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To: Current and Prospective MMCP Licensees
From: Director John Hudak, Office of Cannabis Policy
Date: December 23, 2024
Subject: Guidance for Verifying the Potency Information on Medical Cannabis & Cannabis Product Labels

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Background

Over the past year, the Office of Cannabis Policy (OCP) has investigated multiple, unrelated complaints regarding the accuracy and consistency of potency values reported for edible cannabis products available to qualifying patients in Maine's medical cannabis program. In several cases, qualifying patients obtained edible cannabis products that included significantly different THC potency than the potency value listed on the label of the cannabis product. One complaint involved an edible cannabis product that contained more than 12 times the amount of THC per serving than was listed on the label. OCP has also investigated other cases in which the real THC amount in a product was far lower than the product label. Additionally, in at least one of these cases, individual samples taken from the same container of edible cannabis products had THC potency values ranging from 12 mg to 52 mg per serving.

OCP is issuing the following guidance regarding the potency information that can be affixed to the label of cannabis for medical use. At the same time, registrants that manufacture edible cannabis products are reminded that, in accordance with 22 MRS § 2429-C, all edible cannabis products must be manufactured in such a way that results in the THC potency of the edible cannabis product being homogenous throughout the entire edible cannabis product. That means each edible cannabis serving must be of consistent THC potency.

Guidance

It is critical that medical cannabis and cannabis products, like all other medications, provide consistent and predictable effects at a particular dosage. Because medical cannabis is prepared and available to qualifying patients in a variety of different formulations and methods of ingestion, the THC potency and cannabinoid information included on the labels of medical cannabis and cannabis products is necessary to facilitate each qualifying patient's medical use of cannabis. Thus, it is important that the information included on those labels reflects accurate, up-to-date information regarding the cannabinoid content and potency of the harvested cannabis.

To ensure the accuracy of such label information, 22 MRS § 2429-A(3) reads: "If a registered caregiver, dispensary or manufacturing facility affixes a label on the packaging of any harvested cannabis provided to a qualifying patient and that label includes information about contaminants,

the cannabinoid profile or potency of the harvested cannabis, the label must be verified by a cannabis testing facility. This subsection does not apply if there is no cannabis testing facility operating in accordance with section 2423-A, subsection 10."

At present, laboratories in the state that have received ISO/IEC 17025 accreditation from a third party accrediting body may accept and test samples of medical cannabis for the purpose of verifying the cannabinoid profile and potency values reported on the label of harvested cannabis and to ensure the homogeneity of cannabinoids reported. While any laboratory that has received ISO/IEC 17025 accreditation can conduct testing in accordance with the requirements of 22 MRS § 2423-A(10), there are four cannabis testing facilities licensed pursuant to Title 28-B, ch. 1 that meet the requirements of 22 MRS § 2423-A(10) and are authorized to accept and test cannabis for medical use.[1] Maine CDC's cannabis testing facility certification process verifies that the equipment and methods used by the testing facilities to test cannabis and cannabis products will produce accurate, reliable results. Those cannabinoid potency results are applicable only to the batch from which the sample was taken and cannot be applied to any other batch of cannabis or cannabis products.

As a reminder, registrants affixing a label that contains information regarding the cannabinoid content or THC potency of cannabis or cannabis products shall ensure that such information has been verified by a cannabis testing facility authorized to accept and test medical cannabis in the state in accordance with the following requirements:

- Registrants will maintain records of all transfers of cannabis plants and harvested cannabis in accordance with 22 MRS § 2430-J;
- Such records shall include sufficient information to determine from which batch a sample of harvested cannabis was taken;
- For the purpose of this guidance, a batch of harvested cannabis means the specific quantity of harvested cannabis that was produced or otherwise manufactured by a particular registrant, at a particular time, using a particular recipe, formulation or process; and
- The cannabinoid content or THC potency values reported on the label of cannabis or a cannabis product must reflect the test results of the batch from which the cannabis or cannabis product was derived. Samples from the batch must reflect the form in which the cannabis or cannabis product will be labeled for transfer to a qualifying patient.

Registrants are not permitted to include on a label cannabinoid content or THC potency values from any batch of cannabis or cannabis products for medical use except those values from the batch from which the cannabis or cannabis product is derived. Under no circumstances may a registrant label cannabis or cannabis products for medical use with cannabinoid content or potency values calculated by the registrant using test results provided for cannabis or cannabis products in an intermediate form. For instance, a registrant may not use the testing facility-verified THC potency of a batch of distillate to calculate the potency of a batch of gummies

[1] Per 22 MRS § 2423-A(12), no registered caregiver, nor any officer or director of a registered dispensary or registered manufacturing facility, may have any financial or other interest in any ISO/IEC 17025 accredited cannabis testing facility conducting testing to verify information included on the label of any harvested cannabis produced by that registrant.

created using a portion of that batch of distillate. Using potency values that have not been verified by an ISO/IEC 17025 accredited testing facility may result in false or deceptive labeling of the harvested cannabis, which is a violation of 22 MRS § 2429-A(2)(C).

Conclusion

To ensure consistent, predictable dosing of edible cannabis products and accurate label information of all harvested cannabis for qualifying patients, the *Maine Medical Use of Cannabis Act*, Title 22, ch. 558-C, requires that any information regarding cannabinoid profile or potency included on the label of any harvested cannabis be verified by an ISO/IEC 17025 accredited cannabis testing facility.

Due to an uptick in complaints regarding the accuracy of potency information included on the labels of cannabis and cannabis products for medical use, OCP is issuing this guidance to ensure the consistency and predictability of the actual cannabinoid content and potency values reported on the labels of all cannabis and cannabis products offered to qualifying patients in the medical cannabis program. OCP is also reminding the manufacturers of edible cannabis products for medical use that such products must be manufactured in a way that results in the potency of all cannabinoids in that product being homogenous throughout. Registrants with questions regarding this guidance can contact OCP's Compliance Team at Compliance.OCP@maine.gov.