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OREGON ADMINISTRATIVE RULES  
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION  
CHAPTER 333

**DIVISION 7**

**MARIJUANA LABELING, CONCENTRATION LIMITS, AND TESTING**

**333-007-0090**

**General Label Requirements; Prohibitions; Exceptions**

(1) Principal Display Panel.

(a) Every container that contains a marijuana item for sale or transfer to a consumer, patient or designated primary caregiver must have a principal display panel, as that term is defined in OAR 333-007-0020.

(b) If a container is placed within packaging for purposes of displaying the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver, the packaging must have a principal display panel as that term is defined in OAR 333-007-0020.

(c) The principal display panel must contain the product identity, net weight, and universal symbol, if applicable.

(d) If the product is a medical grade cannabinoid product, concentrate or extract processed by a licensee the principal display panel must include the medical grade symbol.

(2) A label required by these rules must:

(a) Be placed on the container and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver.

(b) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2016), Uniform Packaging and Labeling Regulation, incorporated by reference.

(c) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;

(d) Be in English, though it can be in other languages; and

(e) Be unobstructed and conspicuous.

(3) A marijuana item may have one or more labels affixed to the container or packaging.

(4) A marijuana item that is in a container that because of its size does not have sufficient space for a label that contains all the information required for compliance with these rules:

(a) May have a label on the container that contains a marijuana item and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver that includes at least the following:

(A) Information required on a principal display panel, if applicable for the type of marijuana item;

(B) Licensee or registrant business or trade name and licensee or registrant number;

(C) For licensees, package unique identification number and for registrants, batch or process lot number;

(D) Concentration of THC and CBD; and

(E) Required warnings; and

(b) Must include all other required label information not listed in subsection (4)(a) of this rule on an outer container or package, or on a leaflet that accompanies the marijuana item.

(c) May:

- (A) Use a peel-back or accordion label with the information required in subsection (4)(b) of this rule, if the peel-back or accordion label can be easily identified by a patient or consumer as containing important information.
- (B) Use 6 point font for the information listed in paragraph (4)(a)(A) to (D) of this rule.
- (5) A marijuana item in a container that is placed in packaging that is used to display the marijuana item for sale or transfer to a consumer, patient, or designated primary caregiver must comply with the labeling requirements in these rules, even if the container qualifies for the exception under section (4) of this rule.
- (6) The universal symbol:
- (a) Must be at least 0.48 inches wide by 0.35 inches high.
- (b) May only be used by licensees or registrants.
- (c) May be downloaded at [www.healthoregon.org/marijuana](http://www.healthoregon.org/marijuana).
- (7) Medical grade symbol. The medical grade symbol must be at least 0.35 inches in diameter.
- (8) A label may not:
- (a) Contain any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims; or
- (b) Be attractive to minors, as that is defined in OAR 845-025-7000.
- (9) A marijuana item that falls within more than one category, for example a product that is both a cannabinoid concentrate and cannabinoid edible, must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product is intended for human consumption or the "BE CAUTIOUS" warning if the effects of the product are customarily felt immediately.
- (10) The THC and CBD amount required to be on a label must be based on the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100, plus or minus five percent. A registrant or licensee that has more than one laboratory test result for THC or CBD from the same batch may either express the THC or CBD amounts on the label:
- (a) As a range, based on the high and low THC and CBD values for each sample that was tested;
- or
- (b) As an average of all the THC values for each sample or an average of all the CBD values for each sample.
- (11) If a marijuana item has more than one test batch number, laboratory, or test analysis date associated with the marijuana item that is being sold or transferred, each test batch number, laboratory and test analysis date must be included on a label.
- (12) If a marijuana item is placed in a package that is being re-used, the old label or labels must be removed and it must have a new label or labels.
- (13) A licensee or registrant must have documentation that demonstrates the validity of the calculation of the amount of sodium, sugar, carbohydrates and total fat in a cannabinoid edible and must make that documentation available to the Commission or the Authority upon request.
- (14) Exit packaging must contain a label that reads: "Keep out of the reach of children."
- (15) A cartridge containing a cannabinoid concentrate, extract or product intended for use with an inhalant delivery system as that is defined in ORS 431.840 is not required to be labeled in accordance with these rules except that the cartridge must have a label with the universal symbol.

All the remaining label requirements must be included on the packaging that is used to display the cartridge for sale or transfer.

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0200**

#### **Concentration and Serving Size Limits: Definitions, Purpose, Scope and Effective Date**

(1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:

- (a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and
- (b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.

(2) OAR 333-007-0200 through 333-007-0220 apply to:

- (a) A Commission licensee as that is defined in OAR 845-025-1015; and
- (b) A person registered with the Authority under ORS 475B.400 to 475B.525 who is not exempt under ORS 475B.630.

(3) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.

(4) The amounts of THC listed on a label are based on an average from samples taken from a harvest or process lot and may not represent the exact amount of THC in a marijuana item purchased by a consumer, patient or designated primary caregiver.

(5) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0220 ~~and until January 1, 2017, OAR 333-008-1500.~~

(6) For purposes of OAR 333-007-0200 through 333-007-0220:

- (a) The definitions in OAR 333-007-0020 apply unless otherwise specified.
- (b) "Cannabinoid capsule" means a small soluble container, usually made of gelatin, that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.
- (c) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.
- (d) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.
- (e) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.
- (f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.
- (g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.

(h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:

- (A) Intuitively determine how much of the product constitutes a single serving; and
- (B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.

Stat. Auth.: ORS 475B.625

Stats. Implemented: ORS 475B.625

### **333-007-0210**

#### **Retail Marijuana Item Concentration and Serving Size Limits**

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a retail adult use marijuana item is listed in Table 1. [Table not included. See ED. NOTE.]

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

- (a) Sold and packaged with a measuring device that measures single servings; or
- (b) Placed in packaging that clearly enables a consumer to determine when a single serving has been consumed.

(3) Serving size is as determined by the processor.

(4) A retail adult use marijuana item that does not fall within a category in Table 1 such as cannabinoid suppositories and transdermal patches or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 1.

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: ~~See 105, ch. 614, OL 2015~~ ORS 475B.625

Stats. Implemented: ~~See 105, ch. 614, OL 2015~~ ORS 475B.625

### **333-007-0220**

#### **Medical Marijuana Item Concentration Limits**

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a medical marijuana item is listed in Table 2.

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

- (a) Sold and packaged with a measuring device that measures single servings; or
- (b) Placed in packaging that clearly enables a patient to determine when a single serving has been consumed, as that serving size is determined by the processor.

(3) Serving size is as determined by the processor.

(4) A medical marijuana item that does not fall within a category in Table 2 or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 2.

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: ~~See 105, ch 614, OL 2015~~ ORS 475B.625

Stats. Implemented: ~~See 105, ch 614, OL 2015~~ ORS 475B.625

### 333-007-0300

#### Marijuana Testing: Purpose and Effective Date

- (1) The purpose of these rules is to establish the minimum compliance testing standards for marijuana items. These rules are applicable to:
- (a) A licensee; and
  - (b) A registrant who is not exempt from the testing requirements.
- (2) The testing requirements do not apply to:
- (a) A grower if the person is transferring usable marijuana or an immature marijuana plant to:
    - (A) A patient who designated the grower to grow marijuana for the patient; or
    - (B) A designated primary caregiver of the patient who designated the grower to grow marijuana for the patient; or
  - (b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.
  - (c) Immature plants or seeds.
- (3) A person registered with the Authority under ORS 475B.400 to 475B.525 who is subject to these rules may not:
- (a) Transfer a marijuana item that is not sampled and tested in accordance with these rules; or
  - (b) Accept the transfer of a marijuana item that is not sampled and tested in accordance with these rules.
- (4) A person licensed by the Commission must comply with these rules at all times.
- ~~(5) Notwithstanding section (3)(a) of this rule, until January 1, 2017, a dispensary may transfer a marijuana item to a patient or caregiver that was transferred to the dispensary before October 1, 2016, and that was not sampled and tested in accordance with these rules if the item contains a label placed on the package where it can easily be seen by the patient or caregiver that reads "DOES NOT MEET NEW TESTING REQUIREMENTS" in 12 point font, and in bold, capital letters.~~

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0310

#### Definitions

For purposes of OAR 333-007-0300 through 333-007-050490:

- (1) "Authority" means the Oregon Health Authority.
- (2) "Batch" means:
  - (a) A quantity of usable marijuana from a harvest lot; or
  - (b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.
- (3) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.
- (4) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.
- (5) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.
- (6)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana.

(b) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate or extract by itself; or

(C) Industrial hemp, as defined in ORS 571.300.

(7) "Cannabinoid capsule":

(a) Means a small soluble container, usually made of gelatin that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(b) Does not mean a cannabinoid suppository.

(8) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(9) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.

(10) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes transdermal patches.

(11) "Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(12) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

(13) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.

(14) "Chain of custody procedures" means procedures employed by laboratory personnel using a chain of custody form to record the possession of samples from the time of sampling through the retention time specified by the Authority or Commission.

(15) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.

(16) "Commission" means the Oregon Liquor Control Commission.

(17) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a marijuana item.

~~(187)~~ "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.

(19) "Control study" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through sampling and testing as described in OAR 333-007-0440.

~~(2018)~~ "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service Number 1972-08-3.

~~(2149)~~(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475B.415(5)(b).

(b) "Designated primary caregiver" does not include the person's attending physician.

~~(220)~~ "Field duplicate sample" means ~~a sample~~ increments taken in an identical manner to sample increments taken for the primary sample ~~from~~ and representative of the same marijuana item being sampled that is analyzed separately from the primary sample, that is used for quality control only.



(234) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(242) "Grower" has the same meaning as "person responsible for a marijuana grow site."

(253) "Grow site" means a specific location registered by the Authority and used by the grower to produce marijuana for medical use by a specific patient under ORS 475B.420.

(264) "Harvest lot" means a specifically identified quantity of marijuana that is ~~uniform in strain,~~ cultivated utilizing the same growing practices, harvested within a 48-hour period at the same time at the same location and cured under uniform conditions.

(275) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.

(286) "Human consumption or human ingestion" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.

(297) "Laboratory" means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS 475B.560.

(30) "Level of quantification" means the minimum levels, concentrations, or quantities of a target variable, for example an analyte, that can be reported by a laboratory with a specified degree of confidence.

(3128) "Licensee" has the meaning given that term in ORS 475B.015.

(3229)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

(330) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

(344) "Marijuana processing site" means a marijuana processing site registered under ORS 475B.435.

(352) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.450.

(363) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

(374) "Patient" has the same meaning as "registry identification cardholder."

(385) "Person responsible for a marijuana grow site" has the same meaning as "grower" and means a person who has been selected by a patient to produce medical marijuana for the patient and who has been registered by the Authority for this purpose under ORS 475B.420.

(396) "Process lot" means:

(a) Any amount of cannabinoid concentrate or extract of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or

(b) Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract as defined in subsection (a) of this section.

~~(37) "Process validation" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through a series of sampling and testing from three consecutive process lots as described in OAR 333-007-0440.~~

- (~~4038~~) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extracts.
- (~~4139~~) "Processing site" means a processor registered with Authority under ORS 475B.435.
- (~~420~~) "Processor" has the meaning given that term in OAR 845-025-1015.
- (~~434~~) "Producer" has the meaning given that term in OAR 845-025-1015.
- (~~442~~) "Producing" means:
- (a) Planting, cultivating, growing, trimming or harvesting marijuana; or
  - (b) Drying marijuana leaves and flowers.
- (~~453~~) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.420, 475B.435 or 475B.450.
- (~~464~~) "Registry identification cardholder" means a person who has been diagnosed by an attending physician with a debilitating medical condition and for whom the use of medical marijuana may mitigate the symptoms or effects of the person's debilitating medical condition, and who has been issued a registry identification card by the Authority under ORS 475B.415(5)(a).
- (~~475~~) "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100..
- (~~486~~) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.
- (~~497~~) "Sample" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.
- (50) "Sample increment" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing or, in the case of a control study, may itself be tested.
- (~~5148~~) "Sterilization" means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.
- (~~5249~~) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.
- (~~530~~) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.
- (~~544~~) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.
- (~~552~~) "These rules" means OAR 333-007-0300 through 333-007-0~~50490~~.
- (~~563~~) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish consensus standards for accrediting environmental laboratories.
- (~~574~~) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab Standards (© 2009 The NELAC Institute), which describe the elements of laboratory accreditation developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies.
- (~~585~~) "Total THC" means the molar sum of THC and THCA.
- (59) "Unit of sale" means an amount of a marijuana item commonly packaged for transfer or sale to a consumer, patient or designated primary caregiver, or capable of being packaged for transfer or sale to a consumer, patient or designated primary caregiver.
- (~~6056~~)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.
- (b) "Usable marijuana" does not include:



- (A) The seeds, stalks and roots of marijuana; or
- (B) Waste material that is a by-product of producing or processing marijuana.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0315

#### Ordering Tests

(1) A registrant or licensee must provide a laboratory, prior to laboratory taking samples, with **at a minimum**, the following **information**:

- (a) The registrant or licensee's registrant or license number.
- (b) The name, address and contact information of the registrant or licensee.
- (c) Type of marijuana item.
- (d) Harvest lot number that is associated with the batch numbers, if applicable.
- (e) Process lot number that is associated with the batch numbers, if applicable.
- (f) Batch numbers to be sampled.
- (g) Total mass or volume of each batch to be sampled.
- (h) For cannabinoid products, the unit of sale.
- (i) Identification of the test or tests ~~A written request of analysis for each test~~ the laboratory is being requested to conduct.
- (j) Whether the test or tests being requested are compliance tests.
- (k) Whether the test or tests being requested are quality control or research and development tests.

(2) ~~Notification of w~~Whether ~~at~~the batch is being re-sampled because of a failed test, ~~the date the failed test result was received by the registrant or licensee and laboratory identification number of the laboratory that conducted the initial test.~~

(m) Whether the marijuana item has successfully passed a control study. ~~and the failed test results.~~

(23) ~~If the registrant or licensee informs a laboratory that a marijuana item is being re-sampled after a failed test or has successfully passed a control study, the registrant or licensee must provide the laboratory with documentation of the failed test or successful control study as applicable. Certification of successful process validation, if applicable, on a form prescribed by the Authority.~~

(4) ~~Proof of a waiver under OAR 333-007-0490, if applicable.~~

(3) ~~It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.~~

(4) ~~A registrant or licensee may only order a compliance test for a marijuana item that the registrant or licensee has produced or processed, as applicable.~~

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0320

#### **Compliance Testing Requirements for Marijuana or Usable Marijuana**

(1) A producer or grower must test every **batch from a** harvest lot of marijuana or usable marijuana intended for use by a consumer or patient prior to selling or transferring the marijuana or usable marijuana for the following:

- (a) Pesticides in accordance with OAR 333-007-0400.

- (b) Water activity and moisture content in accordance with OAR 333-007-0420.
- (c) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (3) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site to make a cannabinoid product for the following:
  - (a) Pesticides in accordance with OAR 333-007-0400.
  - (b) Water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (4) A producer or grower must test a batch from a harvest lot of marijuana or usable marijuana for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.  
Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0330**

#### **Compliance Testing Requirements for Cannabinoid Concentrates and Extracts**

- (1) A processor or processing site must test every process lot of cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following, except as provided in section (6) of this rule:
  - (a) Pesticides in accordance with OAR 333-007-0400.
  - (b) Solvents in accordance with OAR 333-007-0410.
  - (c) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following, except as provided in section (6) of this rule:
  - (a) Pesticides in accordance with OAR 333-007-0400.
  - (b) Solvents in accordance with OAR 333-007-0410.
- (3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:
  - (a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and
  - (b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or
  - (c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.
- (4) A processor or processing site must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the

Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

(6) If a processor or a processing site has all usable marijuana used by the processor or processing site to make cannabinoid concentrate or extract tested for pesticides and only uses usable marijuana that has passed pesticide testing in accordance with OAR 333-007-0320 when making a cannabinoid concentrate or extract, the processor or processing site is only required to have the concentrate or extract tested for pesticides once a year.

(a) The Authority or the Commission will notify the processor or processing site on a random yearly basis which process lot must be tested for pesticides.

(b) A processor or processing site that is only required to test its cannabinoid concentrates or extracts for pesticides once a year under this section must maintain and retain documentation for at least two years that demonstrates that all usable marijuana used to make a cannabinoid concentrate or extract was tested for pesticides and that the usable marijuana passed pesticide testing.

(7) Nothing in this rule prohibits the Authority or the Commission from requesting that a processor or processing site have a concentrate or extract tested for pesticides, at any time.

(8) If a processor or processing site that is only required to test its cannabinoid concentrates or extracts for pesticides once a year under section (6) of this rule has a failed pesticide test, the processor or processing site must test the next five batches for pesticides.

(a) If any of those five batches fail pesticide testing, the processor or processing site must test every batch for pesticides for two months from the date of the first failed test.

(b) If the five batches pass pesticide testing the processor or processing site may return to yearly random testing.

(c) If during the two month period referenced in subsection (a) of this section any batch fails pesticide testing the processor or processing site must have every batch tested for pesticides, unless otherwise ordered by the Authority or Commission.

(d) If during the two month period all batches pass pesticide testing, the processor or processing site may return to yearly random testing in accordance with section (6) of this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0340**

#### **Compliance Testing Requirements for Cannabinoid Products Intended for Human Consumption or Ingestion and Cannabinoid Suppositories**

(1) A processor or processing site must test every process lot of a cannabinoid product intended for human consumption or ingestion, including cannabinoid edibles, capsules, and tinctures, and cannabinoid suppositories for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A processor or processing site must test a process lot for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0345

#### **Compliance Testing Requirements for Cannabinoid Topicals and Cannabinoid Transdermal Patches**

- (1) A processor or processing site must test every process lot of a cannabinoid topical or transdermal patch for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test a process lot of a cannabinoid topical or transdermal patch for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0350

#### **Batch Requirements for Compliance Testing**

- (1) Usable marijuana.
  - ~~(a) A producer or grower must separate each harvest lot into no larger than 10 pound batches.~~
  - ~~(b) Notwithstanding subsection (1)(a) of this rule, a producer or grower may combine harvest lots together for purposes of having a batch sampled if each batch is intended for use by a processor or processing site to make a cannabinoid concentrate or extract and each harvest lot was:
    - ~~(A) Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;~~
    - ~~(B) Harvested at the same time; and~~
    - ~~(C) If cured prior to sampling, cured under uniform conditions.~~~~
  - ~~(c) A producer or grower may not combine harvest lots into a batch for purposes of sampling and testing for THC or CBD.~~
  - ~~(d) If harvest lots are combined in accordance with subsection (1)(b) of this rule the batch must be labeled so that it identifies the different harvest lots that were combined.~~
- (2) Cannabinoid concentrates and extracts ~~and cannabinoid products.~~
  - (a) A process lot is considered a batch.
  - (b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that concentrate, extract or product for purposes of sampling and testing after a control study has been certified.
- (3) Cannabinoid products. A processor or processing site must separate process lots into not larger than 35,000 unit batches.
- (4) A grower and processing site must assign each batch a unique batch number and that unique batch number must be:
  - (a) Documented and maintained in the grower and processing site records for at least two years and available to the Authority upon request;

(b) Provided to the individual responsible for taking samples; and  
(c) Included on the batch label as required in OAR 333-007-0380.

(54) A grower and processing site may not reuse a unique batch number.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### 333-007-0360

#### Sampling and Sample Size Requirements for Compliance Testing

(1) Usable marijuana.

(a) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a processor or processing site to make a cannabinoid concentrate or extract.

(b) Sample increments taken must in total represent a minimum of 0.5 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in OAR 333-064-0100(2).

(c) A portion of sample increments taken from multiple batches of usable marijuana may be combined into one sample for purposes of testing for THC and CBD if the batches are the same strain, regardless of the size of the multiple batches.

(d) A portion of sample increments taken from multiple batches of usable marijuana may be combined into one sample for purposes of testing for pesticides if the multiple batches in total do not exceed 10 pounds. If the sample fails for pesticides all the batches from which sample increments were taken, fail.

(2) Cannabinoid concentrates, extracts and products.

~~(a) Unless a cannabinoid concentrate, extract or product has successfully passed process validation, The minimum number of sample increments that must be taken are established in Exhibit B, Table 5 or 6, incorporated by reference. e~~Enough sample increments from a batch must be taken to ensure that the required attributes in the batch to be tested are homogenous and must be taken in a manner consistent with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

~~(b) For If a cannabinoid concentrate or, extract that or product has successfully passed a control study, the minimum number of sample increments that must be taken for future batches of that concentrate or extract are established in Exhibit B, Table 7, incorporated by reference. process validation only a primary sample and- The sample increments may be combined into a primary sample and a field duplicate sample in accordance with OAR 333-007-0440 and must be taken from a batch in accordance with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2). Both the primary sample and the field duplicate sample must be tested and may not be combined.~~

(c) For a cannabinoid product that has successfully passed a control study, only one unit of sale chosen at random is required for the primary sample and only one unit of sale chosen at random is required for the field duplicate sample for future batches of that product in accordance with OAR 333-007-0440 and OAR 333-064-0100(2). Both the primary sample and the field duplicate sample must be tested and may not be combined.

(3) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.

[ED. NOTE: Tables referenced are not included in rule text. [Click here for PDF copy of table\(s\).](#)]

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0370**

#### **Sampling Personnel Requirements; Sampling Recordkeeping**

(1) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples.

(2) Sampling may be conducted at a licensee's or registrant's premises or the licensee or registrant may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.

~~(3) Laboratory personnel that perform sampling must:~~

~~(a) Follow the laboratory's accredited sampling policies and procedures;~~

~~(b) Follow chain of custody procedures consistent with TNI EL Standard VIM2 5.7 and 5.8; and~~

~~(c) After taking samples document the samples in accordance with OAR 333-064-0100(2) and if sampling for a licensee record the sampling and transfer information in the Commission's seed to sale system, as required by the Commission.~~

~~(4) A laboratory must maintain the documentation required in these rules for at least two years and must provide that information to the Authority upon request.~~

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0390**

#### **Standards for ~~Testing~~ Microbiological Contaminants Compliance Testing**

(1) A marijuana item required to be tested for microbiological contaminants under OAR 333-007-0320 to 333-007-0345 must be sampled using appropriate aseptic technique and tested by a laboratory for total coliform count.

(2) If a laboratory detects the presence of any coliforms the sample must be assessed for Escherichia coli (E. coli).

(3) A batch fails microbiological contaminant testing if the laboratory detects the presence of E. coli at more than 100 colony forming units per gram in a sample:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1).

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0400**

#### **Standards for ~~Testing~~ Pesticides Compliance Testing**

(1) A marijuana item required to be tested for pesticides must be tested by a laboratory for the analytes listed in Exhibit A, Table 3, incorporated by reference. [Table not included. See ED. NOTE.]

(2) A batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action levels listed in Exhibit A, Table 3 in a sample:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1). [Table not included. See ED. NOTE.]



(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.

[ED. NOTE: Tables referenced are not included in rule text. [Click here for PDF copy of table\(s\).](#)]

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0410**

#### **Standards for ~~Testing Solvents~~ Compliance Testing**

(1) A marijuana item required to be tested for solvents must be tested by a laboratory for the analytes listed in Exhibit A, Table 4 incorporated by reference.

(2) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) Detects the presence of a solvent above the action level listed in Exhibit A, Table 4 in a sample; or [Table not included. See ED. NOTE.]

(b) Calculates a RPD of more than 20 percent between the field primary result of the sample and the field duplicate result.

(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years

[ED. NOTE: Tables referenced are not included in rule text. [Click here for PDF copy of table\(s\).](#)]

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0420**

#### **Standards for ~~Testing Water Activity and Moisture Content~~ Compliance Testing**

(1) Usable marijuana must be tested by a laboratory for:

(a) Water activity; and

(b) Moisture content.

(2) If a sample has a water activity rate of more than 0.65 Aw the sample fails.

(3) If a sample has a moisture content of more than 15 percent the result must be reported to the licensee but the sample does not fail.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0430**

#### **Standards for THC and CBD Compliance Testing**

(1) A laboratory must test for the following when testing a marijuana item for potency:

(a) THC.

(b) THCA.

(c) CBD.

(d) CBDA.

(2) A process lot of a cannabinoid concentrate, extract or product that has not successfully completed ~~a control study~~process validation fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

- (a) The amount of THC, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 30 percent RSD; or
- (b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in package by over 5 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.
- (3) A process lot of a cannabinoid concentrate, extract or product that has successfully completed ~~a control study~~~~process validation~~ fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):
  - (a) The amount of THC, as calculated pursuant to OAR 333-064-0100, between the sample and the field duplicate exceeds 20 percent RPD; or
  - (b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in a package by over 5 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable
- (4) A sample cannot fail CBD testing.
- (5) Notwithstanding section (2)(a) and (3)(a) of this rule, a sample that has less than 5 mg of THC as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in section (2)(a) or (3)(a) of this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0440**

#### **Process ValidationControl Study**

- (1) A laboratory may perform ~~a control study~~~~process validation tests~~ on ~~a three consecutive~~ process lots of cannabinoid concentrates, extracts or products for a processor or processing site if the processor or processing site informs the laboratory, in writing:
  - (a) That sampling and testing is for the purposes of ~~a control study~~~~process validation~~; and
  - (b) For cannabinoid products, the expected THC range for the product.
- (2) Sample ~~increments~~ taken for purposes of ~~a control study~~~~process validation testing~~ may not be combined.
- (3) Sample ~~increments~~ ~~from a~~ cannabinoid concentrate ~~or and~~ extracts must be tested for:
  - (a) Pesticides in accordance with OAR 333-007-0400.;
  - (b) Solvents in accordance with OAR 333-007-0410.
- (4) Sample ~~increments~~ ~~from~~ ~~of a~~ cannabinoid products must be tested for THC concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.
- (5) During ~~a control study~~~~process validation~~ a batch passes:
  - (a) Pesticide testing if each sample increment is below the action limit established in OAR 333-007-0400.
  - (b) Solvent testing if:
    - ~~(A) Each sample increment~~ is below the action limit established in OAR 333-007-0410; and
    - ~~(B) The results above the LOQ are not greater than 30 percent RSD between samples.~~
  - (c) THC concentration testing if:
    - (A) The amount of THC, as calculated pursuant to OAR 333-064-0100, between sample ~~increments~~ taken from the batch does not exceed 30 percent RSD; and
    - (B) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100, does not exceed the maximum concentration limit permitted in a package by more than 5 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(6) A laboratory must identify on a form prescribed by the Authority if a batch undergoing a control study~~process validation~~ has passed for any of the following, and must send the form at the client's request to the Authority or the Commission:

(a) Pesticides, if applicable.

(b) Solvents, if applicable.

(c) THC concentration as calculated pursuant to OAR 333-064-0100, if applicable.

(7) A control study fails if:

(a) Any sample increment exceeds an action limit in OAR 333-007-0400 or 333-007-0410.

(A) A sample increment that exceeds an action limit may not be reanalyzed and retested under OAR 333-007-0450(1) unless the laboratory determines that the result is due to laboratory error and the laboratory error is ~~must be~~ reported to the Authority or the Commission.

(B) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400 or 333-007-0410 may not be remediated under OAR 333-007-0450(5)(a) or (7)(c) for purposes of passing the control study.

(C) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400 or 333-007-0410 may be remediated for purposes of selling or transferring the cannabinoid concentrate, extract or product, if permitted under OAR 333-007-0450, but sample increments from that batch may not be resubmitted for a control study.

(b) The amount of THC in a cannabinoid concentrate, extract or product, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch exceeds 30 percent RSD.

(c) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limit permitted in a package by more than 5 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(A) A batch that has a sample increment fail under subsections (b) or (c) of this section may not be re-mixed or re-packaged under OAR 333-007-0450(8)(a) or (b) for purposes of passing the control study.

(B) A batch that has a sample increment fail under subsections (b) or (c) of this section may be re-mixed or re-packaged for purposes of selling or transferring the cannabinoid concentrate, extract or product as permitted under OAR 333-007-0450(8)(a) or (b), but sample increments from that batch may not be resubmitted for a control study.

(8) A process lot sampled and tested for purposes of a control study~~process validation~~ may be sold or transferred if the sample ~~increments~~ pass all the required tests.

(9) If a cannabinoid concentrate, extract or product successfully passes a control study and the control study has been certified by the Authority or the Commission, as applicable, the following applies to sampling of future batches for one year:

(a) For cannabinoid concentrates and extracts, sample increments may be collected and combined into a primary sample and a field duplicate sample as described in OAR 333-007-0360, Exhibit B, Table 7, OAR 333-064-0100, ORELAP-SOP-002 Rev. 3.1.

(b) For cannabinoid products, at a minimum, one unit of sale must be collected, at random, for the primary sample, and one unit of sale must be collected at random for the field duplicate sample.

(c) Both the primary sample and the field duplicate sample must be tested and may not be combined.

(10) The certification of a control study is invalidated:

~~(a) If a processor or processing site A processor or processing site must undergo process validation for a product again or must have batches sampled and tested as if the product had not undergone process validation if makes any changes:~~

~~(Aa) TThere are any changes to the standard operating procedures for that product.~~

~~(Bb) There are any changes iIn the type of ingredient in the product.~~

~~(b) If a cannabinoid concentrate, extract or product fails a THC test under OAR 333-007-0430(3)(a).~~

~~(11) For purposes of subsection (10)(a) of this rule it is not considered a change to standard operating procedures or a change in the type of ingredient if the processor or processing site is using:~~

~~(a) Different ,except for a difference in the strains of usable marijuana in batches.~~

~~(b) An ingredient with a different level of purity as long as the purity of the ingredient complies with the Authority's or the Commission's processing rules.~~

~~(c) Different flavors or colors in batches, as long as the different flavors or colors do not have an effect on the potency of the product, or the purity of an ingredient.~~

~~(12) A processor or processing site does not qualify for reduced sampling and testing under a control study until either the Authority or Commission:~~

~~(a) Reviews documentation associated with the control study;~~

~~(b) Certifies the control study; and~~

~~(c) Notifies the laboratory and the processor that the control study is considered certified.~~

~~(9) Process validation is only valid for two years.~~

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0450**

#### **Failed Test Samples**

(1) If a sample, sample increment, or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.

(a) If a registrant or licensee wishes to have a sample reanalyzed, the registrant or licensee must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the registrant or licensee. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.

(b) If a registrant or licensee has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the registrant or licensee has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

(c) A registrant or licensee must inform the Authority or the Commission immediately, of the following, in a manner prescribed by the Authority or the Commission:

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated or sterilized in accordance with this rule; or

(b) If it is not or cannot be remediated or sterilized under this rule, must be destroyed in a manner specified by the Authority or the Commission.

(3) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.

(4) Failed microbiological contaminant testing.

(a) If a sample from a batch of usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(b) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.

(5) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampld and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.

(6) Failed water activity testing.

(a) If a sample from a batch of usable marijuana fails for water activity the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract; or

(B) Continue to dry or cure.

(b) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be sampled and tested in accordance with these rules.

(7) Failed pesticide testing.

(a) If a sample from a batch of usable marijuana fails pesticide testing the batch may not be remediated and must be destroyed as ordered in a manner approved by the Authority or the Commission, except as permitted under subsection (c) of this section. A batch may not be destroyed without obtaining permission from the Authority or the Commission.

(b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample of usable marijuana failed a pesticide test.

(c) If a sample from a batch of usable marijuana fails pesticide testing but only for the analytes piperonyl butoxide or pyrethrins, and the Oregon Department of Agriculture determines that only products from the Department's Guidelist for Pesticides and Cannabis were applied by the producer or grower and the product was applied in accordance with the label, the Authority or the Commission may permit the producer or grower to remediate the usable marijuana using procedures that would reduce the concentration of pesticides to less than the action level. A batch of usable marijuana that is permitted to be remediated must be re-sampled and re-tested for pesticides in accordance with these rules.

(d) If a processor or a processing site is only using usable marijuana that has passed pesticide testing under OAR 333-007-0320, in accordance with OAR 333-007-0330(6), and a sample from a batch of a cannabinoid concentrate or extract fails pesticide testing the batch may be remediated using procedures that would reduce the concentration of pesticides to less than the action level.

(e) A batch that is remediated in accordance with subsection (d) of this section must be sampled and tested in accordance with these rules. A batch that is remediated and after being re-sampled and re-tested fails pesticide testing must be destroyed as ordered by the Authority or the Commission.

(8) Failed potency testing.

(a) A marijuana item that fails potency testing under OAR 333-007-0430(2)(~~ba~~) or (3)(~~ba~~) may be repackaged in a manner that enables the item to meet the concentration limit standards in OAR 333-007-~~0210430(2)(a) or (3)(a)~~ and 333-007-0220, as applicable. A marijuana item that is repackaged in accordance with this subsection must be re-sampled and tested in accordance with these rules.

~~(b) A marijuana item that is repackaged in accordance with this section must be sampled and tested in accordance with these rules.~~ A marijuana item that fails potency testing under OAR 333-007-0430(2)(a) or (3)(a) may be re-mixed in an effort to meet the standards in OAR 333-007-0430(2)(a) or (3)(a). A marijuana item that is re-mixed must be re-sampled and re-tested in accordance with these rules.

(9) If a sample fails a test after undergoing remediation or sterilization as permitted under this rule the batch must be destroyed in a manner approved by the Authority or the Commission.

~~(10) An Authority representative must witness the destruction of a batch if destruction is required by this rule.~~

~~(11) A registrant must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.~~

~~(12)~~ A registrant must, as applicable:

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

(12) If a batch fails a test under these rules a registrant:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.



Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0480**

#### **Audit and Random Testing**

(1) The Authority may require a registrant to submit samples identified by the Authority to a laboratory of the registrant's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-050490, ~~and may require additional testing that is not required by these rules.~~

(2) A laboratory doing audit testing under section (1) of this rule 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.~~

(3) The Authority may, at any time, require a registrant to permit the sampling of or submit a sample of a marijuana item to the Authority for testing. Such testing may include testing for:

(a) Any microbiological contaminant.

(b) Heavy metals.

(c) Other contaminants that may pose a risk to public health and safety must establish a process for the random testing of marijuana items for microbiological contaminants that ensures each registrant tests every product for microbiological contaminants at least once a year.

(4) Any testing ordered under this rule must be paid for by the registrant.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0490**

#### **Waiver of Sampling and Testing Requirements**

~~(1) Solvent testing-~~

~~(a) The Commission or the Authority may, upon receipt of a written request from a licensee or registrant, waive a requirement that every batch of a process lot be tested for solvents, if the licensee or registrant can demonstrate that none of the batches from any of the previous four process lots tested failed a solvent test.~~

~~(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.~~

~~(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver and how long the waiver will be in effect.~~

~~(d) If the Commission or the Authority waives the testing requirement the licensee or registrant is subject to random testing and the Commission or the Authority shall notify the licensee or registrant when a process lot must be tested in accordance with these rules.~~

~~(2) Sampling-~~

~~(a) The Commission or the Authority may, upon receipt of a written request from a processor or processing site waive the sampling requirements in OAR 333-007-0360(2)(a) for a particular product if the processor processing site:~~

~~(A) Can demonstrate that none of the batches from any of the previous four process lots tested failed any test;~~

~~(B) Submits to the Commission or the Authority detailed processing standard operating~~

~~procedures that demonstrate the product is uniform and uniform from process lot to process lot;~~

~~(C) Can demonstrate that it has and follows quality control measures; and~~

~~(D) Can demonstrate that subjecting a product to process validation under OAR 333-007-0440 is cost prohibitive.~~

~~(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.~~

~~(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver, how long the waiver will be in effect, and the sampling that is required of the product for which the waiver was approved.~~

~~Stat. Auth.: ORS 475B.555~~

~~Stats. Implemented: ORS 475B.555~~

### **333-007-0500**

#### **Quality Control and Research and Development Testing**

(1) A registrant or a licensee may request that a laboratory conduct testing for the purpose of assuring quality control or for research and development, except as provided in section (2) of this rule.

(2) A grower or producer may not request that a laboratory conduct pesticide testing on usable marijuana for the purpose of quality control or for research and development. A pesticide test on usable marijuana is considered by the Authority and the Commission to be a compliance test.

(3) A registrant or licensee that submits a marijuana item for quality control or research and development testing is not subject to OAR 333-007-0320 to 333-007-0470.

(4) A laboratory result from a quality control or research and development test cannot be used as a compliance test result and a marijuana item that has only undergone a quality control or research and development test may not be transferred or sold, unless the marijuana item is not required to have a compliance test before being transferred or sold.

(5) Registrants and licensees must maintain and retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Authority or the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-2000**

#### **OLCC Licensee Pesticide Testing Requirements**

(1) Notwithstanding OAR 333-007-0320, the Commission may establish the frequency of pesticide testing required by a producer or wholesaler as long as at least 20 percent of the batches in a harvest lot are tested. The producer or wholesaler must permit the laboratory that conducts the sampling to choose the batches to sample from and may not direct the laboratory to sample from specific batches.

(2) If any sample taken from a batch in accordance with section (1) of this rule fails a pesticide test, every batch from the harvest lot must be tested for pesticides.

(3) If all samples from each randomly chosen batch of a harvest lot pass pesticide testing, the entire harvest lot is considered to have passed pesticide testing and may be transferred or sold.

(4) Nothing in this rule is intended to change the requirement that a processor who qualifies for yearly random testing must have all usable marijuana tested for pesticides and may only use usable marijuana that has passed pesticide testing in the processor's cannabinoid concentrates or extracts.

Stat. Auth.: ORS 475B.555

## DIVISION 8

### MEDICAL MARIJUANA

#### **333-008-0033**

##### **Approval of New or Renewal PRMG and Grow Site Application; Change of PRMG**

(1) The Authority must register a PRMG and a grow site address listed on an application if:

(a) The PRMG:

(A) Meets the age requirements;

(B) Passes the criminal background check;

(C) Has not violated a provision of ORS 475B.400 to 475B.525, ORS 475B.580, ORS 475B.650, OAR chapter 333, division 7, these rules, or an ordinance adopted pursuant to ORS 475B.500; and

(D) Pays the applicable fee.

(b) The grow site address does not exceed the plant limits in ORS 475B.428(3) or (4).

(2) If the Authority registers a marijuana grow site it will issue an identification card and a grow site registration card that contains at least the following information:

(a) The PRMG's name, address, date of birth, and identification card number.

(b) The effective date, date of issuance, and expiration date of the identification card.

(c) The grow site address.

(d) The patient's registry identification card number.

(3) A PRMG, except for a patient growing only for him or herself at his or her residence who is not transferring usable marijuana, seeds or immature plants to a registered processing site or dispensary, must create an online account with the Authority through which the individual must at a minimum submit the information required in OAR 333-008-0630.

(4) ~~The Authority must notify a~~ PRMG is responsible for knowing how many at the time the grow site is registered the current number of mature marijuana plants are legally permitted at the grow site address.

(5) The Authority shall also notify a patient if the PRMG and grow site address has been approved.

(6) The Authority may only register one grow site per patient, and may only register grow sites in Oregon.

Stat. Auth.: ORS 475B.420, 475B.525

Stats. Implemented: ORS 475B.420

#### **333-008-0550**

##### **General Person Responsible for a Marijuana Grow Site Requirements**

(1) A PRMG may not grow marijuana for more than four patients at any one time.

(2) A PRMG must display a marijuana grow site registration card at the marijuana grow site at all times for each patient for whom marijuana is being produced.

(3) All seeds, immature marijuana plants, mature marijuana plants and usable marijuana associated with the production of marijuana for a patient by a PRMG are the property of the patient and must be provided to the patient upon request, unless the patient has assigned a

portion of the right to possess the seeds, immature plants and usable marijuana to the PRMG in accordance with ORS 475B.425.

(4) All marijuana produced for a patient must be provided to the patient or designated primary caregiver when the PRMG ceases producing marijuana for the patient, unless the patient has assigned a portion of the right to possess the seeds, immature plants and usable marijuana to the PRMG in accordance with ORS 475B.425.

(5) All usable marijuana associated with the production of marijuana for a patient must be transferred to a marijuana processing site upon the patient's request.

(6) All seeds, immature marijuana plants and usable marijuana associated with the production of marijuana for a patient must be transferred to a medical marijuana dispensary upon the patient's request.

(7) If a patient terminates the designation of a PRMG that PRMG may not be designated to produce marijuana by another patient unless the grow site address is authorized to have no more than 48 mature marijuana plants.

(8) A PRMG must return the grow site registration card to the Authority when the person's designation has been terminated by a patient or the person ceases producing marijuana for him or herself or another patient.

(9) A PRMG registered with the Authority, except for a patient growing only for him or herself at his or her own residence and not transferring usable marijuana, seeds or immature plants to a registered processing site or dispensary, must create an online account with the Authority through which the individual must at a minimum submit the information required in OAR 333-008-0630.

(10) A PRMG must comply with the advertising restrictions in OAR 333-008-2070 and must remove any sign, display or advertisement if the Authority determines the PRMG has violated OAR 333-008-2070.

(11) On and after July 1, 2017, a PRMG who transfers or sells usable marijuana to a registered processing site or sells or transfers seeds, immature plants or usable marijuana to a registered dispensary must own, maintain and use a weighing device that is licensed by the Oregon Department of Agriculture. Licensed weighing devices must be used by a PRMG whenever marijuana items are:

(a) Transferred to or from the PRMG to a registered processing site or dispensary and the transfer is by weight;

(b) Packaged for transfer by weight to a registered processing site or dispensary; or

(c) Weighed for purposes of documenting information required in OAR 333-008-0630 for transfers to registered processing sites or dispensaries.

(12) A PRMG may only use pesticides in accordance with ORS chapter 634 and OAR chapter 603, division 57.

(13) The Authority may investigate any violation of this rule based on:

(a) A failed pesticide test;

(b) Information provided by any other state agency;

(c) A grow site inspection; or

(d) The receipt of a complaint alleging unlawful pesticide use.

(14) If the Authority determines that a violation of section (12) of this rule has occurred, it may provide information obtained by the Authority to the Oregon Department of Agriculture in accordance with ORS 475B.460(5).

Stat. Auth.: ORS 475B.420 - 475B.428 & 475B.525  
Stats. Implemented: ORS 475B.420 - 475B.428

### **333-008-0570**

#### **Designation of Plants at Grow Site Address**

(1) A PRMG producing marijuana at a grow site where multiple PRMGs are registered must:  
(a) Physically identify the marijuana plants at a grow site address that are being grown by that PRMG by either:

(A) Tagging each marijuana plant with the PRMG's name, identification card number and patient identification number; or

(B) Fencing or cordoning off the PRMG's marijuana plants and posting all grow site registration cards at the location where the plants are located; or

(b) Post a plot plan or graphic matrix depicting the plant layout configuration within the grow site and the PRMG and patient associated with each plant. For purposes of such grow site mapping, a keyed or alphanumeric legend must be included that includes means to confirm the assigned PRMG name and identification number and the patient name and identification number for each plant.

(2) If during an investigation the Authority determines that marijuana plants have not been designated by a PRMG in accordance with section (1) of this rule or there are marijuana plants at the grow site designated by an individual who is not authorized to produce marijuana at that grow site the Authority may suspend or revoke the registration of the grow site address for all PRMGs at that grow site and all the PRMG's identification cards.

(3) If during an investigation the Authority determines that a PRMG is producing marijuana plants in excess of the number of plants allowed in ORS 475B.428 the Authority may suspend or revoke the registration of the PRMG for each patient who has designated the PRMG.

(4) Each PRMG registered at a grow site is jointly and severally responsible for ensuring compliance with ORS 475B.428.

Stat. Auth.: ORS 475B.428, 475B.525  
Stats. Implemented: ORS 475B.428

### **333-008-0600**

#### **PRMG Labeling, Packaging and Testing Requirements**

On and after October 1, 2016, a PRMG who transfers usable marijuana to a registered processing site or dispensary must comply with the labeling requirements in OAR 333-007-0010 to 333-007-0100, the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060, and the testing requirements in OAR 333-007-0300 to 333-007-050490, including but not limited to assigning and documenting a unique batch number for each batch of usable marijuana, and providing that batch number to registered processing sites and dispensaries at the time of transfer or sale.

Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-008-0650**

#### **Pesticides**

(1) A PRMG may only use pesticides in accordance with ORS Chapter 634 and OAR chapter 603, division 57.

~~(2) The Authority may investigate any violation of this rule based on:~~

~~(a) A failed pesticide test received on or after October 1, 2016;~~

~~(b) Information provided by any other state agency;~~

~~(c) A grow site inspection; or~~

~~(d) The receipt of a complaint alleging unlawful pesticide use.~~

~~(3) If the Authority determines that a violation of this rule has occurred, it may provide information obtained by the Authority to the Oregon Department of Agriculture.~~

~~Stat. Auth.: ORS 475B.420, 475B.525, 475B.555—~~

~~Stats. Implemented: ORS 475B.420, 475B.555~~

### **333-008-1020**

#### **Medical Marijuana Dispensaries: Application for Medical Marijuana Dispensary Registration**

(1) To register a medical marijuana dispensary a person must:

(a) Submit an initial application on a form prescribed by the Authority that includes but is not limited to:

(A) The name of the individual who owns the dispensary or, if a business entity owns the dispensary, the name of each individual who has a financial interest in the dispensary;

(B) The name of the individual or individuals responsible for the dispensary, if different from the name of the individual who owns the dispensary, with one of the individuals responsible for the dispensary identified as the primary PRD;

(C) The physical and mailing address of the medical marijuana dispensary; and

(b) Application and registration fee.

(2) An initial application for the registration of a dispensary must be submitted electronically via the Authority's website, [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp).

(3) If an initial application is submitted along with the required fees the Authority will notify the applicant in writing that the application has been received and that within 30 calendar days of the date the written notice is mailed or sent electronically the following information must be received by the Authority:

(a) For each individual named in the application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and

(C) An Individual History Form and any information identified in the form that is required to be submitted;

(b) A written statement from an authorized official of the local government that the proposed location of the dispensary is not located in an area that is zoned for residential use as that term is defined in OAR 333-008-0010;

(c) Proof that the business is registered or has filed an application to register as a business with the Oregon Office of the Secretary of State, including proof of registration for any DBA (doing business as) registration;

(d) Documentation, in a format prescribed by the Authority that the proposed location of the dispensary is not within 1,000 feet of:

(A) The real property comprising a public or private elementary or secondary school, except as provided in Oregon Laws 2016, chapter 83, section 29; or



- (B) A registered dispensary.
- (e) A scaled site plan of the parcel on which the premises proposed for registration is located, including:
- (A) Cardinal directional references;
  - (B) Bordering streets and the names of the streets;
  - (C) Identification of the building or buildings in which the proposed dispensary is to be located;
  - (D) The dimensions of the proposed premises of the dispensary;
  - (E) Identification of other buildings or property owned by or under the control of the applicant on the same parcel or tax lot as the premises proposed for registration that will be used in the business; and
  - (F) Identification of any residences on the parcel or tax lot.
- (f) A scaled floor plan of all enclosed areas of the premises at the proposed location that will be used in the business with ~~clear identification of the overall dimensions of the dispensary and the dimensions of interior rooms and spaces, a description of the intended uses of all spaces and clear identification and location of:~~
- ~~(A) Walls;~~
  - ~~(B) Partitions;~~
  - ~~(C) Counters;~~
  - ~~(D) Windows;~~
  - ~~(E) Safes;~~
  - ~~(F) All areas of ingress and egress; intended uses of all spaces and a~~
  - ~~(G) All limited access areas;~~
  - ~~(H) Secure rooms; and~~
  - ~~(I) Designated limited access areas or designated areas required under OAR 333-08-1110(12);~~
- and
- (g) Documentation that shows the applicant has lawful possession of the proposed location of the dispensary.
- (4) The documentation required in section (3) of this rule may be submitted electronically to the Authority or may be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293.
- (a) If documentation is mailed it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the initial application was received or the application will be considered incomplete.
- (b) If documentation is submitted electronically it must be received by the Authority by 5 p.m. Pacific Time within 30 calendar days of the date the Authority mailed the notice to the applicant that the initial application was received or the application will be considered incomplete.
- (5) Application and registration fees must be paid online at the time of application.
- (6) Criminal background check fees must be paid by check or money order and must be mailed to the Oregon Medical Marijuana Program, PO Box 14116, Portland, OR 97293, and must be received by the Authority in accordance with provisions in section (4) of this rule.
- (7) If the Authority does not receive a complete application, including all documentation required in sections (1) and (3) of this rule, and all required fees within the time frames established in this rule, the application will be ~~considered declared~~ incomplete.
- (8) If an applicant provides the documentation required in section (3) of this rule the Authority will review the information to determine if it is ~~completesufficient~~.

(a) If the documentation required under section (3) of this rule is not complete or is insufficient the Authority must notify the applicant in writing and the applicant will have 10 calendar days from the date such written notice is mailed or sent electronically by the Authority to provide the additional documentation.

(b) If the applicant does not provide the additional documentation within 10 calendar days or if any responsive documents are incomplete, insufficient or otherwise do not demonstrate compliance with ORS 475B.450 and these rules the application will be declared incomplete.

(9) A person who wishes to register more than one location must submit a separate application, registration fees, and all documentation described in sections (1) and (3) of this rule for each location.

(10) An application that is declared incomplete is treated by the Authority as if it was never received.

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1030**

#### **Dispensary Fees**

(1) The initial fees for the registration of a dispensary are:

(a) A non-refundable application fee of \$500; and

(b) A \$3,500 registration fee.

(2) The annual renewal fees for the registration of a dispensary are:

(a) A \$500 non-refundable renewal fee; and

(b) A \$3,500 registration fee.

(3) The criminal background check fee is \$35 per individual.

(4) The Authority must return the registration fee if:

(a) An application is incomplete; or

(b) An applicant withdraws an application.

(5) The Authority may return the registration fee if an application is denied.

(6) For an application received on or after [insert effective date of rule] the Authority may not refund a registration fee if the Authority has issued the applicant a 60-day letter under OAR 333-008-1040(6) and the applicant subsequently withdraws the application or the applicant does not comply with the 60-day deadline under OAR 333-0080-1040(7).

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1070**

#### **Expiration and Renewal of Dispensary Registration**

(1) A dispensary's registration expires one year following the date of application approval.

(2) A dispensary registrant must submit not more than 90 but at least 30 calendar days before the registration expires:

(a) A renewal application on a form prescribed by the Authority;

(b) Renewal fees;

(c) For each individual named in the renewal application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020;

(C) An Individual History Form and any information identified in the form that is required to be submitted; and

(d) Current proof of business registration with the Secretary of State, including all DBA (doing business as) registrations;

~~(e) Documentation that shows the applicant has lawful possession of the location of the registered dispensary;~~

~~(f) Any information required during an initial application; and~~

~~(g) A current scaled floor plan of all enclosed areas at the registered dispensary that are used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, and all limited access areas.~~

(3) A dispensary registrant who files a completed renewal application, fees and all the information required in section (2) of this rule with the Authority prior to the expiration date of the registration may continue to operate, even after the registration expiration date, pending a decision on the renewal application by the Authority.

(4) A dispensary registrant that does not submit timely renewal application, fees, and all the information required under ~~documentation in accordance with sections (1) and (2)~~ of this rule may be denied or subject to the imposition of civil penalties.

(5) The Authority may notify a dispensary registrant who, prior to the registration's expiration, submits an incomplete application and may give the registrant 10 calendar days to submit the missing information. The Authority may deny the renewal application of a registrant who fails to comply with this section.

~~If a dispensary registrant does not submit all the forms, fees and information required in section (2) of this rule prior to the registration's expiration, the registration is expired and is no longer valid.~~

(6) Renewals will be processed in accordance with OAR 333-008-1040 to 333-008-1060, as applicable.

(7) A renewal applicant may be required to submit a Readiness Form, as described in OAR 333-008-1040 and may be subject to inspection prior to the Authority acting on a renewal application.

(8) For purposes of this rule a renewal application is considered complete when the Authority receives the completed application form, fees and information required in section (2) of this rule. ~~a completed application shall be deemed submitted upon receipt by the Authority of all application forms, supporting documents and renewal fees described in section (2) of this rule.~~

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1200**

#### **Medical Marijuana Dispensaries: Operation of Registered Dispensaries**

(1) Policies and Procedures. In order to obtain a registration and to retain registration a dispensary registrant must have written detailed policies and procedures and training for employees on the policies and procedures that, at a minimum, cover the following:

(a) Security;

(b) Transfers of marijuana items to and from the dispensary;

(c) Operation of a registered dispensary;

(d) Required record keeping;

- (e) Testing requirements, including review of testing results prior to accepting transfers of marijuana items;
  - (f) Packaging and labeling requirements;
  - (g) Employee training;
  - (h) Compliance with these rules, including but not limited to violations and enforcement; and
  - (i) Roles and responsibilities for employees and PRDs in assisting the Authority during inspections or investigations.
- (2) Employees. A registered dispensary may employ an individual between the ages of 18 and 20 if the individual is a patient. Otherwise, dispensary employees must be 21 years of age or older.
- (3) Standardized Scales. In order to obtain a registration and to retain registration a dispensary registrant must own, maintain on the premises and use a weighing device that is licensed by the Oregon Department of Agriculture. Licensed weighing devices must be used by a registered dispensary whenever marijuana items are:
- (a) Transferred to or from the dispensary and the transfer is by weight;
  - (b) Packaged for transfer by weight; or
  - (c) Weighed for purposes of documenting information required in OAR 333-008-1230, 333-008-1245, 333-008-1247 and 333-008-1248.
- (4) Inventory Tracking and Point of Sale System: In order to obtain a registration and to retain registration a registered dispensary must have an installed and fully operational integrated inventory tracking and point of sale system that can and does, at a minimum:
- (a) Produce bar codes or similar unique identification numbers for each marijuana item lot transferred to a registered dispensary;
  - (b) Trace back or link each transfer of a marijuana item to a patient or caregiver to the marijuana item lot;
  - (c) Capture all information electronically that is required to be documented in OAR 333-008-1230 and 333-008-1245;
  - (d) Generate inventory, transaction, and transfer reports viewable in excel format; and
  - (e) Produce all the information required to be submitted to the Authority pursuant to OAR 333-0080-1248.
- (5) Online Verification of Registration Status. A dispensary must verify an individual's registration status with the Authority when receiving or making the transfer of a marijuana item if the Authority has available an online system for such verification.
- (6) Inventory On-Site. Marijuana items must be kept on-site at the dispensary. The Authority may take enforcement action against a dispensary registrant if during an inspection a dispensary registrant cannot account for its inventory or if the amount of usable marijuana at the registered dispensary is not within five percent of the documented inventory.
- (7) Testing. A dispensary registrant may not:
- ~~(a) Accept a transfer of a marijuana item that has not been tested in accordance with OAR 333-007-0300 to 333-007-050490 or that has failed a test under OAR 333-007-0450.~~
  - ~~(b) Transfer a marijuana item that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490 or that has failed a test under OAR 333-007-0450 unless it was transferred to the dispensary prior to October 1, 2016 and is labeled in accordance with OAR 333-007-0300(5).~~
  - ~~(c) Transfer a marijuana item that was received prior to October 1, 2016, that has not been tested in accordance with OAR 333-007-0300 to 333-007-0490, after December 31, 2016.~~
- (8) Packaging and Labeling. A dispensary may not accept a transfer of a marijuana item or transfer a marijuana item that does not comply with the labeling requirements in OAR 333-007-

0010 to 333-007-0100, or that does not comply with the packaging requirements in OAR 845-025-7000 to 845-025-7020 and 845-025-7060.

(9) Oregon Department of Agriculture Licensure. ~~A~~~~On and after January 1, 2017,~~ a registered dispensary that sells or handles food, as that term is defined in ORS 616.695, or a cannabinoid concentrate, extract or product intended for human consumption as that term is defined in OAR 333-007-0020 ~~edibles~~, must be licensed by the Oregon Department of Agriculture under ORS 616.706.

(10) Industrial Hemp Products.

(a) A dispensary may only accept the transfer of and may only transfer a product that contains THC or CBD that is derived from marijuana.

(b) Nothing in this section prohibits a dispensary from buying or selling hemp products not intended for human application, consumption, inhalation, ingestion, or absorption, such as hemp clothing.

(11) Tobacco and Nicotine. A dispensary may not offer or sell tobacco or nicotine products in any form including, but not limited to, loose tobacco, pipe tobacco, cigarettes as defined in ORS 323.010, ~~and~~ cigarillos as that is defined in OAR 333-015-0030, liquid nicotine containers as that is defined in OAR 333-007-0305 or pre-filled nicotine inhalant delivery devices.

(12) For purposes of this rule "marijuana item lot" means a quantity of seeds, immature plants, usable marijuana, medical cannabinoid products, concentrates or extracts transferred to a registered dispensary at one time and that is from the same harvest lot or process lot as those terms are defined in OAR 333-007-0020.

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1205**

#### **Registered Dispensary Signage**

(1) In order to obtain a registration and to retain registration a dispensary registrant must post:

(a) At every entrance to the dispensary:

(A) ~~If a dispensary does not participate in limited marijuana retail sales a sign that reads "Medical Marijuana Patients Only" ;~~

(B) ~~If a dispensary is permitted to sell limited marijuana retail products in accordance with OAR 333-008-1500, signs that comply with OAR 333-008-1500 and 333-008-1501(1)(b); and~~  
(C) "No On-Site Consumption of Marijuana".

(b) At all areas of ingress to a limited access area signs that reads:

(A) "Restricted Access Area — Authorized Personnel Only".

(B) "No Minors Allowed".

(c) At all areas of ingress to a point of sale area a sign that reads: "Restricted Access Area — No Minors Allowed".

(d) At the point of sale, the following posters prescribed by the Authority, measuring 22 inches high by 17 inches wide that can be downloaded at [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp):

(A) A Pregnancy Warning Poster; and

(B) A Poisoning Prevention Poster.

(2) All signs required by this rule must be:

(a) Legible, not less than 8 1/2 inches by and 11 inches, composed of letters not less than one-half inch in height;

(b) In English and Spanish, if a Spanish version is available through the Authority; and

(c) Posted in a conspicuous location where the signs can be easily read by individuals entering or on the dispensary premises.

(3) All signs may be downloaded at [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp).

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1220**

#### **Labeling**

~~(1) This rule is in effect from March 1, 2016, until October 1, 2016. Nothing in this rule prohibits a dispensary from complying with the labeling rules in OAR 333-007-0010 to 333-007-0100 prior to October 1, 2016.~~

~~(2) Prior to transferring a marijuana item a PRD must ensure that a label is affixed to the marijuana item that includes but is not limited to:~~

~~(a) Usable marijuana:~~

~~(A) Percentage of THC and CBD;~~

~~(B) Weight in grams;~~

~~(C) Testing batch number and date tested;~~

~~(D) Who performed the testing; and~~

~~(E) Description of the product (strain).~~

~~(b) Seeds:~~

~~(A) Weight in grams; and~~

~~(B) Description of the product (strain).~~

~~(c) Immature plants: Description of the product (strain).~~

~~(d) Marijuana items other than usable marijuana, seeds or immature plants:~~

~~(A) THC and CBD potency expressed as a percentage of weight or volume;~~

~~(B) The weight or volume of usable marijuana in the product in grams, milligrams, or milliliters, as applicable;~~

~~(C) Testing batch number and date tested;~~

~~(D) Who performed the testing; and~~

~~(E) Warning label in accordance with section (3) of this rule.~~

~~(3) If the registered facility transfers a cannabinoid product, concentrate or extract the PRD must ensure it has a warning label on the outside of the packaging that includes the following:~~

~~"WARNING: MEDICINAL PRODUCT—KEEP OUT OF REACH OF CHILDREN" in bold capital letters, in a font size that is larger than the type size of the other printing on the label such that it is easy to read and prominently displayed on the product.~~

~~Stat. Auth.: ORS 475B.450 & 475B.525—~~

~~Stats. Implemented: ORS 475B.450—~~

### **333-008-1230**

#### **Medical Marijuana Dispensaries: Transfers to a Registered Dispensary**

(1) Transfer of Usable Marijuana, Seeds and Immature Plants. A patient, caregiver, or PRMG may transfer usable marijuana, seeds and immature plants produced by a PRMG to a registered dispensary, subject to the requirements in this rule.

(a) A registered dispensary may only accept a transfer of usable marijuana, seeds or immature marijuana plants from a caregiver or PRMG if the individual transferring the usable marijuana, seeds or immature plants provides the original or a copy of a valid:



- (A) Authorization to Transfer form prescribed by the Authority; or
- (B) Personal agreement as that is defined in OAR 333-008-0010.
- (b) Authorization to Transfer Forms. In order to be valid an Authorization to Transfer form must include at least:
  - (A) The patient's name, OMMP card number or receipt number and expiration date and contact information;
  - (B) The name and contact information of the individual who is authorized to transfer the usable marijuana, seeds or immature marijuana plants to the registered dispensary and that individual's OMMP card number and expiration date;
  - (C) The name and address of the registered dispensary that is authorized to receive the usable marijuana, seeds or immature marijuana plants; and
  - (D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card.
- (c) Personal Agreements. In order to be valid a personal agreement must include at least:
  - (A) The patient's name, OMMP card number and expiration date and contact information;
  - (B) The name and contact information of the PRMG to whom the patient's property rights have been assigned and the producer's OMMP card number and expiration date, and the grow site address;
  - (C) The portion of the patient's rights to possess seeds, immature plants and usable marijuana that is being assigned to the producer.
- (2) A registered dispensary may accept the transfer of usable marijuana from a producer licensed by the Commission under ORS 475B.070 who is also registered by the Commission to produce marijuana for a patient. The Commission licensed producer must provide the registered dispensary with:
  - (a) Proof of licensure under ORS 475B.070; and
  - (b) A copy of the patient agreement as described in OAR 845-025-2510.
- (3) Transfer of medical cannabinoid products, concentrates, and extracts.
  - ~~(a) Beginning October 1, 2016, until January 1, 2017, a registered dispensary may accept the transfer of a medical cannabinoid product or concentrate from an applicant that has submitted a complete application for registration of a marijuana processing site.~~
  - ~~(b) On and after January 1, 2017, a A registered dispensary may only accept a transfer of a medical cannabinoid product, concentrate or extract from a registered medical marijuana processing site.~~
  - ~~(c) Beginning October 1, 2016, until January 1, 2017, a registered dispensary may accept the transfer of a medical cannabinoid extract from an applicant that has submitted a complete application for registration of a marijuana processing site.~~
- ~~(3) A registered dispensary may only accept a transfer of cannabinoid products, concentrates or extracts from registered processing site if it~~The individual transferring the products, concentrates or extracts must provides the dispensary with a Processing Site Authorization to Transfer form prescribed by the Authority. In addition to retaining a copy of the Processing Site Authorization to Transfer form the dispensary must obtain a copy of the photo identification of the individual transferring the cannabinoid product, concentrate or extract as required in paragraphsection
- (4)(b)(B) of this rule.
- (4) Transfer Records. At the time a marijuana item is transferred to a dispensary the dispensary registrant must:
  - (a) Document, on a form prescribed by the Authority, as applicable:

- (A) The weight in metric units of all usable marijuana received by the registered dispensary;
  - (B) The number of seeds and immature plants received by the registered dispensary;
  - (C) The amount of a medical cannabinoid product, concentrate, or extract received by the registered dispensary, including, as applicable, the weight in metric units, or the number of units;
  - (D) The name of the marijuana item;
  - (E) The date the marijuana item was received;
  - (F) The harvest or process lot numbers, and batch numbers; and
  - (G) The amount paid by the registered dispensary.
- (b) Obtain and maintain a copy of, as applicable:
    - (A) Documents required in sections (1) and (2) of this rule including the date it was received;
    - (B) The photo identification of the individual transferring the marijuana item to the dispensary, if such a copy is not already on file;
    - (C) The OMMP card of the individual transferring usable marijuana, seeds or immature plants;
    - (D) The medical marijuana processing site registration; and
    - (E) Test results for marijuana items transferred to the dispensary.
  - (c) Review laboratory testing results and confirm that the:
    - (A) Test results are associated with the marijuana items being transferred; and
    - (B) Marijuana item has passed all required testing.
- (5) Nothing in these rules requires a dispensary registrant to accept a transfer of a marijuana item.
- (6) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system or the electronic data management system described in OAR 333-008-1247.

Stat. Auth.: ORS 475B.450 & 475B.525

Stats. Implemented: ORS 475B.450

### **333-008-1245**

#### **Transfers From a Registered Dispensary to a Patient or Designated Primary Caregiver**

- (1) A dispensary registrant must, prior to permitting an individual to enter a point of sale area on the dispensary premises, ~~except as permitted under OAR 333-008-1500,~~ verify that the individual is a current patient or designated primary caregiver.
- (2) A registered dispensary must, prior to transferring a marijuana item to a patient or a designated primary caregiver:
  - (a) Verify the individual is currently registered with the Authority by viewing the individual's government issued photo identification and Authority issued patient or caregiver card, or the patient's receipt, as described in OAR 333-008-0023(6) or OAR 333-008-0040(5) and making sure the identities match.
  - (b) Obtain and retain, if not already on file, a copy of the patient's or caregiver's:
    - (A) OMMP identification card or receipt; and
    - (B) Government issued photo identification.
  - (c) Document:
    - (A) The name, OMMP card number and expiration date of the card of each person to whom the registered facility transfers a marijuana item;
    - (B) If the marijuana item was transferred to a designated primary caregiver, the patient's name and registration number for whom the caregiver was receiving the transfer;
    - (C) The amount of usable marijuana transferred in metric units, if applicable;

- (D) The number of seeds or immature plants transferred, if applicable;
  - (E) The amount of a medical cannabinoid product concentrate, or extract, if applicable;
  - (F) The brand name of the marijuana item and a description of what was transferred;
  - (G) The date of the transfer; and
  - (H) The amount of money paid by the patient or designated primary caregiver for the transfer.
- (3) A dispensary registrant may not transfer at any one time to a patient or designated primary caregiver, within one day, more than:
- (a) 24 ounces of usable marijuana;
  - (b) 16 ounces of a medical cannabinoid product in solid form;
  - (c) 72 ounces of a medical cannabinoid product in liquid form;
  - (d) 16 ounces of a cannabinoid concentrate whether sold alone or contained in an inhalant delivery system;
  - (e) Five grams of a cannabinoid extract whether sold alone or contained in an inhalant delivery system;
  - (f) Four immature marijuana plants; and
  - (g) 50 seeds.
- (4) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system or the electronic data management system described in OAR 333-008-1247.
- Stat. Auth.: ORS 475B.450 & 475B.525  
Stats. Implemented: ORS 475B.450

### **333-008-1248**

#### **Registered Dispensary Reporting to the Authority**

- (1) On and after June 1, 2016, a PRD must submit to the Authority electronically in a manner specified by the Authority, by the 10th of each month, the following information:
- (a) The amount of usable marijuana transferred to and by the medical marijuana dispensary during the previous month.
  - (b) The amount and type of medical cannabinoid products transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:
    - (A) Cannabinoid edibles;
    - (B) Cannabinoid topicals;
    - (C) Cannabinoid tinctures;
    - (D) Cannabinoid capsules;
    - (E) Cannabinoid suppositories;
    - (F) Cannabinoid transdermal patches and
    - (G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.
  - (c) The amount and type of cannabinoid concentrates transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:
    - (A) Cannabinoid concentrate in solid form; and
    - (B) Cannabinoid concentrate in liquid form.
  - (d) The amount and type of cannabinoid extracts transferred to and by the medical marijuana dispensary during the previous month. For purposes of this section "type" means:
    - (A) Cannabinoid extract in solid form; and
    - (B) Cannabinoid extract in liquid form.

- (e) The quantity of immature marijuana plants transferred to and by the medical marijuana dispensary during the previous month.
  - (f) The quantity of seeds transferred to and by the medical marijuana dispensary during the previous month.
  - (2) Information submitted to the Authority under this rule must:
    - (a) List each type of marijuana item separately;
    - (b) Provide the total aggregate amount of a type of marijuana item transferred to a dispensary by each patient, designated primary caregiver, PRMG, ~~or~~ processing site or Commission licensed producer during the previous month; and
    - (c) Provide the total aggregate amount of a type of marijuana item transferred by a dispensary to each patient or designated primary caregiver during the previous month.
  - (3) In addition to submitting the information as required by section (1) of this rule, a person responsible for a dispensary must keep a record of the information described in section (1) of this rule for two years after the date on which the person submits the information to the Authority.
- Stat. Auth.: ORS 475B.450 & 475B.525  
 Stats. Implemented: ORS 475B.450

**333-008-1500**

**Medical Marijuana Dispensaries: Limited Marijuana Retail Sales**

- ~~(1) For purposes of OAR 333-008-1500 through 333-008-1505 the following definitions apply:~~
  - ~~(a) "Cannabinoid concentrate" means a substance obtained by separating cannabinoids from marijuana by:
 
    - ~~(A) A mechanical extraction process;~~
    - ~~(B) A chemical extraction process using a nonhydrocarbon based solvent, such as vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or~~
    - ~~(C) A chemical extraction process using the hydrocarbon based solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure.~~~~
  - ~~(b) "Cannabinoid edible" means:
 
    - ~~(A) A food or potable liquid into which a cannabinoid concentrate, cannabinoid extract or dried marijuana leaves or flowers have been incorporated.~~
    - ~~(B) "Cannabinoid edible" does not include a tincture or a cannabinoid product intended to be placed under the tongue or in the mouth using a dropper or spray delivery method, such as but not limited, to a sublingual spray.~~~~
  - ~~(c) "Cannabinoid extract" means a substance obtained by separating cannabinoids from marijuana by:
 
    - ~~(A) A chemical extraction process using a hydrocarbon based solvent, such as butane, hexane or propane; or~~
    - ~~(B) A chemical extraction process using the hydrocarbon based solvent carbon dioxide, if the process uses high heat or pressure.~~~~
  - ~~(d)(A) "Cannabinoid product" means a cannabinoid edible and any other product intended for human consumption or use, including a product intended to be applied to the skin or hair, which contains cannabinoids or dried marijuana leaves or flowers.~~
    - ~~(B) "Cannabinoid product" does not include:
 
      - ~~(i) Usable marijuana by itself;~~
      - ~~(ii) A cannabinoid concentrate by itself;~~
      - ~~(iii) A cannabinoid extract by itself; or~~~~

- ~~(iv) Industrial hemp, as defined in ORS 571.300.~~
- ~~(e) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.~~
- ~~(f) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.~~
- ~~(g) "Dried leaves and flowers of marijuana" means the cured and dried leaves and flowers from a mature marijuana plant that have not been chemically altered or had anything added to them.~~
- ~~(h) "Immature marijuana plant" means a marijuana plant that is not flowering.~~
- ~~(i) "Individual" means a person 21 years of age or older who is not a patient or designated primary caregiver.~~
- ~~(j) "Limited marijuana retail product" means:~~
  - ~~(A) The seeds of marijuana;~~
  - ~~(B) The dried leaves and flowers of marijuana;~~
  - ~~(C) An immature marijuana plant;~~
  - ~~(D) Cannabinoid edibles;~~
  - ~~(E) Nonpsychoactive medical cannabinoid products intended to be applied to a person's skin or hair; and~~
  - ~~(F) Prefilled receptacles of cannabinoid extracts.~~
- ~~(k) "Low dose cannabinoid edible" means a cannabinoid edible that has no more than 15 milligrams of THC in a unit.~~
- ~~(l) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.~~
- ~~(m) "Medical cannabinoid product" has the meaning given that term in ORS 475B.410.~~
- ~~(n) "Medical marijuana dispensary" or "dispensary" means an entity registered with the Oregon Health Authority under ORS 475B.450.~~
- ~~(o) "Nonpsychoactive medical cannabinoid product intended to be applied to a person's skin or hair":~~
  - ~~(A) Means a cannabinoid topical with a THC content of not more than six percent that does not affect the mind or mental processes.~~
  - ~~(B) Does not mean a transdermal patch.~~
- ~~(p) "Photographic identification" means valid government issued identification with a photograph of the individual that includes the individual's last name, first name, and date of birth.~~
- ~~(q) "Prefilled receptacle of cannabinoid extract" means a single use receptacle prefilled with a cannabinoid extract by itself.~~
- ~~(r) "Unit" means a package for sale.~~
- ~~(2) Until January 1, 2017, a medical marijuana dispensary may sell limited marijuana retail product to an individual in accordance with this rule if:~~
  - ~~(a) The dispensary, five days prior to selling any limited marijuana retail product notifies the Authority, on a form prescribed by the Authority, that the dispensary intends to sell limited marijuana retail product;~~
  - ~~(b) The city or county in which the dispensary operates has not adopted an ordinance prohibiting the sale of limited marijuana retail product; and~~
  - ~~(c) The Authority has not prohibited the dispensary from selling limited marijuana retail product under section (14) of this rule.~~
- ~~(3) A dispensary that is permitted to sell limited marijuana retail product:~~

- ~~(a) Must examine the photo identification of all individuals before entering the dispensary to ensure the individual is 21 years of age or older.~~
- ~~(b) Must verify at the time of sale that the individual is 21 years of age or older by examining the individual's photographic identification.~~
- ~~(c) May only sell limited marijuana retail product as specified in sections (4) to (6) of this rule.~~
- ~~(4) A dispensary may sell one quarter ounce of dried leaves and flowers to an individual per day.~~
- ~~(5) Between June 2 and December 31, 2016 a dispensary may sell:~~
- ~~(a) One unit of a single serving, low dose cannabinoid edible to an individual per day. A unit of a low dose cannabinoid edible can contain more than one edible as long as the total THC in the unit does not exceed 15 milligrams.~~
- ~~(b) One prefilled receptacle of a cannabinoid extract that does not contain more than 1,000 milligrams of THC to an individual per day.~~
- ~~(c) Nonpsychoactive medical cannabinoid products intended to be applied to a person's skin or hair.~~
- ~~(6) A dispensary may sell up to four immature marijuana plants to the same individual at any time between October 1, 2015 and December 31, 2016.~~
- ~~(7) A dispensary may not:~~
- ~~(a) Offer, sell or provide a cannabinoid product, extract or concentrate to an individual except as provided in sections (4) through (6) of this rule; or~~
- ~~(b) Give away a limited marijuana retail product to an individual.~~
- ~~(8) For each limited marijuana retail product sale, a dispensary must document:~~
- ~~(a) The limited marijuana retail product that was sold and the amount in metric units or number sold as applicable;~~
- ~~(b) The birth date of the individual who bought the product;~~
- ~~(c) The sale price; and~~
- ~~(d) The date of sale.~~
- ~~(9) A dispensary may sell non-marijuana items to an individual, such as but not limited to branded clothing.~~
- ~~(10) A dispensary is not required to maintain a record of the name of the individual to whom a limited marijuana retail product was sold but the dispensary must have a system in place that is outlined in its policies and procedures for ensuring that an individual is not sold more than the amount or number of a limited retail marijuana product permitted under this rule.~~
- ~~(11) Records of sale transactions and the documentation required in section (8) of this rule shall be maintained in accordance with the Authority's record keeping requirements for dispensaries.~~
- ~~(12) A dispensary that chooses to sell limited marijuana retail product to individuals must:~~
- ~~(a) Post at the point the sale, the following posters prescribed by the Authority, measuring 22 inches high by 17 inches wide that can be downloaded at [www.healthoregon.org/marijuana](http://www.healthoregon.org/marijuana):~~
- ~~(A) A Pregnancy Warning Poster; and~~
- ~~(B) A Poisoning Prevention Poster.~~
- ~~(b) Post at the point of sale a color copy of the "Educate Before You Recreate" flyer measuring 22 inches high by 17 inches wide that can be downloaded at [WHATSLEGALOREGON.COM](http://WHATSLEGALOREGON.COM).~~
- ~~(c) Distribute to each individual at the time of sale, a Marijuana Information Card, prescribed by the Authority, measuring 3.5 inches high by 5 inches long that can be downloaded at [www.healthoregon.org/marijuana](http://www.healthoregon.org/marijuana).~~



~~(d) Comply with all rules in OAR chapter 333, divisions 7 and 8 that apply to dispensaries including but not limited to all security, testing, labeling, except as provided in section (13) of this rule, packaging and documentation rules except rules that:~~

- ~~(A) Prohibit individuals from entering or being present in a dispensary; and~~
- ~~(B) Prohibit a dispensary from transferring marijuana to an individual.~~

~~(e) On and after January 4, 2016:~~

- ~~(A) Collect a tax of 25 percent of the retail sales price of a limited marijuana retail product in the same manner that a marijuana retailer that holds a license under section 22, chapter 1, Oregon Laws 2015, collects the tax imposed under section 2, chapter 699, Oregon Laws 2015;~~
- ~~(B) Comply with all requirements in sections 1 through 13, chapter 699, Oregon Laws 2015, and any applicable administrative rules adopted by the Department of Revenue; and~~
- ~~(C) If requested by the Authority, sign an authorization to permit the sharing of information between the Authority and the Department of Revenue concerning tax collection required by section 21a, chapter 699, Oregon Laws 2015.~~

~~(13) A dispensary:~~

- ~~(a) May substitute a warning that reads "For use by adults 21 and older. Keep out of reach of children" for the warning "For use by OMMP patients only. Keep out of reach of children" on labels for limited marijuana retail products.~~
- ~~(b) Must:~~

- ~~(A) Comply with the packaging requirements in OAR 845-025-7000 to 845-025-7060 for all limited marijuana retail products.~~
- ~~(B) Comply with any labeling requirements in OAR 333-007-0010 to 333-007-0100 for limited marijuana retail products that would be applicable to a similar item sold by an Oregon Liquor Control Commission licensee.~~

~~(14) The Authority may, if it determines that a dispensary has violated OAR 333-008-1500 through 333-008-1505:~~

- ~~(a) Prohibit a dispensary from selling limited marijuana retail product; and~~
- ~~(b) Take any action authorized under OAR 333-008-2190.~~

~~(15) A dispensary may not sell limited marijuana retail product to individuals if the dispensary is located in a city or county that has adopted an ordinance prohibiting such sales in accordance with section 3, chapter 784, Oregon Laws 2015.~~

~~(16) A dispensary that has had its registration suspended may not sell limited marijuana retail product while the registration is suspended.~~

~~(17) This rule is only in effect until January 1, 2017.~~

~~Stat. Auth.: ORS 475.314 & 475.338, OL 2015, ch. 784 & sec. 21a, ch. 699, OL 2015-~~

~~Stats. Implemented: ORS 475.314, OL 2015, ch. 784 & sec. 21a, ch. 699, OL 2015~~

### **~~333-008-1501~~**

#### **~~Dispensary Signs~~**

~~(1) Between October 1, 2015 and December 31, 2016, a registered dispensary must post signs at any point of public entry that read:~~

- ~~(a) "Medical Marijuana Patients Only"; or~~
- ~~(b) If a dispensary has properly notified the Authority that it intends to sell limited marijuana retail products:~~

- ~~(A) "Medical Marijuana Patients and Persons 21 and Older Permitted"; and~~

~~(B) "NO PERSON UNDER 21 PERMITTED ON THE PREMISES WITHOUT AN OMP CARD".~~

~~(2) The signs described in section (1) of this rule must be:~~

~~(a) In bold, 80 point Times New Roman, Helvetica or Arial font; and~~

~~(b) Affixed to the exterior of the dispensary in a conspicuous location that can be easily seen by the public from outside the dispensary.~~

~~Stat. Auth.: ORS 475.314 & 475.338, OL 2015, ch. 784—~~

~~Stats. Implemented: ORS 475.314, OL 2015, ch. 784—~~

### **333-008-1505**

#### **Medical Marijuana Dispensaries: Reporting Requirements**

~~(1) A dispensary that is selling limited marijuana retail products to individuals must by April 10, 2016, July 10, 2016, October 10, 2016, and January 10, 2017, report to the Authority, in a manner prescribed by the Authority, the information required to be documented in OAR 333-008-1500(4) for the previous quarter.~~

~~(2) A dispensary must submit, by April 10, 2016, the information required to be documented in OAR 333-008-1500(4) for October 1, 2015 through December 31, 2015.~~

~~(3) A dispensary selling limited marijuana retail products to individuals must provide proof to the Authority by May 10, 2016, August 10, 2016, November 10, 2016, and February 10, 2017, in a manner prescribed by the Authority, that it has paid the tax required by the Department of Revenue for the previous quarter. Documentation may include but is not limited a copy of the marijuana tax returns, reports, payment vouchers, payment receipts or any related documents filed with the Department.~~

~~Stat. Auth.: ORS 475B.450 & 475B.525, OL 2015, ch. 784—~~

~~Stats. Implemented: ORS 475B.450, OL 2015, ch. 784~~

### **333-008-1620**

#### **Medical Marijuana Processors: Application for Medical Marijuana Processing Site Registration**

(1) This rule applies to any initial application filed on or after ~~June 28, 2016~~[insert effective date of rules] and to any initial application filed prior to [insert effective date of rules]~~June 28, 2016~~ that the Authority has not yet approved or denied.

(2) To register a medical marijuana processing site a person must:

(a) Submit an initial application on a form prescribed by the Authority that includes but is not limited to:

(A) The name of the individual who owns the processing site or, if a business entity owns the processing site, the name of each individual who has a financial interest in the processing site;

(B) The name of the individual or individuals responsible for the processing site, if different from the name of the individual who owns the processing site, with one of the individuals responsible for the processing site identified as the primary PRP;

(C) The physical and mailing address of the marijuana processing site; and

(b) Application and registration fees.

(c) An initial application for the registration of a processing site must be submitted electronically via the Authority's website, [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp).

(3) If an initial application is submitted along with the required fees the Authority will notify the applicant that the initial application has been received and that within 30 calendar days of the

date the written notice is mailed or sent electronically the following information must be received by the Authority:

- (a) For each individual named in the application:
  - (A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;
  - (B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and
  - (C) An Individual History Form and any information identified in the form that is required to be submitted.
- (b) If the applicant intends to process extracts, proof from the local government that the proposed location of the processing site is not located in an area that is zoned for residential use;
- (c) Proof that the business is registered or has filed an application to register as a business with the Oregon Office of the Secretary of State, including proof of registration of any DBA (doing business as) registration;
- (d) A scaled site plan of the parcel or premises on which the premises proposed for registration, is located, including:
  - (A) Cardinal directional references;
  - (B) Bordering streets and the names of the streets;
  - (C) Identification of the building or buildings in which the proposed processing site is to be located;
  - (D) The dimensions of the proposed premises of the processing site;
  - (E) Identification of other buildings or property owned by or under the control of the applicant on the same parcel or tax lot as the premises proposed for registration that will be used in the business; and
  - (F) Identification of any residences on the parcel or tax lot.
- (e) A scaled floor plan of all enclosed areas of the premises at the proposed location that will be used in the business with the overall dimensions of the dispensary and the dimensions of the interior rooms and spaces, a description of the intended uses of all spaces and clear identification and location of:
  - (A) Walls;
  - (B) Partitions;
  - (C) Counters;
  - (D) Windows;
  - (E) Safes;
  - (F) All areas of ingress and egress;
  - (G) All limited access areas;
  - (H) Secure rooms; and
  - (I) Designated limited access areas or designated areas required under OAR 333-008-1730(8) of walls, partitions, counters, windows, all areas of ingress and egress, intended uses of all spaces;
- (f) Documentation that shows the applicant has lawful possession of the proposed location of the processing site;
- (g) A description of the type of products to be processed, a description of equipment to be used, including any solvents, gases, chemicals or other compounds used to create extracts or concentrates on a form prescribed by the Authority; and
- (h) The proposed endorsements as described in OAR 333-008-1700.

- (4) The information and documentation required in section (3) of this rule may be submitted electronically to the Authority or may be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293.
- (a) If documentation is mailed, it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the application was received or the application will be considered incomplete.
- (b) If documentation is submitted electronically it must be received by the Authority within 30 calendar days of the date the Authority mailed the notice to the applicant that the application was received or the application will be considered incomplete.
- (5) Application and registration fees must be paid online at the time of application.
- (6) Criminal background check fees must be paid by check or money order and must be mailed to the Oregon Medical Marijuana Program, Oregon Health Authority, PO Box 14116, Portland, OR 97293 and must be received by the Authority in accordance with provisions in section (4) of this rule.
- (7) If the Authority does not receive a complete application, all documentation required in sections (2) and (3) of this rule, and all required fees within the time frames established in this rule, the application will be ~~considered-declared~~ incomplete.
- (8) If the applicant provides the documentation required in section (3) of this rule, the Authority will review the information to determine if it is ~~sufficiente~~ complete.
- (a) If the documentation required under section (3) of this rule is not complete or is insufficient the Authority must notify the applicant in writing and the applicant will have 10 calendar days from the date such written notice is mailed ~~or sent electronically~~ by the Authority to provide the additional documentation.
- (b) If the applicant does not provide the additional documentation within 10 calendar days or if any responsive documents are incomplete, insufficient or otherwise do not demonstrate compliance with ORS 475B.450 and these rules the application will be declared incomplete.
- (9) A person who wishes to register more than one location must submit a separate application, registration fees, and all documentation described in sections (2) and (3) of this rule for each location.
- (10) An application that is ~~declared~~ incomplete is treated by the Authority as if it was never received.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

### **333-008-1630**

#### **Processing Site Fees**

- (1) The initial fees for the registration of a processing site are:
- (a) A non-refundable application fee of \$500; and
- (b) A \$3,500 registration fee.
- (2) The annual renewal fees for the registration of a processing site are:
- (a) A \$500 non-refundable renewal fee; and
- (b) A \$3,500 registration fee.
- (3) The criminal background check fee is \$35 per individual.
- (4) The Authority must return the registration fee if:
- (a) An application is incomplete; or
- (b) An applicant withdraws an application.

(5) The Authority may return the registration fee if an application is denied.

(6) For an application received on or after [insert effective date of rule] the Authority may not refund a registration fee if the Authority has issued the applicant a 60-day letter under OAR 333-008-1650(6) and the applicant subsequently withdraws the application or the applicant does not comply with the 60-day deadline under OAR 333-0080-1650(7).

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

### **333-008-1690**

#### **Expiration and Renewal of Registration for Processing Site**

(1) A processing site's registration expires one year following the date of application approval.

(2) A processing site registrant must submit not more than 90 but at least 30 calendar days before the registration expires:

(a) A renewal application on a form prescribed by the Authority;

(b) Renewal fees;

(c) For each individual named in the renewal application:

(A) A legible copy of the individual's valid government issued photographic identification that includes last name, first name and date of birth;

(B) Information, fingerprints and fees required for a criminal background check in accordance with OAR 333-008-2020; and

(C) An Individual History Form and any information identified in the form that is required to be submitted; ~~and-~~

(d) Current proof of business registration with the Secretary of State, including all DBA (doing business as) registrations.;

~~(e) Documentation that shows the applicant has lawful possession of the location of the registered processing site; and~~

~~(f) A current sealed floor plan of all enclosed areas at the proposed location that will be used in the business with clear identification of walls, partitions, counters, windows, all areas of ingress and egress, uses of all spaces and all limited access areas.~~

(3) A processing site registrant who files a completed renewal application, fees, and all the information required in section (2) of this rule with the Authority prior to the expiration date of the registration may continue to operate, even after the registration expiration date, pending a decision on the renewal application by the Authority.

(4) A processing site registrant that does not submit a timely application, fees and all the information required in section (2) of this rule may be denied or subject to the imposition of civil penalties.

~~(5) If a processing site registrant does not submit the renewal application, fees and all the information required in section (2) of this rule prior to the registration's expiration, the registration is expired and is no longer valid. he Authority may notify a processing site registrant who, prior to the registration's expiration, submits an incomplete application and may give the registrant 10 calendar days to submit the missing information. The Authority may deny the renewal application of a registrant who fails to comply with this section.~~

(6) Renewals will be processed in accordance with OAR 333-008-1650 to 333-008-1670, as applicable.

(7) A renewal applicant may be required to submit a Readiness Form, as described in OAR 333-008-1650(9) and may be subject to inspection prior to the Authority acting on a renewal application.

(8) For purposes of this rule, a renewal application is considered complete when the Authority receives the completed application form, fees and information required in section (2) of this rule.

Stat. Auth.: ORS 475B.435

Stats. Implemented: ORS 475B.435

### **333-008-1760**

#### **Medical Marijuana Processors: Transfers to a Registered Processing Site**

(1) Transfers of Marijuana by a Patient or Designated Primary Caregiver to Process for Return to a Patient. A patient or designated primary caregiver may transfer marijuana to a registered processing site for no compensation for the purpose of the registered processing site processing the marijuana into a cannabinoid product, concentrate or extract and returning the product, concentrate or extract to the patient or designated primary caregiver.

(a) If a designated primary caregiver is transferring the marijuana, a registered processing site may only accept a transfer of marijuana under this section if the caregiver provides the original or a copy of a valid Authorization to Transfer form prescribed by the Authority.

(b) In order to be valid an Authorization to Transfer form must include at least:

(A) The patient's name, OMMP card number, OMMP receipt number if applicable and expiration date and contact information;

(B) The name and contact information of the individual who is authorized to transfer the usable marijuana to the registered processing site and that individual's OMMP card number and expiration date;

(C) The name and address of the registered processing site that is authorized to receive the usable marijuana; and

(D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card or receipt.

(2) Transfer of Usable Marijuana. A patient, caregiver, or PRMG may transfer usable marijuana to a registered processing site, for no consideration, subject to the requirements in this rule.

(a) A registered processing site may only accept a transfer of usable marijuana if the individual transferring the usable marijuana provides the original or a copy of a valid:

(A) Authorization to Transfer form prescribed by the Authority; or

(B) Personal agreement as that is defined in OAR 333-008-0010.

(b) Authorization to Transfer Forms. In order to be valid an Authorization to Transfer form must include at least:

(A) The patient's name, OMMP card number and expiration date and contact information;

(B) The name and contact information of the individual who is authorized to transfer the usable marijuana to the registered processing site and that individual's OMMP card number and expiration date;

(C) The name and address of the registered processing site that is authorized to receive the usable marijuana; and

(D) The date the authorization expires, if earlier than the expiration date of the patient's OMMP card.

(c) Personal Agreements. In order to be valid a personal agreement must include at least:

(A) The patient's name, OMMP card number and expiration date and contact information;



(B) The name and contact information of the PRMG to whom the patient's property rights have been assigned and the producer's OMMP card number and expiration date;

(C) The portion of the patient's rights to possess usable marijuana that is being assigned to the producer.

(3) A registered processing site may accept the transfer of usable marijuana from a producer licensed by the Commission under ORS 475B.070 who is also registered by the Commission to produce marijuana for a patient. The Commission licensed producer must provide the registered dispensary with:

(a) Proof of licensure under ORS 475B.070; and

(b) A copy of the patient agreement as described in OAR 845-025-2510.

(4) Transfer of medical cannabinoid products, concentrates or extracts. A registered processing site may only accept a transfer of a medical cannabinoid product, concentrate or extract from another registered medical marijuana processing site.

(45) A registered processing site may only accept a transfer of a medical cannabinoid product, concentrate or extract from a registered processing site that provides a Processing Site Authorization to Transfer form, prescribed by the Authority. In addition the registered processing site must obtain a copy of the photo identification of the individual transferring the product, concentrate or extract as required in section (5)(b)(B) of this rule.

(65) Transfer Records. At the time marijuana, usable marijuana or a medical cannabinoid product, concentrate or extract is transferred to a registered processing site a processing site representative must:

(a) Document, on a form prescribed by the Authority, as applicable:

(A) The weight in metric units of all usable marijuana received by the processing site;

(B) The amount of a medical cannabinoid product, concentrate or extract received by the processing site, including, as applicable, the weight in metric units, or the number of units;

(C) The name of the usable marijuana or medical cannabinoid product, concentrate or extract;

(D) The date the usable marijuana or medical cannabinoid product, concentrate or extract was received;

(E) The harvest or process lot numbers; and

(F) The amount paid by the registered processing site.

(b) Obtain and maintain a copy of, as applicable:

(A) Documents required in sections (1) through (3) of this rule including the date it was received;

(B) The photo identification of the individual transferring the usable marijuana or medical cannabinoid product, concentrate or extract to the registered processing site, if such a copy is not already on file;

(C) The OMMP card of the individual transferring usable marijuana;

(D) The medical marijuana processing site registration; and

(E) Test results for marijuana items transferred to the processing site unless the processing site plans to arrange for the testing of the marijuana item.

(76) Nothing in these rules requires a registered processing site to accept a transfer of a marijuana item.

(87) All documentation required in this rule must be maintained electronically in an integrated inventory tracking and point of sale system.

Stat. Auth.: ORS 475B.435, 475B.440

Stats. Implemented: ORS 475B.435, 475B.440, 475B.443

### **333-008-1810**

#### **Cannabinoid Topical, Tincture, Capsule, Suppository or Transdermal Patch Processor**

(1) A processing site endorsed to make cannabinoid topicals, tinctures, capsules, suppositories or transdermal patches may not engage in processing in a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited service restaurant or single-event temporary restaurant licensed under ORS chapter 624.

(2) A registered processing site making cannabinoid capsules and tinctures may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, with the exception of OAR 603-025-0020(17), and division 28.

Stat. Auth.: ORS 475B.435 & 475B.440

Stats. Implemented: ORS 475B.435 & 475B.440

### **333-008-1830**

#### **Registered Marijuana Processing Site Required Reporting to the Authority**

(1) The individual or individuals responsible for a marijuana processing site shall maintain documentation of each transfer of usable marijuana, medical cannabinoid products, cannabinoid concentrates and cannabinoid extracts and on and after June 1, 2016, must submit to the Authority electronically, by the 10th of each month, the following information:

(a) The amount of usable marijuana transferred to the marijuana processing site during the previous month.

(b) The amount and type of a medical cannabinoid concentrate or extract transferred by another registered processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid concentrate in solid form; and

(B) Cannabinoid concentrate in liquid form.

(c) The amount and type of medical cannabinoid products transferred by the marijuana processing site to a dispensary. For purposes of this section "type" means:

(A) Cannabinoid edibles;

(B) Cannabinoid topicals;

(C) Cannabinoid tinctures;

(D) Cannabinoid capsules;

(E) Cannabinoid suppositories;

(F) Cannabinoid transdermal patches; and

(G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.

(d) The amount and type of cannabinoid concentrates transferred by the marijuana processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid concentrate in solid form; and

(B) Cannabinoid concentrate in liquid form.

(e) The amount and type of cannabinoid extracts transferred by the marijuana processing site during the previous month. For purposes of this section "type" means:

(A) Cannabinoid extract in solid form; and

(B) Cannabinoid extract in liquid form.

(f) The amount and type of medical cannabinoid products transferred by the marijuana processing site to a patient or the patient's designated primary caregiver during the previous month. For purposes of this section "type" means:

(A) Cannabinoid edibles;

- (B) Cannabinoid topicals;
  - (C) Cannabinoid tinctures;
  - (D) Cannabinoid capsules;
  - (E) Cannabinoid suppositories;
  - (F) Cannabinoid transdermal patches; and
  - (G) Cannabinoid product other than products listed in paragraphs (A) to (F) of this subsection.
- (g) The amount and type of cannabinoid concentrates or extracts transferred by the marijuana processing site to a patient or the patient's designated primary caregiver during the previous month. For purposes of this section "type" means;
- (A) Cannabinoid concentrate or extract in liquid form; and
  - (B) Cannabinoid concentrate or extract in solid form.
- (2) Information submitted to the Authority under this rule must:
- (a) List each type of marijuana item separately;
  - (b) Provide the total aggregate amount of a type of marijuana item transferred to a processing site by a patient, designated primary caregiver, PRMG, ~~or~~ other registered processing site, or Commission licensed producer during the previous month; and
  - (c) Provide the total aggregate amount of a type of marijuana item transferred from a processing site to a registered dispensary, patient, designated primary caregiver, or other registered processing site during the previous month.
- (3) In addition to submitting the information as required by section (1) of this rule, a person responsible for a processing site must keep a record of the information described in section (1) of this rule for two years after the date on which the person submits the information to the Authority.

Stat. Auth.: ORS 475B.438

Stats. Implemented: ORS 475B.438

### **333-008-2180**

#### **Violations**

- (1) It is a violation for an applicant for a registration, registrant or registrant representative to:
  - (a) Fail to cooperate with an inspection;
  - (b) Submit false or misleading information to the Authority;
  - (c) If the registrant is a dispensary, transfer a marijuana item to an individual who is not a patient or a designated primary caregiver;
  - (d) If the registrant is a processing site, transfer a medical cannabinoid product, concentrate or extract to anyone who is not a registered processing site representative, a registered dispensary representative, or a patient or a designated primary caregiver, as permitted under these rules; ~~or~~ a patient or a designated primary caregiver, as permitted under these rules;
  - (e) Accept the transfer of a marijuana item from an individual who is not registered with the Authority;
  - (f) Accept the transfer of a marijuana item that was produced or processed in another state;
  - (g) Possess a mature marijuana plant;
  - (h) Fail to submit a plan of correction in accordance with OAR 333-008-2190;
  - (i) Fail to comply with an emergency suspension order or final order of the Authority, including failing to pay a civil penalty;
  - (j) Fail to comply with ORS 475B.435 to 475B.443, 475B.450 to 475B.453, 475B.555, 475B.605, 475B.615, these rules, or OAR chapter 333, division 7; ~~or~~
  - (k) Alter or falsify a laboratory test report or result; ~~or~~

(l) Alter or falsify a receipt issued under OAR 333-008-0023 or 333-008-0040;  
(m) Submit false or misleading information to the Commission for the purpose of pre-approval of packaging and labeling as required by OAR 333-007-0100; and  
(n) Submit false or misleading information to a laboratory for the purpose of compliance testing under OAR 333-007-0300 to 333-007-0500.

(2) It is a violation of ORS 475B.450 and these rules to operate a dispensary without being registered by the Authority.

(3) It is a violation of ORS 475B.435 and these rules to operate a processing site without being registered by the Authority unless an exemption applies.

Stat. Auth.: ORS 475B.435, 475B.450 & 475B.525

Stats. Implemented: ORS 475B.435 & 475B.450

### **333-008-2210**

#### **Penalty Matrix**

(1) The Authority has established Category I, II, III and IV violations with Category I violations posing the highest risk to public health and safety, and category IV violations being generally technical in nature.

(2) The Authority may allege multiple violations in a single notice or may count violations alleged in notices issued within the previous two year period toward the total number of violations. In calculating the total number of violations, the Authority may consider a proposed violation for which the Authority has not yet issued a final order.

(3) If the Authority finds one or more mitigating or aggravating circumstances, it may assess a lesser or greater sanction, up to and including revocation. The Authority may decrease or increase a sanction to prevent inequity or to take account of particular circumstances in the case.

(4) The Authority may consider the following mitigating circumstances when determining what sanction to impose:

(a) Making a good faith effort to prevent a violation.

(b) Extraordinary cooperation in the violation investigation demonstrating the licensee or permittee accepts responsibility.

(5) The Authority may consider the following aggravating circumstances when determining what sanction to impose:

(a) Receiving a prior warning about one or more compliance problems.

(b) Repeated failure to comply with laws.

(c) Efforts by person or registrant to conceal a violation.

(d) Intentionally committing a violation.

(e) A violation involving more than one consumer or employee.

(f) A violation involving a transfer of a marijuana item to anyone other than a patient, designated primary caregiver, grower or registrant.

(g) A violation resulting in injury or death.

(h) Three or more violations within a two-year-period, regardless of the category, where the number of the proposed or final violations indicate a disregard for the law or failure to control the premises.

(6) A registrant may not avoid the sanction for a violation or the application of the provision for successive violations by changing the corporate structure for example, by adding or dropping a partner or converting to another form of legal entity when the individuals who own, operate, or control the business are substantially similar.

Stat. Auth.: ORS 475B.025

Stats. Implemented: ORS 475B.210, 475B.295, 475B.560 & 475B.635

### ~~333-008-9900~~

#### ~~Waiver of Replacement Card Fee~~

~~Notwithstanding OAR 333-008-0021(5) or 333-008-0047(1)(b), until January 1, 2017, the Authority will not impose or collect a \$100 replacement card fee if the reason for the replacement card is that the patient is designating a new PRMG or new grow site address.~~

~~Stat. Auth.: ORS 475B.415, 475B.420, 475B.525~~

~~Stats. Implemented: ORS 475B.415~~

### ~~333-008-9910~~

#### ~~Processing Site Applicants~~

~~(1) A person who submitted a complete processing site application to the Authority on or before October 1, 2016, who is permitted to transfer cannabinoid products, concentrates or extracts to a medical marijuana dispensary under OAR 333-008-1230(2)(a) must comply with all applicable processing site rules while operating.~~

~~(2) Failure to comply with applicable processing site rules while operating may result in a denial of an application.~~

~~(3) A person who submitted a processing site application to the Authority after October 1, 2016 may not operate unless the application is approved.~~

~~Stat. Auth.: ORS 475B.435~~

~~Stats. Implemented: ORS 475B.435~~

## DIVISION 64

### ACCREDITATION OF LABORATORIES

#### ~~333-064-0100~~

##### ~~Marijuana Item Sampling Procedures and Testing~~

~~(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.~~

~~(2) Sampling.~~

~~(a) A laboratory must prepare marijuana item sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from a marijuana item in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures must be appropriate to the matrix being sampled.~~

~~(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken. The policies and procedures must be consistent with the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:~~

~~(A) Usable Marijuana: ORELAP-SOP-001 Rev ~~32.0~~; ~~and~~~~

~~(B) Concentrates, ~~and~~ Extracts, ~~and~~ Products: ORELAP-SOP-002 Rev ~~3.12.0~~; ~~and~~~~

~~(C) Cannabis Products: ORELAP SOP 003 Rev 2.0. [Sampling protocols may be found on the ORELAP and Cannabis Testing webpage,~~

public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx]

(c) Laboratory personnel that perform sampling must:

(A) Comply with the education and training requirements in the sampling protocols referenced in subsection (2)(b) of this rule;

(B) Follow the laboratory's accredited sampling policies and procedures;

(C) Follow chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8;

(D) After taking samples document the samples in accordance with subsection (2)(e) of this rule and if sampling for a licensee record the sampling and transfer information in the Commission's seed to sale system, as required by the Commission; and

(E) Take Care ~~should be taken by laboratory personnel~~ while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.

(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

(e) A laboratory must comply with any recording requirements for samples and ~~sub~~sample ~~increments~~ in the accredited policies and procedures and at a minimum:

(A) Record the location of each sample and ~~sub~~sample increment taken.

(B) Assign a field identification number for each sample, ~~sub~~sample increment and field duplicate that have an unequivocal link to the laboratory analysis identification.

(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, ~~sub~~sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.

(E) Place the laboratory identification code as a durable mark on each sample container.

(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.

(f) Combining ~~sub~~sample increments.

(A) ~~Sample increments~~~~subsamples~~ collected from the same batch must be combined into a single sample by a laboratory prior to testing unless the batch is undergoing a control study~~process validation~~ or has not yet gone through a control study~~process validation~~.

(B) ~~Sub~~sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360.

(C) Field duplicates may not be combined with the primary samples.

(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.

(4) Calculating total THC and total CBD.



(a) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:

$M \text{ total delta-9 THC} = M \text{ delta-9 THC} + 0.877 \times M \text{ delta-9 THCA}$ .

(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:

$M \text{ total CBD} = M \text{ CBD} + 0.877 \times M \text{ CBDA}$ .

(c) Each test report must include the total THC and total CBD.

(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$P \text{ total THC(dry)} = P \text{ total THC(wet)} / [1 - (P \text{ moisture}/100)]$

$P \text{ total CBD(dry)} = P \text{ total CBD(wet)} / [1 - (P \text{ moisture}/100)]$

(6) Calculating RPD and RSD.

(a) A laboratory must use the following calculation for determining RPD:

$RPD = (sample \ result - duplicate \ result) / (sample \ result + duplicate \ result) \times 2$

(b) A laboratory must use the following calculation for determining RSD:

$\% RSD = s \times 100\%$

$s = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}}$

(c) For purposes of this section:

(A) S = standard deviation.

(B) n = total number of values.

(C) xi = each individual value used to calculate mean.

(D) x = mean of n values.

(d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.

(7) Tentative Identification of Compounds (TIC).

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.

(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).

(c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.

(d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.

(A) The top five matches over 90 percent must be reported by the lab

(B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.

(8) A laboratory must provide:

(a) Any pesticide test result to the Department of Agriculture upon that agency's request.

(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.

(9) A laboratory performing tests for a licensee must enter any information required by the Commission in the Commission's seed to sale tracking system.

(10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.

(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-~~050490~~ and these rules based on the state's needs.

(12) A laboratory must be able to demonstrate that its LOQ is at or below any action level established in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 and 4.

(13) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant or licensee may use methods not approved by the Authority but the laboratory may not identify those test results as accredited results.

Stat. Auth.: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555.

Stats. Implemented: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555

### **333-064-0110**

#### **Reporting Marijuana Test Results**

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) A test report must clearly identify for the licensee or registrant:

(a) Whether a sample has exceeded an action limit for an analyte in Exhibit A, Tables 3 or 4, or has otherwise failed a test as described in OAR 333-007-0300 to 333-007-0500.

(b) A "detected" pesticide result as required in section (6) of this rule.

(c) The batch unique identification number required under OAR 333-007-0350 and the test batch number associated with the samples tested, as required by OAR 333-064-0100.

(d) On and after July 1, 2017, identification of the test as a compliance test or a quality control or research and development test.

(3) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-~~050490~~ except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:

(a) Into the Commission's seed to sale tracking system if performing testing for a licensee; and

(b) To the Authority electronically at [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp) if performing testing for a registrant, along with a copy of the test order information required in OAR 333-007-0315.

(4) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-~~050490~~ that have not been reported under section (~~32~~) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee.

(5) A laboratory must determine and include on each test report its limit of quantification (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3 and OAR 333-007-0410 Table 4.

(6) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 53:1 and meets identification criteria with a result of "detected."

(7) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.

(a) Batch quality control samples are the method blank and laboratory control sample.

(b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.

~~(6) A test report must include any associated test batch numbers and the date each test was completed.~~

(87) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section ~~(32)~~ of this rule must report the failed test at the same time or before reporting to the licensee or registrant.

~~(98) If requested by the Authority, In addition to reporting failed test results in accordance with section (2) of this rule a laboratory must report sampling and testing information to the Authority, in a manner prescribed by the Authority conducting testing for a registrant must report to the Authority electronically at [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp) any pesticide testing report with a "detected" as described in section (5) of this rule.~~

(109) Test results expire after one year.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555