Implementation of the Medical Cannabis Regulation and Safety Act

Pre-Regulatory Stakeholder Meeting

Distributors Discussion Topics and Background

The Medical Cannabis Regulation and Safety Act (Act) requires the Bureau of Medical Cannabis Regulation (BMCR) to regulate the distribution of medical cannabis and medical cannabis products. All medical cannabis and medical cannabis products are required to go through a distributor prior to market. The distributor ensures testing is performed and does quality-assurance checks. Distributors may enter into service contracts to store product and have it tested, or they may buy wholesale. ("Wholesale" is a sale to a distributor for resale.)

At the pre-regulatory stakeholder meetings, we will examine these topics with the public and collect feedback on alternative solutions. In the following pages, you will find some critical topics BMCR is examining along with potential regulatory solutions and BMCR's thoughts for regulation. Please review the information and either submit comments at www.dca.ca.gov/webapps/bmcr/public_comment.php (link available at www.bmcr.ca.gov) or come prepared to share your ideas at our pre-regulatory meetings! Please note that due to time constraints we will not be able to discuss all aspects of each license type, however you will have many opportunities to submit your comments to BMCR.

Topics To Be Covered

1. Product quality assurance
2. Repurposing of medical cannabis
3. Labeling
4. Sample collection for testing purposes

Action Items for the Public

BMCR has researched multiple alternatives for the direction of a variety of regulatory concepts. Now we are looking for your feedback!

- Please review the attached documents.
- How do you feel about BMCR's thoughts for the topics attached?
- What are your suggested alternatives and reasons for supporting them?
- Provide us with your feedback in one or both of the following ways:
    - Visit www.dca.ca.gov/webapps/bmcr/public_comment.php or www.bmcr.ca.gov to provide comments.
    - Register and participate in one of our pre-regulatory meetings! If you have not registered, please visit www.bmcr-omcs-prereg.eventbrite.com.

For more background, information, and proposals for each topic, please see the following attachments.

TOPIC #1: PRODUCT QUALITY ASSURANCE

Objective: Clarify the Act by requiring distributors to take certain steps to ensure the quality of the product remains intact when the product is being tested by the lab and stored by the distributor

Existing Law: The Act requires distributors to inspect medical cannabis and medical cannabis products upon receipt of medical cannabis and medical-cannabis products from cultivators, manufacturers, or licensees holding a producing-dispensary license. The Act also requires distributors to perform a quality-assurance review and ensure a random sample of the medical cannabis or medical-cannabis product is tested by a testing laboratory.

Options for Regulations

1. Require specific storage conditions based on product type:
    a. Dried flower: Humidity 60-65%, dark area out of direct sunlight
    b. Concentrates and infused products: Refrigerated ≤4°C, dark area out of direct sunlight, well-ventilated area
    c. Edibles: Refrigerated at 4°C
    d. All products: sealed bags, dark containers, locked up
2. Owner of the product at time of storage with distributor determines the conditions
3. Other alternative

BMCR's Thoughts: Option #1, requiring specific storage conditions

TOPIC #2: REPURPOSING MEDICAL CANNABIS

Objective: Determine whether to allow distributors to re-sell flower to manufacturers when the flower cannot be sold to consumers as is because of a failed certificate of analysis from a testing lab, and, if so, under what conditions

Existing Law: The Act requires distributors to inspect medical cannabis and medical-cannabis products upon receipt of medical cannabis and medical-cannabis products from cultivators, manufacturers, or licensees holding a producing-dispensary license. The Act also requires distributors to perform a quality-assurance review and ensure a random sample of the medical cannabis or medical cannabis product is tested by a testing laboratory.

Options for Regulations

1. Allow processing of medical-cannabis flower if contamination levels are below limits set by BMCR. Limits will be set using scientific studies and will ensure safety of any medical-cannabis product for human use. Any product found with contamination levels higher than those limits set by BMCR will require destruction.
2. No resale allowed; required destruction of flower if failed certificate of analysis
3. Other alternative

BMCR's Thoughts: Option #1, allow processing of medical-cannabis flower if contamination levels are under limits set by BMCR.

TOPIC #3: LABELING

Objective: Determine who can label medical cannabis and medical cannabis products.

Existing Law: The Act requires all medical cannabis and medical cannabis products to be sent to a distributor for quality assurance and testing. Once the medical cannabis and medical cannabis products have been sent to a distributor, they may not go back to the cultivator or manufacturer. The Act authorizes BMCR to establish labeling requirements.

Options for Regulations

1. At cultivators' or manufacturers' premises prior to medical cannabis and medical cannabis products being sent to distributor
2. By distributor at the distributor's premises
3. By a third party at the distributor's premises
4. Either options #1, 2, or 3
5. Other alternative

BMCR's Thoughts: Option #4, allow labeling by cultivator or manufacturer, distributor, or a third party, all under specified conditions.

TOPIC #4: SAMPLE COLLECTION FOR TESTING PURPOSES

Objective: Determine protocols for sample collection of medical cannabis and medical cannabis products for testing purposes.

Existing Law: The Act requires all medical cannabis and medical cannabis products to be sent to a distributor for quality assurance and testing. Once the medical cannabis and medical cannabis products have been sent to a distributor, they may not go back to the cultivator or manufacturer. The Act prohibits testing laboratories from transferring or transporting medical cannabis and medical cannabis products. The Act also requires distributors to ensure a random sample of all medical cannabis and medical cannabis products is tested by a testing laboratory.

Options for Regulations

1. All sample collection for testing purposes shall be done by an agent of a licensed testing laboratory, under the surveillance of a distributor; sample collection shall follow a standard operating procedure approved by BMCR, and be performed under video surveillance. All sample collection shall occur under one of the following conditions:
    a. A testing lab agent comes to the distributor's licensed premises to select a random sample for laboratory testing; or,
    b. The distributor transports all medical cannabis and medical cannabis products from one testing batch to the laboratory and a testing lab agent selects a random sample
2. Same as #1, but require either sub-option (a) or (b).
3. Other alternative

BMCR's Thoughts: Option #1, allow testing lab agent to come to distributor to select sample or distributor transports all medical cannabis and medical cannabis products to testing lab for sample selection.