor is required to be listed directly above the required warning in 19 CSR 100-1.120(1)(C)2.M if a licensee chooses to include this additional information.
- The licensee may display the final marijuana product source package tag number directly under the tag number associated with the mandatory testing results for the final marijuana product required by 19 CSR 100-1.120(1)(C)2.F if a licensee chooses to include this additional information.

DCR has determined the good cause for granting this variance is that licensees may use the same generic packaging for different strains or flavors. Additionally, a licensee may utilize the source package information to assist with proper statewide track and trace system tracking requirements of final marijuana product.

Please reach out to the Product Compliance Team at <u>CannabisProductCompliance@health.mo.gov</u> if you have any questions.

Thank you,

Andrea Balkenbush, Deputy Director Division of Cannabis Regulation Department of Health & Senior Services

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Appendix **B**



Missouri Department of Health and Senior Services P.O. Box 570, Jefferson City, MO 65102-0570 | Phone: 573-751-6400 | FAX: 573-751-6010

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Michael L. Parson Governor

February 5, 2024

To: Marijuana Facility Licensees

RE: Variance from 19 CSR 100-1.120(1)(C)2

Licensees,

Pursuant to 19 CSR 100-1.020(1)(A), the Division of Cannabis Regulation (DCR) is granting a variance to the requirement in 19 CSR 100-1.120(1)(C)2.A. Licensees will be considered in compliance with the rule by complying with an alternative requirement for flavoring ingredients for ingestible marijuana product.

19 CSR 100-1.120(1)(C)2.A requires the marijuana product container label to disclose:

All active and other ingredients, which shall not include groupings of ingredients that obscure the actual ingredients, such as "natural flavors" or "botanically derived terpenes" and shall include solvents used in the manufacturing process.

Licensees may comply with this rule for ingestible marijuana-infused products, by following the modified language:

All active and other ingredients, which shall not include groupings of ingredients that obscure the actual ingredients and shall include solvents used in the manufacturing process. Components of natural and artificial flavorings for ingestible marijuana products may be grouped, such as "lime flavoring", "natural banana flavoring", or "artificial strawberry flavoring".

This variance does not apply to marijuana-infused products that are to be vaporized or smoked (inhaled products).

DCR determined the good cause for granting this variance is that food flavorings used as intended do not pose any significant health risks to consumers and patients. Requiring disclosure of all components of flavorings may pose an undue burden on licensees in that flavoring manufacturers often do not disclose all components of flavorings, citing trade secrets. Because flavoring additives can pose a health risk when inhaled, there is good cause to keep requirement to list all ingredients in place for marijuana-infused product administered by smoking or vaporizing, such as a vape cartridge.

This variance only applies to what is disclosed on packaging. Per 19 CSR 100-1.030(3)(B), licensee may be required to show proof of ingredients to the Department at any time. Should such disclosure be requested, a licensee can label the information as "proprietary business information" if it believes the information is a trade secret. In such instances, the Department will maintain confidentiality of the information as required by Article XIV Section 2.4(7) and applicable law.

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Per 19 CSR 100-1.020(3)(D), concealing non-flavoring ingredients within a flavoring grouping is considered false or misleading information and may result in penalties.

Please reach out to your compliance officer if you have any questions.

Andrea Balkenbush, Deputy Director Division of Cannabis Regulation Department of Health & Senior Services

Appendix C



Missouri Department of Health and Senior Services

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Michael L. Parson Governor

May 29, 2024

Missouri Facility Licensees

RE: Variance from 19 CSR 100-1.120(1)(C)2

On March 8, 2024, pursuant to 19 CSR 100-1.020(1)(A), the Division of Cannabis Regulation (DCR) granted a variance from certain labeling requirements in 19 CSR 100-1.120(1)(C)2. Through the implementation process, DCR determined the addition of per gram measurement related to the cannabinoid percent value to be unnecessary. This revised is noted below, however the variance to display a standard barcode associated with the package tag number has not changed. This variance supersedes the March 8, 2024 variance to 19 CSR 100-1.120(1)(C)2 as follows:

- The licensee may display a standard barcode associated with the package tag number. The barcode must be directly next to, or under the required statewide track and trace system tag number associated with the mandatory testing results for the final marijuana product as required by 19 CSR 100-1.120(1)(C)2.F; or directly next to, or under the final marijuana product source package tag number allowed through the August 18, 2023 variance, if a licensee chooses to include this information.
- The licensee may list the cannabinoid percent (%) per package values, including Total delta-9tetrahydrocannabinol (Δ9-THC) and Total cannabidiol (CBD) on the final marijuana product label if the percent and total calculations were made for the representative sample collected by the testing licensee for mandatory testing.
 - To compliantly list the cannabinoid percentages on the final marijuana product label, a licensee must:
 - Select "Additional Mandatory Cannabinoid % and Totals" at the time the test sample is created in the statewide track and trace system.
 - This should be selected *in addition to* the product's appropriate "Mandatory" testing category.
 - Include cannabinoid % results on the final marijuana product label directly after the milligrams per serving/dose (mg/serving-dose) for each of the required cannabinoids listed in 19 CSR 100-1.120(1)(C)2.H.
 - Include the following total cannabinoid reporting areas directly below the cannabinoid profile required by 19 CSR 100-1. 120(1)(C)2:
 - Total Δ9-THC (mg/serving-dose) (%)
 - Total CBD (mg/serving-dose) (%)
 - Licensees <u>are not</u> permitted to send a separate sample to a testing licensee for independent cannabinoid percent and total calculations and include the results on the final marijuana product label.

In order to comply with these variances, a licensee must review the associated FAQs to ensure compliance with the variances and rule. This information may be found at <u>https://health.mo.gov/safety/cannabis/facility-comms-guidance.php</u>.

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The variance above related to mandatory testing will be effective on June 3, 2024.

DCR has determined the good cause for granting these variances is that licensees may utilize a standard barcode to assist with proper statewide track and trace system tracking requirements of final marijuana product; and licensees may list cannabinoid percentages, including Total Δ 9-THC and Total CBD, to assist patients and consumers with final marijuana product administration.

Thank you,

Andrea Balkenbush, Deputy Director Division of Cannabis Regulation Department of Health & Senior Services

Appendix D



Missouri Department of Health and Senior Services

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Paula F. Nickelson Director Michael L. Parson Governor

October 18, 2024

Missouri Facility Licensees

RE: Department-initiated variance for Product Packaging Design

Licensees,

On May 29, 2024, the Division of Cannabis Regulation (DCR) issued a variance to 19 CSR 100-1.120(1)(C)2 allowing licensees to display a standard barcode or designated space for a barcode on their label. Pursuant to 19 CSR 100-1.020(1)(A), DCR is further modifying the provisions of 19 CSR 100-1.120 as follows.

Dispensary licensees receiving final marijuana product without a standard barcode or designated space for a barcode on their label may add a standard barcode to the packaging outside of the label. The standard barcode shall not cover any information required by 19 CSR 100-1.120, nor add any additional information.

DCR has determined the good cause for granting this variance is that it provides dispensary licensees a mechanism to maintain accurate inventory and seed-to-sale tracking in compliance with rule.

Amy Moore, Director Division of Cannabis Regulation Department of Health & Senior Services

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