

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing accompanies this form.

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Oregon Health Authority, Public Health Division
Agency and Division

333
Administrative Rules Chapter Number

Marijuana Labeling and Testing; Medical Marijuana Growers, Processors, Dispensaries and Cards

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Adopting, amending and repealing Oregon Administrative Rules in chapter 333, division 7, 8 and 64 related to labeling, testing, medical marijuana growers, processors, dispensaries and cards.

Statutory Authority:

ORS 438.605, 438.610, 438.615 & 438.620, 475B.025, 475B.420 - 475B.428, 475B.435, 475B.438, 475B.440, 475B.450, 475B.525, 475B.555, 475B.605, 475B.625

Other Authority:

Statutes Implemented:

ORS 438.605, 438.610, 438.615 & 438.620, 475B.210, 475B.295, 475B.420 - 475B.428, 475B.435, 475B.438, 475B.440, 475B.443, 475B.450, 475B.555, 475B.560, 475B.605, 475B.625, 475B.635

Need for the Rule(s):

Senate Bill 1511 (Oregon Laws 2016, Ch. 83, Sec.2) Allows an OLCC producer to grow marijuana for a registered patient and sell any excess marijuana to registered dispensaries and processors.

Changes to chapter 333, divisions 7, 8 and 64 rules are housekeeping changes relating to marijuana labeling, testing, and medical marijuana growers, processors, and dispensaries. Revisions to these rules include:

- Allow THC and CBD on a label to be expressed as either a range, based on the high and low THC and CBD calculated, or an average of the values of THC calculated.
- Clarify language for a cannabinoid product intended for human consumption, which is not specifically categorized in the concentration and serving size limits found in Table 1 and 2, must meet the concentration and serving size limits for a cannabinoid edible.
- Clarify language and add requirements for registrants and licensees regarding ordering laboratory tests.
- Include requirements for testing usable marijuana intended for processing into a cannabinoid product.
- Allow for random testing for pesticides for cannabinoid concentrates and extracts and provides testing requirements following failed pesticide tests.
- Minor changes to the control study rule, in particular what happens when a sample from a control study fails.
- Decreasing minimum amount of samples needed for future testing for potency for cannabinoid products once it has passed a control study.
- Clarify language related to requirements for batches failing control studies.
- Amend certain sampling requirements for batches passing control studies.
- Allow for remediation of cannabinoid concentrates and extracts that fail for pesticides under certain circumstances.
- Allow for remediation of usable marijuana that failed for pyrethrin and piperonyl butoxide pesticide analytes under certain circumstances.
- Clarify requirements and options for batches of marijuana items that fail testing.
- Include the testing of heavy metals as a part of registrant and licensee audit and random testing.
- Adopt rules to allow registrants and licensees to conduct quality control and research and development testing.
- Adopt a rule that allows at a minimum 20% of batches from OLCC licensees to be tested for pesticides.
- Amend rules adding requirements for laboratories related to sampling, setting limits of quantification and non-compliance testing.
- Adopting a rule pertaining to marijuana test result reporting requirements for laboratories.
- Adopt language that states scales used by a person responsible for a grow site must be licensed by the Oregon Dept. of Agriculture (ODA).
- Adopt requirements for designation of plant at medical marijuana grow sites.
- Adopt language that allows OHA to share information with ODA when a violation of Oregon's pesticide law has occurred.
- Include rule references and clarify language regarding labeling, packaging, and testing for a person responsible for a grow site.

- Adopt language that indicates a dispensary or processor may not request a refund of the registration fee if a 60-day letter has been issued.
- Adopt and clarify requirements regarding new and renewal applications for dispensaries and processors.
- Adopt changes to circumstances when the Authority may refund dispensary and processor application fees.
- Clarify language around products intended for human consumption must be made and handled in a manner consistent with ODA statutes.
- Include language that states nicotine product may not be sold in a dispensary.
- Removing previous and nonapplicable rules regarding labeling, signage, and limited marijuana retail sales from registered dispensaries.
- Allow for the transfer of marijuana from a licensed producer to a medical marijuana dispensary or registered processor.
- Adopt rules for a penalty matrix for levels of rule violations by registrants.

Documents Relied Upon, and where they are available:

Oregon Revised Statutes Chapter 475B

https://www.oregonlegislature.gov/bills_laws/ors/ors475B.html

Senate Bill 1511 (Oregon Laws 2016, chapter 83)

<https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/SB1511/Enrolled>

Fiscal and Economic Impact:

Testing:

Current testing costs for a grower or producer to test one 10 pound batch of usable marijuana is approximately \$300. Potency testing costs for an edible processor for a 10,000 unit process lot is approximately \$1000. Testing costs for a two pound process lot of cannabinoid extract is about \$500. Rule revisions to testing requirements for registered and licensed marijuana processors, allowing for the option of randomized testing and removing testing requirements for certain solvents would reduce costs associated with testing cannabinoid concentrates, extracts and other items. Allowing for OLCC to set frequency of testing for batches of usable marijuana above a minimum of 20% of batches within a harvest lot may lead to reduced testing costs for licensed producers. Reducing the amount of samples to be tested once a product has passed a control study would also reduce testing costs for processors. Rule revisions that reduce the frequency of required testing of usable marijuana and marijuana items would reduce testing costs for marijuana processors and producers, reduce wholesale prices for marijuana retailers and reduce the ultimate cost to the consumer purchasing cannabinoid products. However, requiring producers and growers to test usable marijuana intended for use in cannabinoid products to be tested for pesticides would increase the testing costs to producers and growers for those usable marijuana batches that are affected and may slightly increase the cost of those products to the consumer. Reducing required testing for marijuana processors could have a negative economic impact on accredited and licensed laboratories.

ORS 475B.555(8) provides that OHA, in adopt testing rules must:

- Consider the cost of a potential testing procedure and how that cost will affect the cost to the ultimate consumer of the marijuana item; and
- Not adopt rules that are more restrictive than is reasonably necessary to protect the public health and safety.

Overall, the proposed amendments to the testing rules should lower the testing costs of producers and processors, thus reducing the costs to the ultimate consumer, to the extent producers and processors are passing the testing costs to consumers. OHA believes that the proposed rules strike a reasonable balance between protecting the public health and safety and the costs to the industry.

Housekeeping rules, division 8:

There is no or minimal increase in costs to the regulated entities or to consumers due to the proposed rule changes in division 8.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

These rules will have some impact on the costs to OHA, OLCC and ODA to assure compliance, however the costs associated with these rules can be absorbed into current agency functions. There is no cost of compliance to local governments and the public.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:

Currently 7 laboratories may perform testing of pesticides on cannabis.

There are about 150 registered and licensed processors.

There are about 445 licensed marijuana producers.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

There will be some small additional costs to small business, especially marijuana testing labs, growers, producers and processors associated with reporting and recordkeeping requirements in the rules. The exact cost of such administrative activities is unknown due to each businesses ability to adapt their own processes and efficiencies to meet the requirements.

c. Equipment, supplies, labor and increased administration required for compliance:

It is anticipated there may be a small increase in labor and administration related to reporting and recordkeeping requirements in the rules. No known increases in equipment and supplies.

How were small businesses involved in the development of this rule?

The Rules Advisory Committee included representatives from medical marijuana grow sites, processors, and labs.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

<u>04-30-2017 5:00 p.m.</u>	<u>Brittany Hall</u>	<u>brittany.a.hall@state.or.us</u>
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address