December 21, 2018
MEDICAL MARIJUANA INFORMATION BULLETIN 2018-08

Subject: New Division 7, 8 & 64 Rules Effective January 1, 2019

The Oregon Medical Marijuana Program (OMMP) has adopted and amended permanent administrative rules that are effective January 1, 2019. This rulemaking permanently adopts rule amendments pertaining to the testing of marijuana. Changes being made will clarify testing requirements and will also clarify standards that cannabis laboratories need to follow. This rulemaking also amends the labeling rules to outline the transition of authority from OHA to OLCC per SB 1057 passed in the 2017 legislative session. Housekeeping changes are being made to Chapter 333 Division 8 which includes moving labeling definitions from Chapter 333 Division 7 and stating a timeframe for how long a grower needs to be in good standing to become a grow site administrator. Definitions are being amended in Chapter 333 Divisions 7, 8, and 64 to match modifications made by OLCC for consistency between the agencies.

This bulletin only provides a summary of the major rule changes. The full rules text may be found on the OMMP rules webpage at www.healthoregon.org/ommprules

Summary of Rule Changes

333-007-0310 Definitions for Cannabis Testing
For consistency and clarity, the following definitions have been modified or added: Batch, Cannabinoid product, Cannabinoid capsule, Cannabinoid tincture, Cannabis Tracking System (CTS), Cured, Finished cannabinoid concentrate or extract, Finished cannabinoid product, Food, High heat, Human use, Remediation, Texture, and Usable marijuana.

333-007-0330 - Testing standards for concentrates made using only animal fat or plant-based oil.
New testing standards are being adopted for a concentrate that is made only using food grade animal fat or food grade plant-based oil. A process lot of a concentrate of this kind is not required to be tested for pesticides if all the following are true:

- All marijuana or usable marijuana used to make the concentrate was tested for pesticides and passed;
- The only solvent used to make the concentrate is food grade animal fat or food grade plant-based oil;
- The concentrate itself is only used to make a cannabinoid product intended for human consumption or use but not intended for inhalation; and
- The concentrate is not sold directly to consumers or patients.

A cannabinoid concentrate meeting all the above-mentioned criteria does not require any testing to be performed on it. Once it is used to make a cannabinoid product, the finished
product must have a potency test performed and meet concentration limits established in rule (OAR 333-007-0210 or 333-007-0220).

333-007-0360 – Sampling for compliance testing
Samples being taken for testing must be from the finished cannabinoid concentrate, extract or product.

- Finished cannabinoid concentrate or extract means a cannabinoid concentrate or extract that is in its final form ready to be packaged for sale or transfer to a patient, designated primary caregiver or consumer.
  - Samples may be taken in bulk as outlined in the sampling protocol and are not required to be in their final packaging.
  - If an extract is to undergo further processing, it’s the final extract made that will be sold or transferred for sale to a patient, designated primary caregiver or consumer that is required to be sampled and tested.
  - If two extracts or concentrates will be blended, it’s the final mixed form of the extract or concentrate that should be sampled and tested.
  - Finished cannabinoid concentrates and extract must be tested for pesticides, solvents and potency.
  - If an extract or concentrate will be mixed with a non-cannabis derived terpene, then the extract or concentrate becomes a product. The extract or concentrate would need to be tested for pesticides and solvents before the non-cannabis terpene is added and tested for just potency after the non-cannabis terpene is added.
  - Modifications to Table 5 and 7 no longer indicate the size requirement per sample increment for a finished cannabinoid concentrate or extract. The laboratory needs to ensure the size of the sample increments collected are adequate for testing.
- Finished cannabinoid product means a cannabinoid product that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids.
  - The product does not need to be in its final packaging but the whole process lot must be available during the sampling event and be ready for final packaging.
  - A finished cannabinoid product is required to be tested for potency and meet concentration limits found in rule (OAR 333-007-0210 or 333-007-0220).

333-007-0400 Standards for Pesticides Compliance Testing
A clarification is being made to the rule language to state that both the primary sample and the field duplicate sample must always be tested for pesticides and have passing test results in order for an item to be considered passing.
333-007-0410, -0420, -0430
The relative standard deviation (RSD) has been reduced from 30% to 20% between the primary and field duplicate samples taken and the relative percent difference (RPD) has been reduced from 20% to 15% between the primary and field duplicate samples taken.

333-007-0420 and 333-007-0450
A sample fails for moisture content if it contains more than 15% moisture. A failed item may be remediated by further curing or may be transferred to be used to make an extract or concentrate if the method for making the extract or concentrate uses an effective sterilization method.

333-007-0440 Control Study
Amending language to outline specifics that a cannabinoid concentrate, extract, or product must meet in order to pass a control study. Also, extending the timeframe that a control study will be valid from one year to two years. Clarifying what is considered a change in the type of ingredient used by a processor that will not result in the control study being considered invalid.
Please refer to the control study guidance document for more information.

333-008-0638 Grow Site Administrators for CTS Tracking
In order for a person responsible for a grow site (PRMG) to be approved as a grow site administrator, the PRMG must be in good standing for the prior three years with OMMP.

333-064-0025 Definitions for Laboratories
For consistency and clarity, the following definitions have been added: Cannabis Tracking System, Finished cannabinoid concentrate or extract, Finished cannabinoid product, Scheduled proficiency testing, and Supplemental proficiency testing.

333-064-0100 Marijuana Item Sampling Procedures and Testing
Clarifying language for sampling of marijuana items in rule and ORELAP’s Protocol for Collecting Samples of Finished Cannabinoid Concentrates, Extracts and Products.

333-064-0110 Reporting Marijuana Test Results
Test results no longer expire after one year. This applies to all test results, even those that were performed before the effective date of this rule.

333-064-0120 Proficiency Testing for Laboratories Accredited for Cannabis Testing
Language has been adopted outlining requirements that cannabis laboratories must follow for proficiency testing.

333-064-0130 Cannabis Laboratory Violations and Enforcement
Language has been adopted regarding cannabis laboratory violations and enforcement.
In addition, the rulemaking also amends the labeling rules found in Chapter 333 Division 7 to outline the transition of authority from OHA to OLCC per SB 1057 passed in the 2017 legislative session. A timeline explaining the transition may be found on the OMMP rules webpage. Housekeeping changes are being made to division 8 which include moving labeling definitions from division 7.

The rules can be found at: healthoregon.org/ommprules