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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 845
OREGON LIQUOR CONTROL COMMISSION

FILED
03/30/2018 1:43 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: The rules adopt packaging and labeling requirements for the marijuana industry.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/30/2018 5:00 PM

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

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Filed By:
Bryant Haley
Rules Coordinator

HEARING(S)

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

DATE: 04/16/2018

TIME: 10:00 AM

OFFICER: Bryant Haley

ADDRESS: Oregon Liquor Control
Commission
9079 SE McLoughlin Blvd.
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NEED FOR THE RULE(S):

Senate Bill 1057, passed during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Senate Bill 1057, available from Legislative Counsel
Oregon Liquor Control Commission rulemaking file, available upon request from the OLCC

FISCAL AND ECONOMIC IMPACT:

This statement takes into account the fiscal impact on: (a) Recreational Marijuana Licensees; (b) Local Government; (c) State Agencies; and (d) the Public.

(a) Recreational Marijuana Licensees.

The Commission expects the proposed rule to have a fiscal impact recreational marijuana licensees whom package and label marijuana items. Specifically, the amendments to the rules will require licensees to reapply for packaging and labeling approval. Licensees may incur fees from having their labels re-designed by a graphics design company.

(b) Local Government.

The Commission expects the proposed amendments to have no impact upon local governments, as the rules does not apply to them.

(c) State Agencies.

The Commission expects the proposed rule to have a positive impact on the Oregon Health Authority, as they will no longer provide oversight or rulemaking on packaging and labeling issues.

(d) The Public.

The Commission expects the proposed rule to have a positive and negative fiscal impact on the public. The Commission foresees a positive impact to the extent that the amendments both clarify and increase the safety of the packaging of marijuana items. However, the consumer may see an increase in cost, as any cost increase to improve safety of products could filter down to the consumer. The Commission is looking forward to hear comment on this issue, as the Commission attempts to balance public safety and costs.

COST OF COMPLIANCE:

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

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

The Commission anticipates no new costs to comply with the proposed amendments for most state agencies and local government. However, the Commission will have sole ownership and increased responsibilities in approving, denying, enforcing and administratively adjudicating packaging and labeling violations.

The consumer may see an increase in cost, as any cost increase to improve safety of products could filter down to the consumer.

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

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

As of March 19, 2018; the Commission had 1,795 recreational marijuana licensees. The packaging and labeling rules effect marijuana licensees differently based upon their operations. Specifically, some licensees may not package or label their products, but may sell their wares to retailers, processors or wholesalers whom repackage the products and design a product label for a product. Thus, the effects of these rules fall to licensees whom are either making the terminal sale of a marijuana item to a consumer or designing a label for a product.

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

Licensees whom are either designing a product for final sale or making a sale to a consumer will need to comply with these rules. In doing so, they must submit and gain approval of their packaging and labeling. This will incur approval fees and the maintaining of approved packaging and labeling. Retail Licensees will need to ensure products on their shelves have been approved and properly packaged when leaving the retail premises.

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

Licensees whom are either designing a product for final sale or making a sale to a consumer will need to comply with these rules. In doing so, they must submit and gain approval of their packaging and labeling. This will incur approval fees and the maintaining of approved packaging and labeling. Retail Licensees will need to ensure products on their shelves have been approved and properly packaged when leaving the retail premises.

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

The Commission held an advisory committee on the subject on March 7, 2018.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

845-025-7000, 845-025-7010, 845-025-7020, 845-025-7030, 845-025-7040, 845-025-7045, 845-025-7050, 845-025-7060, 845-025-7070, 845-025-7080, 845-025-7090, 845-025-7100, 845-025-7110, 845-025-7120, 845-025-7130, 845-025-7140, 845-025-7150, 845-025-7160, 845-025-7170, 845-025-7180, 845-025-7190

AMEND: 845-025-7000

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The amendments clarify definitions.

CHANGES TO RULE:

845-025-7000

Packaging and Labeling - Definitions ¶

For the purposes of OAR 845-025-7000 ~~through 845-025-7060:~~¶

~~(1190, unless otherwise specified: ¶~~

~~(1) "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item. ¶~~

~~(2) "Added substances" means any additional component or ingredient added to a marijuana concentrate or extract during or after processing that is present in the final product. This includes added flavors, terpenes, and any substances used to change viscosity or consistency of the cannabinoid product. ¶~~

~~(3) "Attractive to minors" means packaging, labeling and marketing that features:¶~~

~~(a) Cartoons;¶~~

~~(b) A design, brand or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors;¶~~

~~(c) Symbols or celebrities that are commonly used to market products to minors;¶~~

~~(d) Images of minors; and¶~~

~~(e) Words that refer to products that are commonly associated with minors or marketed by minors.¶~~

~~(2) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.¶~~

~~(34) "Authority" means the Oregon Health Authority. ¶~~

~~(5) "Cannabinoid" for the purposes of labeling means any of the chemical compounds that are the active constituents of marijuana or industrial hemp. ¶~~

~~(6) "Cannabinoid capsule" means a small, soluble pill, tablet, or container that contains liquid or powdered cannabinoid product, concentrate or extract and is intended for human ingestion.¶~~

~~(7) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process. ¶~~

~~(48)(a) "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.¶~~

~~(5; or ¶~~

~~(B) For purposes of labeling, includes any marijuana, cannabinoid concentrate, extract or cannabinoid product that is intended for human consumption or marketed in a manner that implies the item is for human consumption. ¶~~

~~(b) For purposes of labeling "cannabinoid edible" does not include a cannabinoid tincture or capsule. ¶~~

~~(9)(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.¶~~

~~(610) "Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of 2 fluid ounces or less that consists of either:¶~~

~~(a) A non-potable solution consisting of at least 35% non-denatured alcohol, in addition to cannabinoid concentrate, extract or usable marijuana, and perhaps other ingredients intended for human consumption or ingestion, that is exempt from the Liquor Control Act under ORS 471.035; or¶~~

~~(b) A non-potable solution of glycerin or plant-based oil, cannabinoid concentrate, extract or usable marijuana, and perhaps other ingredients intended for human consumption or ingestion that does not contain any added sweeteners. ¶~~

~~(11) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair. ¶~~

~~(12) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:¶~~

- (a) The use of comically exaggerated features;¶
- (b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or¶
- (c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.¶
- ~~(713) "CBD" means cannabidiol. ¶~~
- (14) "Child resistant" means designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly.¶
- ~~(815) "Consumer":¶~~
- ~~(a) "Commission" means the Oregon Liquor Control Commission. ¶~~
- (16) "Consumer" has the meaning given that term in ORS 475B.015; or¶
- ~~(b) Means and does not include a patient or designated primary caregiver receiving a transfer from a medical marijuana dispensary. ¶~~
- (17) "Container" ¶
- (a) Means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed and any outer receptacle intended to display a marijuana item for ultimate sale to a consumer. ¶
- (b) Does not mean:¶
 - (A) Inner wrapping or lining; ¶
 - (B) An exit package; or¶
 - (C) A shipping container used to transfer marijuana items or industrial commodities or products in bulk from one licensee or registrant to another. ¶
- (18) "Date of harvest" means the date the mature marijuana plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media. ¶
- ~~(19) "Container" means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed prior to being sold to a consumer.¶~~
- ~~(10) "Exit Package" means a sealed container provided at the retail point of sale in which any marijuana items already within a container are placed~~Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis. ¶
- (20)(a) "Designated primary caregiver" means an individual: ¶
 - (A) Who is 18 years of age or older; ¶
 - (B) Who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and ¶
 - (C) Who is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority. ¶
- (b) "Designated primary caregiver" does not include a person's attending physician. ¶
- (21) "Exit Package" means a sealed, child-resistant certified container into which marijuana items already within a container are placed at the point of sale.¶
- (22) "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. ¶
- (23) "Generic label" means a label that contains only the information required by rule.¶
 - (a) A generic label may not contain any graphics, pictures, or logos.¶
 - (b) A generic label may include additional test information not required by rule or additional information described in OAR 845-025-7160(7)(c)(A) and (B).¶
- (24) "Grower" has the same meaning as "person responsible for a marijuana grow site." ¶
- (25) "Health claim" means any claim made on the label that expressly states or implies a relationship between a substance and a disease or health-related condition.¶
- (26) "Hemp symbol" means the image, established by the Commission and made available to licensees, indicating

the item contains industrial hemp.

(27) "Industrial hemp commodity or product" means an item processed by a handler or processor containing any industrial hemp or containing any chemical compounds derived from industrial hemp, including CBD derived from industrial hemp. "Industrial hemp commodity or product" does not include industrial hemp that has been minimally processed or has not been processed in any form.

(28) "Intended for human consumption" means intended for a human to eat, drink, or otherwise put in the mouth but does not mean intended for human inhalation.

(29) "Intended for human use" means intended to be used by applying it to a person's skin or hair or otherwise consuming the product except through the mouth or through inhalation.

(30) "Label" means any display of written, printed, or graphic matter printed on or affixed to any container, wrapper, liner, or insert accompanying the marijuana item or industrial hemp commodity or product.

(131) "Licensee" has the meaning given that term in OAR 845-025-1RS 475B.015.

(132) "Marijuana

or food allergen" means an ingredient that contains any of the foods or food groups listed in subsections (a) to (h) or an ingredient that contains protein derived from one of the foods listed in subsections (a) to (h):

(a) Milk;

(b) Egg;

(c) Fish;

(d) Crustacean shellfish;

(e) Tree nuts;

(f) Wheat;

(g) Peanuts; and

(h) Soybeans.

(33)(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.

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

(14) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extract.

(35) "Medical grade cannabinoid product, cannabinoid concentrate or cannabinoid extract" means a cannabinoid product, cannabinoid concentrate or cannabinoid extract that has a concentration of THC that is permitted under ORS 475B.625 in a single serving of the cannabinoid product, cannabinoid concentrate or cannabinoid extract for a patient.

(36) "Medical grade symbol" means the image established by the Authority and made available to licensees indicating the cannabinoid product, concentrate or extract may only be sold or transferred to a designated primary caregiver or patient, for use only by a patient.

(37) "Medical marijuana dispensary" means a facility registered under ORS 475B.858.

(38)(a) "Net quantity of contents" means a statement on the principal display panel of the net weight or net volume of the product expressed in the terms of weight, measure, or numerical count.

(39) "Net volume" means the fluid measure of a liquid product expressed as milliliters and fluid ounces.

(40) "Net weight" means the gross weight minus the tare weight of the packaging expressed as ounces and grams or milligrams. "Net weight" as applied to pre-rolled marijuana includes the dried marijuana leaves and flowers, the rolling paper, and the filter or tip.

(41)(a) "Other Cannabinoid Product" means a cannabinoid product that contains two or more ingredients and is not intended for human consumption, including but not limited to products that combine usable marijuana and concentrates or extracts; or usable marijuana, concentrates or extracts that contain added substances.

(15b) "Producing" means:

(a) Planting, cultivating, growing, trimming or harvesting marijuana. "Other Cannabinoid Product" does not include

pre-rolled marijuana consisting of only dried marijuana leaves and flowers, an unflavored rolling paper and a filter or tip. ¶

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

(43) "Person responsible for a marijuana grow site" 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 and has the same meaning as "grower." ¶

(44) "Place of address" means the name, mailing address, city, state and zip code of the processor who made the cannabinoid edible. ¶

(45) "Principal display panel" means the part of a label on a package or container that is most likely to be displayed, presented, shown or seen under customary conditions of display for sale or transfer. ¶

(46) "Processor" means a person: ¶

(a) Licensed by the Commission to process marijuana under ORS 475B.090; or ¶

(b) Drying marijuana leaves and flowers. ¶

~~(16) Registered with the Authority under ORS 475B.840 as a processing site and who is not exempt from labeling requirements under ORS 475B.605~~ ¶

(47) "Producer" means a person: ¶

(a) Licensed by the Commission to produce marijuana under ORS 475B.070; and ¶

(b) Registered with the Authority under ORS 475B.810 as a grower and who is not exempt from labeling requirements under ORS 475B.605. ¶

(48) "Product identity" means a truthful or common name of the product that is contained in the package. ¶

(49) "Registrant" means a person registered with the Authority under ORS 475B.420, 475B.435, or ORS 475B.45785 to 475B.949. ¶

(50) "Registry identification cardholder" means a person to whom a registration card has been issued under ORS 475B.797. ¶

(51) "Serving" or "serving size" means an amount of product that is suggested for use by a consumer or patient trying the item for the first time. ¶

(52) "THC" means tetrahydrocannabinol and includes both THCA and delta 9 THC. ¶

(53) "These rules" means OAR 845-025-7000 through 845-025-7190. ¶

~~(17) Usable M~~(54) "UID number" for the purpose of labeling, means the unique identification number generated by the Commission's seed to sale tracking system at the time the marijuana item was packaged and labeled for ultimate sale to a consumer, patient, or designated primary caregiver. ¶

(55) "Ultimate sale" means the final sale from a retail location or dispensary to a consumer, patient, or designated primary caregiver. ¶

(56) "Universal symbol" means the image, established by the Authority and made available to licensees and registrants, indicating the marijuana item contains marijuana. ¶

(57)(a) "Usable marijuana" means the dried leaves and flowers of marijuana. ¶

(b) "Usable Marijuana" includes pre-rolled marijuana as long as the pre-roll consists of only dried marijuana leaves and flowers, an unflavored rolling paper and a filter or tip. ¶

(c) "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.

Statutory/Other Authority: ORS 475B.6105

Statutes/Other Implemented: ORS 475B.600, 475B.615

ADOPT: 845-025-7010

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7010

Purpose, Scope and Effective Date

(1) The purpose of OAR 845-025-7000 through 845-025-7190 is to set the minimum standards for the packaging and labeling of marijuana items and industrial hemp commodities and products that are for ultimate sale or transfer to a consumer, patient, or designated primary caregiver at a dispensary or retail store. These minimum standards are applicable to: ¶

(a) A Commission licensee as defined in OAR 845-025-1015; and ¶

(b) A person registered with the Authority under ORS 475B.785 to 475B.949 who is not exempt from the labeling requirements as described in section (2) of this rule. ¶

(2) The labeling requirements in these rules do not apply to: ¶

(a) A grower if the grower 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. ¶

(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) A licensee or registrant transferring a bulk quantity or amount of marijuana items to another licensee or registrant for processing or packaging. ¶

(d) A licensee, hemp handler, or hemp grower transferring a bulk quantity or amount of industrial hemp or industrial hemp commodities or products to a licensee for processing or packaging. ¶

(e) A marijuana processor registered under ORS 475B.139 when the marijuana processor receives marijuana or usable marijuana from a patient or a designated primary caregiver and processes the marijuana or usable marijuana into cannabinoid products, cannabinoid concentrates and cannabinoid extracts and transfers the processed marijuana items back to the patient or designated primary caregiver. ¶

(3) Nothing in these rules prohibits the Commission, the Authority, or the Oregon Department of Agriculture from: ¶

(a) Imposing additional labeling requirements in their respective rules governing licensees and registrants as long as those additional labeling requirements are not inconsistent with these rules; or ¶

(b) Requiring licensees or registrants to provide informational material to a consumer, patient or designated primary caregiver at the point of sale.

Statutory/Other Authority: ORS 475B.605, ORS 475B.615

Statutes/Other Implemented: ORS 475B.605, ORS 475B.615

AMEND: 845-025-7020

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7020

Packaging for Sale to Consumer ¶

~~(1) The purpose of this rule is to set the minimum standard~~ Containers for the packaging of marijuana items that are sold to the consumer, applicable to:¶

~~(a) A licensee; or¶~~

~~(b) On and after October 1, 2016, a registrant who is not exempt from the labeling requirements.¶~~

~~(2) Containers or packaging for marijuana item and industrial hemp commodities or products~~ must protect a marijuana the packaged item from contamination and must not impart any toxic or deleterious substance to the marijuana packaged item.¶

~~(3) Marijuana items for ultimate sale to a consumer, except for~~ and industrial hemp commodities or products for ultimate sale to a consumer, patient, or designated primary caregiver, except for usable marijuana, immature plants and seeds, must:¶

~~(a) Be packaged in a container that is child-resistant as certified by a qualified third party child-resistant package testing firm or placed within an exit package that is resealable and continually child-resistant as certified by a qualified third party child-resistant package testing firm prior to final sale to consumer;¶~~

~~(b) Be packaged in a container or placed within an exit package that is capable of being resealable and made continually child-resistant again after it has been opened, as certified by a qualified third party child-resistant package testing firm if the marijuana item is a cannabinoid product that contains more than 15 mg of THC, or if the item is an extract or concentrate prior to final sale or transfer to consumer, patient, or designated primary caregiver;¶~~

~~(e) Not be packaged or labeled in a manner that is attractive to minors; and¶~~

~~(d) Be labeled in accordance with OAR 333-007-845-025-70040 to 333-007-010845-025-7190.¶~~

~~(4) Packaging may not contain any text that makes an untruthful or misleading statement content.¶~~

~~(5) Nothing in this rule:¶~~

~~(a) Prevents the re-use of packaging that is capable of continuing to be child-resistant, as long as the package is in good working order and maintains its child-resistant properties, and as permitted by rules established by the Commission or the Authority; or¶~~

~~(b) Prohibits the Commission or the Authority from imposing additional packaging requirements in their respective rules governing licensees and registrants.¶~~

~~(6) A licensee or registrant must provide to the Commission or the Authority upon that agency's request, additional information about the testing that was performed by the qualified third party child-resistant package testing firm in accordance with 16 CFR 1700.¶~~

~~(6) Licensees and registrants are prohibited from selling packages, containers or devices intended for intravenous delivery.~~

Statutory/Other Authority: ORS 475B.615

Statutes/Other Implemented: ORS 475B.070, 475B.090, 475B.100, ~~475B.110~~, 475B.615

AMEND: 845-025-7030

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7030

~~Labeling for Sale to Consumer-General Label Requirements; Prohibitions; Exceptions~~

~~In addition to requirements of OAR 333-007-0010 to 3(1) A label required by these rules must:~~ ¶

~~(a) Be printed on or affixed to the container holding the marijuana item or industrial hemp commodity or product and printed on or affixed to any outer package or container that is used to display the marijuana item or industrial hemp commodity or product 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) Contain all required information in any typed, legible font that is easy to read and contrasts sufficiently with the background and is at least 1/16th of an inch in height based on the uppercase "K";~~ ¶

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

~~(e) Be unobstructed and conspicuous.~~ ¶

~~(2) 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 that 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.~~ ¶

~~(3) Principal Display Panel.~~ ¶

~~(a) Every container that holds a marijuana item or industrial hemp commodity or product 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 845-025-7000.~~ ¶

~~(b) If a container holding the marijuana item or industrial hemp commodity or product is placed within another container for sale or transfer to a consumer, patient or designated primary caregiver, both containers must have a principal display panel as that term is defined in OAR 845-025-7000 in addition to the other labeling requirements provided in these rules.~~ ¶

~~(c) The principal display panel must contain the product identity, net quantity of contents, and universal symbol or hemp symbol, whichever is applicable.~~ ¶

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

~~(e) If the product is an industrial hemp commodity or product processed by a licensee, the principal display must include the hemp symbol in place of the universal symbol.~~ ¶

~~(4) Product Identity~~ ¶

~~(a) The product identity be in bold type, in a size reasonably related to the most prominent printed matter on the principal display panel, and shall be parallel to the base on which the package rests as it is designed and displayed.~~ ¶

~~(b) The product identity must clearly identify whether the item is derived from marijuana or hemp. An item that contains both industrial hemp and marijuana must identify the item as a marijuana item.~~ ¶

~~(c) The product identity for extracts and concentrates must correctly identify whether the product is an extract or a concentrate.~~ ¶

~~(5) Net Quantity Declaration~~ ¶

- (a) The net quantity of contents provided on the principal display panel must be the average net quantity of contents of packages in a batch.¶
- (b) The net quantity declaration shall be in terms of fluid measure if the item is liquid, or in terms of weight if the item is solid, semi-solid, or viscous.¶
- (c) The net quantity declaration shall be a distinct item separated from other printed label information on all sides by at least a space equal to the height of the lettering used in the declaration. The declaration shall be presented in bold type in the bottom 30 percent of the principal display panel and in lines generally parallel with the base of the container.¶
- (6) Potency Labeling ¶
- (a) The THC and CBD amount required to be on a label must be the value calculated by the laboratory that did the testing in accordance with OAR 333-00764-0100:¶
- (1) No label may be attractive to minors as defined in OAR 845-025-7000(1); and¶
- (2) The Commission may require that marijuana items sold at retail be labeled with a Universal Product Code. A label may not have a THC value that exceeds the applicable maximum concentration limit. ¶
- (b) A label may make a voluntary declaration of the target amount of THC and CBD for the item on the principal display panel as long as: ¶
- (A) The THC and CBD amounts are based on the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100, plus or minus ten percent, and ¶
- (B) The actual THC and CBD amounts calculated by the laboratory are also provided elsewhere on the label.¶
- (7) The universal symbol. The universal symbol must be at least 0.48 inches wide by 0.35 inches high and can be downloaded on the Commission's website. ¶
- (8) Medical grade symbol. The medical grade symbol must be at least 0.35 inches in diameter and can be downloaded at marijuana.oregon.gov. ¶
- (9) Hemp symbol. The hemp symbol must be at least 0.48 inches wide by 0.35 high and can be downloaded on the Commission's website.¶
- (10) A marijuana item or industrial hemp commodity or product may have one or more label panels printed on or affixed to the container or packaging. ¶
- (11) Small Container Label. A marijuana item or industrial hemp commodity or product 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, in lieu of a label that has all the information required in OAR 845-025-7000 to 845-025-7190, have a label printed on or affixed to the container holding the marijuana item or industrial hemp commodity or product that includes at least the following: ¶
- (A) Information required on a principal display panel; ¶
- (B) Licensee business or trade name and license number or registrant business or trade name and registrant number; ¶
- (C) UID number; ¶
- (D) Concentration of THC and CBD in the container; and ¶
- (E) Required warnings. ¶
- (i) For a retail marijuana item or industrial hemp commodity or product, the following warning is required on the label: "For use only by adults 21 and older. Keep out of reach of children." ¶
- (ii) For a medical marijuana item, the following warning is required on the label: "For use by OMP patients only. Keep out of reach of children." ¶
- (b) Must include all required label information on an outer container or other required label information not listed in subsection (11)(a) of this rule on a hangtag attached to the marijuana item or industrial hemp commodity or product. ¶
- (c) May use a peel-back or accordion label with the information required in subsection (11)(b) of this rule on the inside of the peel-back or accordion label, if the peel-back or accordion label can be easily identified by a patient or consumer as containing important information. ¶

- (12) Tiny Container Label. A marijuana item or industrial hemp commodity or product that is in a container that has a complete surface area available for applying a label that is less than 2 inches squared:¶
- (a) May have a label printed on or affixed to the container that holds the marijuana item or industrial hemp commodity or product that includes at least the following:¶
- (A) The universal symbol and product identity; ¶
- (B) UID number;¶
- (C) Concentration of THC and CBD in the container;¶
- (D) Licensee or registrant business or trade name and licensee or registrant number; and¶
- (E) A warning that reads: "Keep out of reach of children."¶
- (b) May use a universal symbol on the principal display panel that is at least 0.32 inches wide by 0.23 inches high. ¶
- (c) Must include all required label information on an outer container or other required label information not listed in subsection (12)(a) of this rule on a hangtag attached to the marijuana item or industrial hemp commodity or product. ¶
- (d) May use a peel-back or accordion label with the information required in subsection (12)(c) of this rule on the inside of the peel-back or accordion label, if the peel-back or accordion label can be easily identified by a patient or consumer as containing important information. ¶
- (13) The outer container used to display the marijuana item or industrial hemp commodity or product for sale or transfer to a consumer, patient, or designated primary caregiver must comply with the labeling requirements in these rules, even if an inner container qualifies for the exception under section (11) or (12) of this rule. ¶
- (14) A marijuana item or industrial hemp commodity or product that simultaneously 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.¶
- (15) If a marijuana item or industrial hemp commodity or product is placed in a package that is being re-used, the old label must be removed and it must have a new label. ¶
- (16) A licensee or registrant must have documentation that demonstrates the validity of the calculation of the amount of sodium, cholesterol, protein, sugar, carbohydrates and total fat in a cannabinoid edible and must make that documentation available to the Commission or the Authority upon request. ¶
- (17)(a) A marijuana item or industrial hemp commodity or product that contains an ingredient consisting of two or more sub ingredients must either:¶
- (A) Use the common name of the ingredient followed by a parenthetical listing of all ingredients in a descending order of predominance; or ¶
- (B) List all sub ingredients as individual ingredients in descending order of predominance.¶
- (b) The list of ingredients must include any substance used in processing, preparing, manufacturing, packaging, or holding the cannabinoid product that is present in the final product, including any cooking or release spray.¶
- (c) The list of ingredients must include the descriptive name of the marijuana or industrial hemp ingredient used to make the product. ¶
- (18) A cannabinoid edible that contains only a single serving may omit the servings per container declaration as long as the label clearly states that the package contains a single serving.¶
- (19) A cannabinoid edible shall use one of the nutrition information formats provided by the Commission to display on the label the amount of calories, sodium, protein, added sugars, cholesterol, total carbohydrates, and total fat per serving, the serving size and number of servings per container and the list of ingredients and potential allergens.¶
- (20) If the container holding the marijuana item or industrial hemp commodity or product does not meet the child resistant standards set out in these rules, the outermost label must contain the following statement: "This package is not child resistant."¶
- (21) Exit packaging must contain a label that reads: "Keep out of the reach of children." ¶
- (22) A cartridge or vaporizing device containing a cannabinoid or hemp concentrate, extract or product intended

for use with an inhalant delivery system as that is defined in ORS 431A.175 is not required to be labeled in accordance with these rules except that the cartridge or device must have a label with the universal symbol or hemp symbol, as appropriate. All the remaining label requirements must be included on the packaging as required by these rules. ¶

(23) The Commission may require that marijuana items and industrial hemp commodities and products sold at retail by Commission licensees be labeled with a Universal Product Code. ¶

(24) Once a label is approved by the Commission, the label identification number provided by the Commission must be prominently displayed on the outer label. ¶

(25) If a cannabinoid concentrate or extract contains any added substances, the item shall be considered a cannabinoid product and labeled under OAR 845-025-7120.

Statutory/Other Authority: ORS 475B.025, 475B.605

Statutes/Other Implemented: ORS 475B.6025

REPEAL: 845-025-7040

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules. This rule has been renumbered to 845-025-7150.

CHANGES TO RULE:

~~845-025-7040~~

~~Wholesaler and Retailer Packaging and Labeling Compliance Requirements~~

~~(1) If a wholesaler or a retailer receives a marijuana item that is not packaged or labeled in accordance with OAR 845-025-7000 to 845-025-7060 or 333-007-0010 to 333-007-0100, the wholesaler or retailer must notify the Commission and return the marijuana item to the licensee who transferred the wholesaler or retailer the marijuana item. The wholesaler or retailer must document the return and the reason for the return in the tracking system.~~

~~(2) Sale of a marijuana item that is not packaged and labeled in accordance with OAR 845-025-7000 to 845-025-7060 and 333-007-0010 to 333-007-0100 is a category III violation.~~

~~Statutory/Other Authority: ORS 475B.615~~

~~Statutes/Other Implemented: ORS 475B.100, 475B.110, 475B.615~~

ADOPT: 845-025-7045

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7045

Marijuana Plant Labeling Requirements

Prior to an immature marijuana plant being sold or transferred to a consumer, patient or designated primary caregiver a tag or label must be affixed to the plant or plant container that has the following information: ¶

(1) Producer's business or trade name and license number; ¶

(2) Business or trade name of licensee that packaged the product, if different from the producer; ¶

(3) Name of the strain; ¶

(4) Product identity; ¶

(5) UID number; and ¶

(6) Universal symbol.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7050

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7050

Marijuana Seed Labeling Requirements

Prior to marijuana seeds being sold or transferred to a consumer, patient or designated primary caregiver the container holding the seeds must have a label that has the following information: ¶

(1) Producer's business or trade name and license number; ¶

(2) Business or trade name of licensee that packaged the product, if different from the producer; ¶

(3) Name of the strain of seed; ¶

(4) Date of harvest; ¶

(5) Number of seeds or net weight in grams and ounces; ¶

(6) Product identity; ¶

(7) UID number; and ¶

(8) Universal symbol.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

REPEAL: 845-025-7060

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules. This rule has been renumbered to 845-025-7160.

CHANGES TO RULE:

~~845-025-7060~~

~~Packaging and Labeling Pre-approval Process~~

~~(1) Prior to a marijuana item being sold to a consumer, a licensee, license applicant or a registrant, if pre-approval is required by the Authority, must submit an application for both package and label pre-approval by the Commission.~~

~~(a) The initial submission shall be made electronically if required by the Commission. The licensee, license applicant or registrant must submit a physical prototype upon request by the Commission.~~

~~(b) If a license applicant submits packages and labels for pre-approval, final determination for packages and labels will not be made until the applicant has been issued a license.~~

~~(2) Except as provided in sections (7) to (9) of this rule, the packaging and labels must be accompanied by the following:~~

~~(a) A fee as specified in OAR 845-025-1060; and~~

~~(b) Information including but not limited to:~~

~~(A) Documentation that the package has been certified for child resistance as defined by 16 CFR 1700 by a qualified third party child-resistant package testing firm;~~

~~(B) A picture of and description of the item to be placed in the package;~~

~~(3) The Commission will evaluate the packaging and label in order to determine whether:~~

~~(a) The packaging:~~

~~(A) Has been certified as child resistant by a qualified third party child-resistant package testing firm;~~

~~(B) Is attractive to minors or is marketed in a manner attractive to minors;~~

~~(C) Contains untruthful or misleading content; and~~

~~(D) Will contain a marijuana item that is not compliant with ORS 475B, OAR 333, Divisions 7 and 8, or these rules.~~

~~(b) The label complies with the Authority's labeling rules, OAR 333-007-0010 to 333-007-0100, or any additional labeling requirements in these rules.~~

~~(4) The Commission must review the packaging and labeling and notify the licensee, licensee applicant or registrant whether the packaging and labeling is approved, and if not approved, a description of the packaging or labeling deficiencies.~~

~~(5) If a licensee or registrant's label is deficient, it must correct the deficiencies and resubmit the label for pre-approval, but the licensee or registrant is not required to submit an additional fee unless the label is found deficient for a second time in which case the licensee must resubmit the packaging or labeling in accordance with section (1) of this rule.~~

~~(6) If a licensee, licensee applicant or registrant's original packaging is deficient because it is not child resistant, the licensee, applicant or registrant may:~~

~~(a) Correct the deficiencies and resubmit the packaging for pre-approval. The licensee or registrant is not required to submit an additional fee unless the packaging is found deficient for a second time in which case the licensee may resubmit the packaging or labeling in accordance with subsection (1) of this rule; or~~

~~(b) The licensee, licensee applicant or registrant may indicate that they wish to satisfy the requirement that a marijuana item be in a container that is child-resistant by using an approved child-resistant exit package.~~

~~(7) If a licensee or registrant's packaging is deficient for reasons other than child resistance it must correct the deficiencies and resubmit the packaging for pre-approval, but the licensee, applicant or registrant is not required to submit an additional fee unless the packaging is found deficient for a second time in which case the licensee~~

must resubmit the packaging or labeling in accordance with subsection (1) of this rule.¶¶

(8) A licensee, applicant or registrant may submit packaging and labeling for approval on the same application for a product that may have different flavors, colors or sizes if the product and packaging is otherwise identical.

Applications for approval of packaging and labeling under this section are subject to a single application fee.¶¶

(9) Packages and labels that have been previously approved do not need to be resubmitted if the only changes to the packaging or label are:¶¶

(a) Changes in the:¶¶

(A) Harvest or processing date;¶¶

(B) Strain;¶¶

(C) Test results;¶¶

(D) Net weight or volume; or¶¶

(E) Harvest or process lot numbers.¶¶

(b) The deletion of any non-mandatory label information.¶¶

(c) The addition, deletion or change in the:¶¶

(A) UPC barcodes or 2D mobile barcodes (QR codes); or¶¶

(B) Website address, phone number, fax number, or zip code of the licensee or registrant.¶¶

(d) The repositioning of any label information on the package, as long as the repositioning of label information is consistent with OAR 333-007-0010 to 333-007-0100.¶¶

(10) The Commission may publish a list of previously approved commercially available packaging. Packaging identified on this list as approved for certain product types does not need to be submitted for approval if used for the type of product for which it is approved and the packaging does not contain any graphics, pictures or logos.¶¶

(11) The Commission may publish a list of products whose package and label have been approved, but require an approved exit package in order to meet the child resistance requirement.¶¶

(12) Labels for marijuana items do not require pre-approval if they contain only the information required by OAR 333-007-0010 to 333-007-0100 and have no graphics, pictures or logos.¶¶

(13) Notwithstanding any provisions of this rule, the Commission may permit or require electronic submission of labels and packaging for approval.

Statutory/Other Authority: ORS 475B.610, 475B.620

Statutes/Other Implemented: ORS 475B.610, 475B.620

ADOPT: 845-025-7070

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7070

Usable Marijuana Labeling Requirements

Prior to usable marijuana being sold or transferred to a consumer, patient or designated primary caregiver the container holding the usable marijuana must have a label that has the following information: ¶

- (1) Producer's business or trade name and license number; ¶
- (2) Business or trade name of licensee that packaged the product, if different from the producer; ¶
- (3) UID number; ¶
- (4) Date of harvest; ¶
- (5) Name of strain; ¶
- (6) Net weight in grams and ounces; ¶
- (7) For pre-rolled marijuana, weight of usable marijuana used in product in grams; ¶
- (8) Concentration of THC and CBD, as calculated under OAR 333-064-0100; ¶
- (9) Universal symbol; ¶
- (10) Product identity; and ¶
- (11) For usable marijuana for sale to a consumer, warnings that state: ¶
 - (a) "For use only by adults 21 and older. Keep out of reach of children." ¶
 - (b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7080

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7080

Cannabinoid Topical Labeling Requirements

Prior to a cannabinoid topical product being sold or transferred to a consumer, patient or designated primary caregiver the container holding the cannabinoid product must have a label that has the following information: ¶

(1) Processor's business or trade name and license number; ¶

(2) Business or trade name of licensee that packaged the product, if different from the processor; ¶

(3) UID number; ¶

(4) Product identity; ¶

(5) Date the product was made; ¶

(6) Net weight or volume in U.S. customary and metric units; ¶

(7) Amount suggested for use by the consumer or patient at any one time; ¶

(8) Concentration of THC and CBD in the container (%); ¶

(9) List of ingredients in descending order of predominance by weight or volume used to process the cannabinoid topical; ¶

(10) Universal symbol; ¶

(11) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease"; ¶

(12) For cannabinoid topicals for sale to a consumer, warnings that state: ¶

(a) "For use only by adults 21 and older. Keep out of reach of children." ¶

(b) "DO NOT EAT" in bold, capital letters.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7090

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7090

Cannabinoid Edible Labeling Requirements

Prior to a cannabinoid edible being sold or transferred to a consumer, patient or designated primary caregiver the container holding the edible must have a label that has the following information: ¶

(1) Processor's business or trade name, place of address, and license number; ¶

(2) Business or trade name and place of address of licensee that packaged the product, if different from the processor; ¶

(3) Product identity; ¶

(4) UID number; ¶

(5) Date the edible was made; ¶

(6) Net weight or volume in U.S. customary and metric units; ¶

(7) Serving size and number of servings per container; ¶

(8) Amount, in milligrams, of THC and CBD in each serving and in the container; ¶

(9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid edible; ¶

(10) List of potential major food allergens; ¶

(a) Using a "contains" statement list the name of the food source of any major food allergen at the end of or immediately adjacent to the ingredient list; or ¶

(b) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen; ¶

(11) The amount of calories, sodium, protein, added sugars, cholesterol, total carbohydrates, and total fat per serving, in grams or milligrams as appropriate; ¶

(12) If the edible is perishable, a statement that the edible must be refrigerated or kept frozen; ¶

(13) Activation time, expressed in words or through a pictogram; ¶

(14) Universal symbol; ¶

(15) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease"; ¶

(16) For cannabinoid edibles for sale to a consumer, warnings that state: ¶

(a) "For use only by adults 21 and older. Keep out of reach of children." ¶

(b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect." ¶

(17) For medical grade cannabinoid edibles for use by a patient, the medical grade symbol and medical warnings that state: ¶

(a) "For use by OMMP patients only. Keep out of reach of children." ¶

(b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect." ¶

(18) For all beverage containers that require a refund value under ORS 459A.702, the label must contain "OR 10?"

..

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7100

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7100

Cannabinoid Concentrate and Extract Labeling Requirements

Prior to a cannabinoid concentrate or extract being sold or transferred to a consumer, patient or designated primary caregiver the container holding the concentrate or extract must have a label that has the following information: ¶

(1) Processor's business or trade name and license number; ¶

(2) Business or trade name of licensee that packaged the product, if different from the processor; ¶

(3) UID number; ¶

(4) Product identity that correctly identifies the item as either a concentrate or extract; ¶

(5) Date the concentrate or extract was made; ¶

(6) Net weight or volume in U.S. customary and metric units; ¶

(7) Serving size and number of servings per container; ¶

(8) Amount, in milligrams, of THC and CBD in each serving and in the container; ¶

(9) Activation time, expressed in words or through a pictogram; ¶

(10) Universal symbol; ¶

(11) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease"; ¶

(12) For cannabinoid concentrates and extracts for sale to a consumer, warnings that state: ¶

(a) "For use only by adults 21 and older. Keep out of reach of children." ¶

(b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

(c) "DO NOT EAT" in bold, capital letters. ¶

(13) For medical grade cannabinoid concentrates and extracts for use by a patient, the medical grade symbol and medical warnings that state: ¶

(a) "For use by OMMP patients only. Keep out of reach of children." ¶

(b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

(c) "DO NOT EAT" in bold, capital letters.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7110

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7110

Cannabinoid Tincture and Capsule Labeling Requirements

Prior to a cannabinoid tincture or capsule being sold or transferred to a consumer, patient or designated primary caregiver the container holding the tincture or capsule must have a label that has the following information: ¶

(1) Processor's business or trade name, place of address and license number; ¶

(2) Business or trade name and place of address of licensee that packaged the product, if different from the processor; ¶

(3) Product identity; ¶

(4) UID number; ¶

(5) Date the product was made; ¶

(6) Net weight or volume in U.S. customary and metric units; ¶

(7) Serving size and number of servings per container; ¶

(8) Amount, in milligrams, of THC and CBD in each serving and in the container; ¶

(9) List of all ingredients in descending order of predominance by weight or volume used to process the product; ¶

(10) Universal symbol; ¶

(11) Activation time expressed in words or through a pictogram if the effects are not felt immediately; ¶

(12) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease"; ¶

(13) For cannabinoid tinctures and capsules for sale to a consumer, warnings that state: ¶

(a) "For use only by adults 21 and older. Keep out of reach of children." ¶

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana." ¶

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid products can take up to 2 hours or more to take effect." ¶

(14) For medical grade cannabinoid tinctures and capsules for use by a patient, the medical grade symbol and medical warnings that state: ¶

(a) "For use by OMMP patients only. Keep out of reach of children." ¶

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana." ¶

(c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid products ingested by mouth can take up to 2 hours or more to take effect."

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7120

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7120

Cannabinoid Products Other than Cannabinoid Edibles, Topicals, Tinctures or Capsules.

Prior to a cannabinoid product other than a cannabinoid edible, topical, tincture or capsule being sold or transferred to a consumer, patient or designated primary caregiver, the container holding the product must have a label that has the following information: ¶

(1) Processor's business or trade name, license number, and place of address; ¶

(2) Business or trade name of licensee, license number, and place of address for licensee that packaged the product, if different from the processor; ¶

(3) Product identity; ¶

(4) UID number; ¶

(5) Date the product was made; ¶

(6) Net weight or volume in U.S. customary and metric units; ¶

(7) Serving size and number of servings per container; ¶

(8) Amount, in milligrams, of THC and CBD in each serving and in the container; ¶

(9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product; ¶

(10) Universal symbol; ¶

(11) Activation time expressed in words or through a pictogram if the effects are not felt immediately; ¶

(12) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease"; ¶

(13) For cannabinoid products for sale to a consumer, warnings that state: ¶

(a) "For use only by adults 21 and older. Keep out of reach of children." ¶

(b) "Do not drive a motor vehicle while under the influence of marijuana." ¶

(c) "DO NOT EAT" in bold, capital letters.¶

(14) For medical grade cannabinoid products for use by a patient, the medical grade symbol and medical warnings that state: ¶

(a) "For use by OMMP patients only. Keep out of reach of children." ¶

(b) "It is illegal to drive a motor vehicle while under the influence of marijuana." ¶

(c) "DO NOT EAT" in bold, capital letters.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7130

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7130

Labeling Requirements for Medical Registrants Registered with the Oregon Health Authority

A person registered with the Authority as a grower, processing site, or dispensary must label a marijuana item for ultimate sale to a patient or caregiver as outlined in 845-025-7000 to 845-025-7120, with the following exceptions:¶

(1) The label must contain the Registrant number instead of the OLCC license number; and ¶

(2) The label must contain the medical warning, "For use by OMMP patients only," in place of the consumer warning, "For use only by adults 21 and older". ¶

(3) The label must contain the name of the lab that performed any test, any associated test batch number and any test analysis date for the final product.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7140

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7140

Labeling Requirements for Industrial Hemp Commodities or Products Intended for Human Consumption or Use

A licensee processing or selling an industrial hemp commodity or product may only possess and offer for sale industrial hemp commodities and products that are labeled and packaged for ultimate sale to a consumer as outlined in 845-025-7000 to 845-025-7120 with the following exceptions:¶

(1) The principal display panel must contain the hemp symbol instead of the universal symbol:¶

(2) The label shall contain the following warning in place of the consumer warnings described in OAR 845-025-7070 to 845-025-7120, "This product is derived from hemp and could contain up to 5% THC. Keep out of reach of children."¶

(3) If the product is a hemp extract, concentrate, topical, or a hemp product other than an edible, tincture, or capsule, the label shall contain the warning, "DO NOT EAT" in bold, capital letters.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605

ADOPT: 845-025-7150

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7150

Wholesaler and Retailer Packaging and Labeling Compliance Requirements

(1) If a wholesaler or a retailer receives a marijuana item or industrial hemp commodity or product that is not packaged or labeled in accordance with OAR 845-025-7000 to 845-025-7190, the wholesaler or retailer must immediately notify the Commission and either:¶

(a) Return the marijuana item or industrial hemp commodity or product to the licensee who transferred the item or product to the wholesaler or retailer; or¶

(b) Correct the label by adding only the label components required to make the label compliant. If the problem cannot be corrected by adding a sticker with the required information, the item or product must be returned to the licensee who transferred it to the wholesaler or retailer. ¶

(2) If a wholesaler or retailer returns a marijuana item or industrial hemp commodity or product to the licensee who transferred the item or product, the wholesaler or retailer must document the return and the reason for the return in CTS.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.100, ORS 475.615

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7160

Packaging and Labeling Pre-approval Process

(1) Prior to selling, offering for sale, or transferring a marijuana item or industrial hemp commodity or product that is for ultimate sale to a consumer, a licensee, a license applicant or a registrant must submit both a package and a label application to and receive approval from the Commission.

(a) The initial submission shall be made electronically if required by the Commission. The licensee, license applicant or registrant must submit a physical prototype upon request by the Commission.

(b) If a license applicant submits packages and labels for pre-approval, final determination for packages and labels will not be made until the applicant has been issued a license.

(2) Except as provided in sections (5) to (7) of this rule, the packaging and label applications must be accompanied by the following:

(a) A fee as specified in OAR 845-025-1060; and

(b) Information including but not limited to:

(A) Documentation that the package has been certified as child resistant as defined by 16 CFR 1700 by a qualified third party child-resistant package testing firm.

(B) A picture of and description of the item to be placed in the package.

(3) The Commission will evaluate the packaging and label in order to determine whether:

(a) The packaging:

(A) Has been certified as child resistant by a qualified third party child-resistant package testing firm;

(B) Is attractive to minors or is marketed in a manner attractive to minors;

(C) Contains untruthful or misleading content; and

(D) Will contain a marijuana item or industrial hemp commodity or product that is not compliant with ORS 475B, OAR 333, Divisions 7 and 8, or OAR 845, Division 25.

(b) The label:

(A) Complies with the labeling rules, OAR 845-025-7000 to 845-025-7190, or any additional labeling requirements in ORS 475B, OAR 333, Divisions 7 and 8 or OAR 845, Division 25.

(B) Contains any material that is attractive to minors; and

(C) Contains untruthful or misleading content.

(4) The Commission must review the packaging and labeling and notify the licensee, licensee applicant or registrant whether the packaging and labeling is approved, and if not approved, a description of the packaging or labeling deficiencies.

(5) If a licensee or registrant's label or package is deficient, it must correct the deficiencies and resubmit the label or package for pre-approval, but the licensee or registrant is not required to submit an additional fee unless the label or package is found deficient for a second time in which case the licensee or registrant must resubmit the packaging or labeling in accordance with section (1) of this rule.

(6) A licensee, applicant or registrant may submit packaging and labeling for approval on the same application for a product that may have different flavors, colors or sizes, if the product and packaging is otherwise identical. Applications for approval of packaging and labeling under this section are subject to a single application fee.

(7) Packages and labels that have been previously approved do not need to be resubmitted if the only changes to the packaging or label are:

(a) Changes in the:

(A) Harvest or processing date;

(B) Strain;¶

(C) Test results;¶

(D) Net weight or volume; or¶

(E) UID numbers.¶

(b) The deletion of any non-mandatory label information.¶

(c) The addition, deletion or change in the:¶

(A) UPC barcodes or 2D mobile barcodes (QR codes); ¶

(B) Website address, phone number, fax number, or zip code of the licensee or registrant; or¶

(C) Instructions for opening or using child-resistant packages¶

(d) The repositioning of any label information on the package, as long as the repositioning of label information is consistent with these rules.¶

(8) The Commission may publish a list of previously-approved, child-resistant, commercially available packaging. Packaging identified on this list as approved for certain product types does not need to be submitted for approval if the packaging is identical to the previously-approved package.¶

(9) The Commission may publish a list of licensees and registrants who have approved label applications.¶

(10) Labels for marijuana items or industrial hemp commodity or products do not require pre-approval if they are generic labels as defined in OAR 845-025-7000 and contain only the information required by these rules and have no graphics, pictures or logos.¶

(11) Packages that are not intended to be child resistant do not require pre-approval. Any package that has not been certified as child-resistant must contain the statement described in OAR 845-025-7030(20).¶

(12) Notwithstanding any provisions of this rule, the Commission may permit or require electronic submission of labels and packaging for approval.

Statutory/Other Authority: ORS 475.610, ORS 475B.620

Statutes/Other Implemented: ORS 475.610, ORS 475B.620

ADOPT: 845-025-7170

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7170

Packaging and Labeling Prohibited Conduct

The Commission may impose a civil penalty of up to \$500 per day per violation for any of the following:¶

(1) Failure to comply with these rules. ¶

(2) Transferring, selling or offering to sell a marijuana item or industrial hemp commodity or product for ultimate sale to a consumer to another licensee that is not packaged or labeled in accordance with these rules.¶

(3) Failing to receive package and label approval prior to transferring, selling, or offering for sale a marijuana item or industrial hemp commodity or product that is for ultimate sale to a consumer. ¶

(4) Transferring, selling, or offering for sale a marijuana item or industrial hemp commodity or product that has not received package or label approval.¶

(5) Selling or offering to sell a marijuana item or industrial hemp commodity or product under a different label or package than what was approved. ¶

(6) Selling a marijuana item or industrial hemp commodity or product in a package that is not resealable and continually child-resistant.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605, ORS 475B.610, ORS 475B.615, ORS 475B.620

ADOPT: 845-025-7180

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7180

Approval Withdrawal

(1) The licensee or registrant is responsible for ensuring that all packages and labels are compliant with OAR 845-025-7000 to 845-025-7190. The Commission may find a package or label violates these rules even if the package or label has received previous approval.¶

(2) After a package or label application has been approved, if the package or label is found to fall below the minimum standards described in these rules, the Commission may withdraw its label or package approval. The Commission will notify the licensee or registrant of the withdrawal of approval and provide the licensee or registrant with the deficiencies that provide the basis for the withdrawal. The licensee or registrant will have 30 days after notification is sent by the Commission to correct the deficiencies. If the deficiencies identified by the Commission are not corrected within 30 days, the application may be denied. If the Commission denies a label or package application, the licensee or registrant has the right to a hearing under the procedures in ORS Chapter 183; OAR chapter 137, division 3; and chapter 845, division 3.¶

(3) With Commission approval, the licensee or registrant may sell down any package or label inventory purchased during the time the application was approved.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605, ORS 475B.610, ORS 475B.615, ORS 475B.620

ADOPT: 845-025-7190

RULE SUMMARY: Senate Bill 1057, pass during the 2017 legislative session, shifted the responsibility of Packaging and Labeling rules from the Oregon Health Authority – Oregon Medical Marijuana Program to the Oregon Liquor Control Commission. The package makes amendments to the previous Oregon Health Authority Rules (OAR 333-007) both clarify and re-organize the packaging and labeling rules.

CHANGES TO RULE:

845-025-7190

Effective Date

(1) These rules become effective on August 15, 2018. On and after August 15, 2018, all package and label applications received by the Commission will be reviewed and evaluated under these rules. ¶

(2) All marijuana items and industrial hemp commodities and products packaged or transferred on or after January 1, 2019 must be labeled and packaged according to these rules. ¶

(3) On and after January 1, 2019, marijuana items and industrial hemp commodities and products with labels approved prior to August 15, 2018, can no longer be sold, offered for sale, or transferred to a consumer, patient, or designated primary caregiver.

Statutory/Other Authority: ORS 475B.605

Statutes/Other Implemented: ORS 475B.605