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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 845
OREGON LIQUOR CONTROL COMMISSION

FILED
02/26/2020 4:07 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends language related to the testing of marijuana and marijuana products.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/22/2020 11:55 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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9079 SE McLoughlin Blvd
Portland, OR 97222

Filed By:
Emily Febles
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 03/16/2020

TIME: 2:00 PM - 3:00 PM

OFFICER: Emily Febles

ADDRESS: OLCC

9079 SE McLoughlin Blvd

Rm 103A

Portland, OR 97222

SPECIAL INSTRUCTIONS:

The hearing will close at 2:15 PM, if no one has signed-in to offer oral comment by that time.

NEED FOR THE RULE(S):

The national outbreak of e-cigarette or vaping product use-associated lung injury (EVALI) has resulted in more than 2,800 hospitalizations and 68 deaths, including 2 deaths in Oregon. At this time neither the Centers for Disease Control and Prevention (CDC), the Federal Food and Drug Administration (FDA), nor the Oregon Health Authority (OHA) have determined the cause of the illness outbreak in Oregon. While studies using cases in other states have identified Vitamin E acetate as one likely cause in those states, there is no evidence of Vitamin E acetate being linked to cases in Oregon and the CDC and FDA have not ruled out other potential causes of the illness outbreak. This rule is needed to assist the OLCC and OHA in the ongoing investigation of the cause of EVALI cases in Oregon as well as to prevent and respond to potential future outbreaks or risks to public safety due to additives, adulterants, microbiological contamination, heavy metals, or other contaminants.

In addition to the recent EVALI outbreak, undisclosed ingredients and additives have been discovered in marijuana products in violation of Commission rules. These ingredients and additives cause public health and safety issues and decrease transparency for members of the public using these products. These rule amendments will allow the OLCC to sample the products of marijuana licensees to determine whether they contain ingredients or additives. Further, the

ability to randomly test acts as a deterrent and discouraging licensees from making marijuana items with illegal or unknown indigents, additives, solvents or pesticides.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

845-05-5760 Testing Rulemaking file (available upon request from the OLCC.)

FISCAL AND ECONOMIC IMPACT:

Marijuana licensees who grow marijuana or make marijuana products may be fiscally and economically impacted by this rule. Under these amendments, the Commission may require any licensee to submit a sample of their marijuana item for testing. The Commission estimates that around 10% of licensees will be required to submit a sample in a given year. Based on fees for similar services in the marijuana industry, the Commission estimates that such a test will cost a licensee \$2,000 dollars. As part of the testing, the tested product(s) will be rendered unsaleable and the Commission estimates these costs could reach \$500 dollars. Currently, the Commission does not have a reference laboratory to run this testing, so the Commission anticipates a positive fiscal impact on laboratory licensees who will perform the testing on behalf of the Commission.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) No state agencies, units of local government or members of the public are likely to be economically affected by the rule amendments. (2)(a) As of February 26, 2020, the Commission has 2,240 licenses of the five recreational marijuana license types (producer, processor, wholesaler, laboratory, and retailer). The Commission estimates that 85% of these would qualify as small businesses. (2)(b) The Commission does not expect a change to expected reporting, recordkeeping or administrative activities. Based on fees for similar services in the marijuana industry, the Commission estimates that such a test, if requested by the Commission, will cost a licensee \$2,000 dollars. (2)(c) The Commission anticipates that if a licensee is selected to have sampling and testing done on a marijuana item, there will be increased costs due to the professional services of a qualified laboratory, along with equipment and supplies needed to collect and transmit the sample to the laboratory and labor and administration needed to enter this sample into the cannabis tracking system (CTS).

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were indirectly involved with the development of these amendments because of the increased awareness of implementation of the temporary rules. In 2019, the Governor issued Executive Order 19-09 (E.O. 19-09) which required rulemaking on issues related to flavored vapor products. As result of E.O. 19-09, temporary rules were also required to allow the Commission to test for the additives resulting in "flavor." These proposed amendments are a result and the Commission is seeking to make the requirement for sampling and testing of marijuana items permanent. During the time period of the release of E.O. 19-09, the Commission received a lot of feedback from stakeholders of all types, including small businesses; however, the Commission did not receive any feedback expressing concern with the testing amendments. The Commission determined that rather than requiring mandatory testing on all products, it would be less onerous to small businesses to require sampling on a random or need basis.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

In 2019, the Governor issued Executive Order 19-09 (E.O. 19-09) which required rulemaking on issues related to

flavored vapor products. As result of E.O. 19-09, temporary rules were also required to allow the Commission to test for the additives resulting in "flavor." These proposed amendments are a result and the Commission is seeking to make the requirement for sampling and testing of marijuana items permanent. During the time period of the release of E.O. 19-09, the Commission received a lot of feedback from stakeholders of all types; however, the Commission did not receive any feedback expressing concern with the testing amendments. Because of the amount of feedback received on this topic, and the fact that during the time that the amendments have been temporarily in force there have been no concerns raised by licensees, the Commission determined that a Rules Advisory Committee would not offer substantially greater or different feedback than that already received.

AMEND: 845-025-5760

RULE SUMMARY: This rule describes audit, compliance, and random testing requirements.

CHANGES TO RULE:

845-025-5760

Audit, Compliance, and Random Testing ¶¶

(1) The Commission may require a licensee to submit samples identified by the Commission to a laboratory of the ~~licensee~~Commission's choosing to be tested in order to determine whether a licensee is in compliance with ~~OAR 333-007-0300 through 333-007-0490~~the marijuana testing rules found in Chapter 333, Division 7 of the Oregon Administrative Rules or any other rules of the Commission and may require additional testing that is not required by these rules. ¶¶

(2) A laboratory doing audit testing must comply with these rules, to the extent they are applicable, and if conducting testing not required by these rules, may only use Authority approved methods, unless otherwise authorized by the Commission. ¶¶

(3) The ~~e~~Commission must establish a process for the random testing of marijuana items for microbiological contaminants that ensures each licensee tests every product for microbiological contaminants at least once a year. ¶¶

(4) The Commission may exempt a product that has successfully completed a control study in accordance with OAR 333-007-0440 from testing for microbiological contaminants. ¶¶

(5) The Commission may, at any time, require a licensee to permit the sampling of or submit a sample of a marijuana item to the Commission for testing. Such testing may include testing for: ¶¶

(a) Any microbiological contaminant. ¶¶

(b) Heavy metals. ¶¶

(c) Other adulterants, pesticides, solvents, additives or contaminants that may pose a risk to public health and safety, or are prohibited by law. ¶¶

(6) A licensee shall submit all samples required for testing under this rule within a timeframe established by the Commission.

Statutory/Other Authority: ORS 475B.550, 475B.555

Statutes/Other Implemented: ORS 475B.550, 475B.555, EO 19-09