



# **Packaging and Labeling Guide**

**Medical Cannabis Products**

**April 2021**

The following guidance is provided by the Maryland Medical Cannabis Commission (Commission) to assist medical cannabis businesses to comply with state laws and regulations governing the labeling and packaging of medical cannabis products. This document includes regulatory changes effective as of April 19, 2021 that impact all medical cannabis products.

This document is not legal advice. It is meant to assist licensed medical cannabis businesses with understanding packaging and labeling requirements, and to comply with State statutes and regulations. Please consult an attorney if you have any questions regarding the legal requirements that apply.

### **General Packaging Requirements**

Pursuant to COMAR 10.62.24.01 and 10.62.29.01, **all medical cannabis finished products** must be individually packaged at the original point of processing, and product packaging must:

- Be plain: Packaging is uniform in color and texture, and may include the product name, manufacturer name, and manufacturer logo.
- Be opaque: Package contents are not visible from outside of the package.
- Display the Universal Symbol issued by the Commission.
- Include the following information:
  - Identify the licensee that grew the medical cannabis or produced the medical cannabis finished product;
  - A finished-product lot number and an expiration date;
  - Any allergen warning or nutrition labeling required by law;
  - A list of any non-medical cannabis ingredients;
  - The telephone number of the licensee to call to report an adverse event;
  - The Maryland Poison Control Center emergency telephone number;
  - A conspicuous itemization, including weight, of all cannabinoid and terpene content; and
  - A personalized label for the qualifying patient.
- Bear clear warnings that:
  - Products may be lawfully consumed only by the qualifying patient listed on the label;
  - It is illegal for any person to possess or consume the contents of the package other than the qualifying patient; and
  - It is illegal to transfer the package or its contents to any person other than for a caregiver to transfer to a qualifying patient.

- Bear the following statements:
  - “Consumption of medical cannabis may impair your ability to drive a car or operate machinery. Please use extreme caution.”
  - “There may be health risks associated with cannabis use, especially during pregnancy or breastfeeding.”
  - “This package contains cannabis. Keep out of the reach of children and animals.”

In addition to the above requirements, pursuant to COMAR 10.62.37.13, *edible cannabis product* packaging must be:

- Food safe and comply with the food additive requirements established in 21 CFR §§174-178.
- Tamper-evident: The package must have one or more indicators or barriers to entry that, if breached or missing, can reasonably be expected to provide visible evidence to patients that tampering has occurred.
- Child-resistant: The packaging must comply with 16 CFR §1700, et.seq. – *Poison Prevention Packaging Act of 1970* (e.g., is designed or constructed to be significantly difficult for children under 5 years of age to open, but not difficult for adults to use properly). If the packaging is intended for multiple openings, it must be capable of being resealed and sustain being child-resistant after the container or package has been opened.
  - **Note:** For all other medical cannabis products, a patient or caregiver may request child resistant packaging.

For multi-serving products, the packaging **must** include a statement indicating the (1) packaging contains multiple servings, and (2) the number of servings contained within.

### General Packaging Restrictions

A medical cannabis finished product package **shall not**:

- Bear any resemblance to a commercially available candy, snack, baked good, or beverage.
- Contain any statement, artwork, or design that could reasonably mislead any person to believe that the package contains anything other than a medical cannabis finished product.
- Contain a design, an illustration, a picture, or a representation that encourages or represents the recreational use of cannabis, or promotes cannabis for use as an intoxicant.
- Bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any state, county, or municipality, or agency.
- Contain any cartoon, color scheme, image, graphic, or feature that might make the package attractive to children.

### **Medical or Therapeutic Claims**

Medical cannabis packaging **may not** contain any medical or therapeutic claims unless:

1. The claim is supported by substantial clinical data or evidence, and
2. The packaging also includes information on the most significant side effects or risks associated with the use of cannabis.

Upon request, any relevant supporting scientific research and/or clinical evidence must be submitted to the Commission for review.

### **General Labeling Requirements**

Pursuant to COMAR 10.62.29.02 **all medical cannabis product** packages must bear a label that is securely attached. The label must include the following information:

- The name of the qualifying patient, certifying provider, product, and licensee where the product was dispensed;
- The date the medical cannabis was dispensed;
- The name of the product;
- The quantity of medical cannabis dispensed, displayed in units appropriate to the dosage form, and concentration of the applicable cannabinoid and terpene compounds;
- Any directions for use of the product; and
- Instructions for proper storage and handling.

In addition to the above requirements, pursuant to COMAR 10.62.37.14, edible cannabis product labeling must:

- List all ingredients and sub-ingredients in descending order of prominence, including any natural or synthetic preservative added;
- A statement of any common food allergens, as indicated in the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. §301, et seq., that an edible cannabis product may contain, including:
  - Eggs;
  - Soybeans;
  - Milk;
  - Wheat;
  - Peanuts;
  - Tree nuts;
  - Fish; or
  - Crustacean shellfish;

- The processing date of the product;
- The product expiration date, which shall be:
  - Supported by scientific evidence, such as formal stability or challenge studies conducted on similar conventional food products;
  - Supported by stability studies conducted following guidelines indicated in the Commission’s current version of technical authority; and
  - Calculated based on a shelf-life approved by the Commission for the specific edible cannabis product; and
- A warning that states:
  - **“CAUTION: When consumed by mouth the effects of this product can be immediate or delayed by 2 or more hours.”**

### **Product Potency**

To help ensure patients clearly understand the potency of medical cannabis products, anywhere tetrahydrocannabinol content is indicated on the package/label must refer specifically to Delta-9 tetrahydrocannabinol.

Processors should avoid combining the amount of tetrahydrocannabinolic acid and Delta-9 tetrahydrocannabinol to create a general amount of tetrahydrocannabinol, sometimes labeled as “total THC,” “potentially active THC,” or simply “THC.” Delta-9 tetrahydrocannabinol can be identified as Delta-9 THC, Δ9 THC, D9 THC, or another similarly clear abbreviation.

### **Directions for Use**

Directions for use of a product must be simple and straightforward. For example, “Consume desired dose by mouth with a glass of water” or “This product is intended to be consumed by mouth” would be adequate and appropriate directions. For products intended to be absorbed sublingually, wording such as “Administer desired dosage under the tongue. Allow to absorb for 30 seconds and then swallow.” is appropriate. Topical products should indicate that the product is intended to be applied topically, and clearly state they are not intended for internal use or oral consumption (e.g. “DO NOT EAT”).

### **UNIVERSAL SYMBOL**

The Commission approved “Universal Symbol” is required on packaging of all medical cannabis products. Please contact [scientificsupport.mmcc@maryland.gov](mailto:scientificsupport.mmcc@maryland.gov) for a high resolution image of the Universal Symbol.

### **REQUIRED FONT SIZE**

Any information printed on the package or label must be at least 1/16 of an inch high, which is equivalent to size 4.5 font.