### Division of Cannabis Regulation Guidance Document – 07.06.23 Topics: Packaging, Labeling, and Product Design

On May 15, 2023, the proposed final rules were filed. The effective date of the proposed rules is July 30, 2023. The requirement for the Division of Cannabis Regulation (DCR) to review and approve all final marijuana product designs, packaging designs, and label designs prior to use is outlined within 19 CSR 100-1.120 – Packaging, Labeling, and Product Design – of the proposed final rules. The proposed final rules are located at: <u>https://health.mo.gov/safety/cannabis/pdf/19csr100-proposed-rules-filed-051523.pdf</u>.

#### What does this mean?

In short, each different final marijuana product SKU produced by each individual licensee, including the packaging, labeling, and product design, will require pre-approval by DCR prior to being made available for sale to patients and consumers to verify compliance with 19 CSR 100-1.120. Once an item has been approved, the licensee will receive an approval number for the marijuana product, packaging, and label design that is to be featured on the label.

In addition, the intent is to allow licensees the ability to use all **existing** final marijuana products and packaging until January 31, 2024, at which time any unsold final marijuana product will be non-compliant. If any non-compliant final marijuana products will not be sold by January 31, 2024, licensees may convert these non-compliant final marijuana products to the approved product, packaging, and labeling design. Beginning February 1, 2024, all marijuana products will require an item approval number from the Department prior to sale.

Further, licensees may submit **new** final marijuana product, packaging and labeling designs to the Department for approval beginning on September 1, 2023.

#### Important Dates and Actions

July 28, 2023: New Item Categories will be available in the statewide track and trace system, Metrc. See guidance for licensee responsibilities.

July 30, 2023: New final rules go into effect.

August 31, 2023: Any **new** final marijuana product, packaging, or labeling design created in a "final packaging" item category in the statewide track and trace system, Metrc, after this date will be required to go through the Item Approval process.

September 1, 2023: The Item Approval process in the statewide track and trace system, Metrc, goes live, and any final marijuana product created in a "final packaging" item category will be required to go through the Item Approval process.

January 31, 2024: Last day for licensees to sell or convert all final marijuana products, packaging, and labeling designs in existence prior to September 1, 2023.

February 1, 2024: All products that do not have an Item Approval number associated with the product, packaging, and labeling design must be pulled from dispensary shelves and may no longer be sold. Any products in the statewide track and trace system, Metrc, without an Item Approval number will be discontinued.

### How will licensees submit new final marijuana product, packaging, and label design requests?

Licensees will submit requests for approval to the DCR through the statewide track and trace system, Metrc. This process is called the Item Approval process. Any new items created in the "final packaging" categories will be automatically submitted for approval. In addition, licensees will be required to provide supplemental documentation including marijuana product ingredients, child-resistant certifications, verification of FDA-approved food contact compliance, etc. DCR will provide guidance at a later date for the supplemental submissions. Additional guidance will be available outlining this process soon.

# When may licensees begin submitting requests for new final marijuana product, packaging, and label designs?

Licensees may start submitting requests to DCR through the Item Approval process on September 1, 2023, for any **newly** created or converted final marijuana products, packaging and label designs.

## How does a licensee comply with the new rule requirements for final marijuana packaging, labeling, and product design on July 30, 2023 when the new rules go into effect?

DCR will allow a grace period for licensees to come into compliance with the new standards as we understand that licensees need time to implement the changes. DCR will allow licensees to continue to use their current stock of packaging and existing items for marijuana product currently on the market until January 31, 2024. With this, it is the Department's expectation that licensees are actively working towards compliance and ensuring all existing final marijuana products have either been sold or converted to compliant product, packaging, and labeling designs for identical final marijuana product SKU; including receiving an Item Approval number from the Department prior to the January 31, 2024 date.

All final marijuana product items created or converted after **August 31, 2023**, will require approval through the Item Approval process prior to being available for sale to patients and consumers. Please note, through the statewide track and trace system, Metrc, a licensee will be restricted from using new marijuana products that are not approved by DCR. Remember to take this into consideration when launching new final marijuana product SKUs.

## What resources are available to licensees to know how to be compliant with the new final marijuana packaging, labeling, and product design standards?

DCR will provide licensees with an updated Packaging and Labeling Guide this month, to assist licensees with the new requirements. DCR will send this guide to licensees through email to their designated contact. It will also be available on our website at <u>https://health.mo.gov/safety/cannabis/facility-comms-guidance.php</u>. In addition, licensees may contact DCR at CannabisProductCompliance@health.mo.gov for questions regarding this rule requirement.

#### How should a licensee begin to prepare for the Item Approval process?

In preparation for the Item Approval process, DCR is making changes to the item categories available in the statewide track and trace system, Metrc. DCR will implement the changes on July 28, 2023. Item Categories in Metrc are the acceptable list of categories that licensees can choose from when creating items. Licensees can create an unlimited number of items, also known as marijuana products or marijuana product SKUs. Changes to the item categories are necessary to ensure only licensees' *final marijuana products* are reviewed for the product, packaging, and label design review process. DCR will provide guidance related to *Metrc Item Categories* this month. Licensees should complete these changes by August 31, 2023.

DCR has outlined a plan to implement the Item Approval process to allow for minimal patient and consumer disruptions. Additional guidance and updates related to final marijuana packaging, labeling, and product design requirements will be provided to licensees through email and the Department's website. If you have not already done so, please review the Packaging Color and Variance Extension dated June 6, 2023. It is imperative that licensees review, understand, and implement the guidance provided to be able to avoid final marijuana product delays.