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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 845
OREGON LIQUOR CONTROL COMMISSION

FILED
10/30/2020 4:04 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Prohibits certain additives and creates additional ingredient disclosure and labeling requirements for inhalable cannabinoid products.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2020 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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Milwaukie,OR 97222

Filed By:
Madeline Kane
Rules Coordinator

HEARING(S)

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

DATE: 11/16/2020
TIME: 2:00 PM - 3:00 PM
OFFICER: Madeline Kane
ADDRESS:
Virtual Hearing via Online &
Telephone
Milwaukie, OR 97222
SPECIAL INSTRUCTIONS:
To listen to, or participate in, this Public Hearing please call: 1 (571) 317-3112 and enter access code: 497-665-445#

In order to offer oral comment, please email: OLCC.rulemaking@oregon.gov, no later than 9:30 am on Monday, November 16, 2020. The hearing will end at 2:15 pm, if no interested parties arrive within that time and none have emailed by 9:30 am to offer comment; or 5 minutes after the last oral comment has been recorded into the record.

NEED FOR THE RULE(S):

This is an updated notice from a previously submitted notice.

This rule package updates the requirements for inhalable cannabinoid products that use non-cannabis additives. The rules are being amended to address technical fixes, define and clarify the requirements for non-cannabis additives in inhalable cannabinoid products, and require more transparent ingredient labeling in order to better enable informed choice by consumers. These rules are intended to reinforce the Oregon Liquor Control Commission's ability to protect public health and safety, by specifying the standards for non-cannabis additives being used in inhalable cannabinoid products related to disclosure of ingredients and declarations of intended use.

There is a public health and safety concern regarding both the acute and chronic health effects of additive ingredients when heated and inhaled. Given the lack of determinative scientific evidence of safety when these ingredients are inhaled, these proposed rules provide more transparency to licensees and consumers so that it is clearer which ingredients were manufactured with the intent to inhale and so that individual, informed choices can be made regarding whether to sell or consume items with these non-cannabis additive ingredients.

845-025-1015

A technical fix is being made to extend the adulteration prohibition to hemp items sold in the OLCC system. The rule is also being updated to more closely align the "adulteration" definition with OLCC's statutory authority to prevent adulterated items from being sold and to protect the public health. This will allow the OLCC to quickly take action, as necessary, to prohibit certain substances that may pose a risk to human health from being included in certain marijuana items. New definitions for "Inhalable cannabinoid product" and "Non-cannabis additive" are added to support the other proposed rule adoptions and amendments.

This rule also incorporates a change in the definition of "licensee" that had been adopted via a temporary rule amendment in October 2020. This change clarified the definition of "licensee" in conjunction with other changes made in the prior temporary rule package. It is of benefit to licensees and streamlines the license application review process. This definition of "licensee" will be reconsidered during an upcoming permanent rule process in 2021 prior to the temporary rule expiring.

845-025-2755

This rule is being updated to apply the same standards to hemp inhalable products sold by hemp handler certificate holders as the new standards for inhalable marijuana products manufactured by OLCC processors. The rule would also apply the sell-down period of prohibited inhalable products to hemp handler certificate holders.

845-025-3220

The rule is being updated to prohibit processors from manufacturing inhalable cannabinoid products with non-cannabis additives that do not meet the updated requirements of this rule package, but also provides a limited sell-down period of these products that are manufactured prior to February 1, 2021. In an effort to further strengthen OLCC's ability to protect the public health, the rule is being updated to remove the limitation that adulterants can only come from non-cannabis sources, and broadened the applicability beyond "additives" to include substances.

845-025-3265

The proposed rule creates additional requirements in order to better protect public health and safety by ensuring that all the contents of non-cannabis additives for use in inhalable cannabinoid products are disclosed to regulators. All non-cannabis ingredients must be clearly stated to be intended for human inhalation. Further, the rule sets prohibitions upon certain ingredients being used in inhalable cannabinoid products that are most likely to cause harm when exposed to cannabis vaping conditions and inhaled.

The companies that provide additives to OLCC licensees are not overseen by state or federal regulatory authorities for products meant for inhalation. The additive ingredients may be “Generally Recognized as Safe” (GRAS), but GRAS-certification is scientifically evaluated only based on use in food products that will be ingested. An ingredient’s GRAS status is irrelevant for the question of whether it is safe to vaporize and inhale. Many of the non-cannabis additive products purchased by OLCC licensees have unknown health effects when used in cannabis products that will be vaporized and inhaled.

Currently, many non-cannabis additives used in these products contain ingredients that are not disclosed to OLCC, retailers selling the products, nor consumers purchasing the products. Without full disclosure, regulators cannot begin to assess the safety of these ingredients and consumers cannot make an informed choice about what they are consuming. These rules also require the maximum concentrations of non-cannabis ingredients within additives to be disclosed to OLCC so that if an ingredient is found to be problematic in certain concentrations, the OLCC can take measures to prohibit or limit its use.

As of this rulemaking, most of the manufacturers of non-cannabis additives utilized in inhalable cannabinoid products state that their products are meant for culinary use and make no claims that the ingredients should be inhaled. However, these same additive companies market their products almost exclusively to the cannabis industry for usage in vaporization products. Many companies add disclaimers related to their additives products’ use for inhalation and some go so far as to put the onus on the end-user to conduct safety assessments. The requirement set forth in this rule for the clear labeling of intended use of human inhalation will make explicit to OLCC licensees which ingredients should be used in inhalable products and which cannot be.

In the United States, 2019 saw an unprecedented outbreak of e-cigarette, or vaping product-use associated lung injury (EVALI), which sickened thousands and killed hundreds due to acute lung injury. Oregon had 23 confirmed cases, 2 of which were fatal. Primarily, EVALI patients have been diagnosed with lipoid pneumonia (inhalation of oil) and/or chemical pneumonitis (chemical burns in the lungs). The precise causative agent of EVALI is still unknown and may never be known due to the many variables and complex chemistry that occurs in vaping products. Researchers have speculated that several factors may be responsible, including cutting agents, flavorings, and pesticides. Research has shown that certain substances, when heated under common cannabis vaping conditions and inhaled into the lungs can have serious negative health consequences. Therefore, the OLCC is proposing to explicitly prohibit the most troublesome substances and will take action should more research arise.

845-025-3270

This proposed rule requires that licensees possessing inhalable cannabinoid products with non-cannabis additives track these items in the cannabis tracking system (CTS) under a new category. Also, the rule requires that licensees record the additive name(s) and manufacturer(s) in these items in a way that matches the information on the additive's required list of ingredients. These two requirements will provide the OLCC with greater line of sight to which specific non-cannabis additives are on the market and in which items. This enables swifter action by OLCC if information emerges that calls the safety of an additive ingredient into question.

845-025-7000, 845-025-7120, 845-025-7160, and 845-025-7190
Amendments to these four rules update the packaging and labeling rules. Specifically, the proposed changes prohibit OLCC licensees from using generic labels for inhalable cannabinoid products that use non-cannabis additives. The OLCC is proposing this change because generic labels, and therefore the items' ingredient lists, are not reviewed by OLCC staff prior to being offered for ultimate sale to a consumer. By requiring pre-approval for labels of inhalable cannabinoid product with non-cannabis additives, the OLCC will have a clearer line of sight as to what ingredients are being placed into these products and whether the ingredients and ingredient disclosure comply with OLCC rules. Requiring pre-approval will also provide consumers a greater level of assurance of accuracy and compliance of these items. This greater level of scrutiny and review is necessary because inhalation of substances is vastly different from ingestion. The human digestive system is better at processing toxicants, however, the lungs are not as adept – as shown by the EVALI outbreak.

The labeling rules have also been updated for inhalable cannabinoid products that contain non-cannabis additives. Among other things, the updated requirements require the products to fully list each ingredient. Due to the unknown safety of some of the additives used by OLCC licensees, this will allow consumers to make a more informed choice about what they are consuming.

These rules require inhalable cannabinoid products manufactured on or after February 1, 2021, and that contain non-cannabis additives to have pre-approved labels compliant with these rules prior to being sold to consumers. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

845-025-8520
Amendments to this rule apply the prohibition to possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not comply with OAR 845-025-3265 on or after July 1, 2021, to all license types. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Governor's Recommendations from the Vaping Public Health Workgroup (available from the Office of Governor Kate Brown).
OLCC's review of non-cannabis additives ("Non-Cannabis Additives in Inhalable Cannabinoid Products: Rationale for

Rulemaking"; available upon request from the OLCC).
ORS 475B.025 (2)(c), 475B.232, 475B.605 & 475B.610 (Available from legislative Counsel)
OLCC rulemaking files (available upon request from the OLCC.)

FISCAL AND ECONOMIC IMPACT:

This statement takes into account the fiscal impact on: (a) Marijuana Licensees, their employees, and Industrial Hemp Certificate Holders; (b) Local Government; (c) State Agencies; and (d) the public.

(a) Marijuana Licensees, their employees, and Industrial Hemp Certificate Holders
It is not possible to firmly estimate the potential fiscal impact of these rules on affected parties because the fiscal impact is contingent on individual business decisions by additive manufacturers about whether they intend to disclose additive contents and make statements of intended use. These rules create minimum standards for input ingredients, not the cannabis products themselves. All products currently on the market can continue to be sold after the rules are in effect so long as ingredient disclosure requirements are met, the items currently contain no banned ingredients and/or are reformulated to no longer contain those banned ingredients, and they are relabeled according to the new ingredient disclosure requirements. OLCC therefore expects all licensees, hemp certificate holders, and third-party additive manufacturers to be able to comply with the requirements with moderate fiscal impact.

The OLCC expects a possible negative fiscal and economic effect on businesses, depending on how many third-party additive manufacturers and/or OLCC processors are unable or unwilling to comply with the new requirements for disclosure of non-cannabis additive ingredients. OLCC estimates that sales of products affected by these rules constitute 5-10% of the OLCC market, or approximately $50-$100 million in the most recent 12 month period. If all of these items were unable to be sold and consumers did not substitute towards other items, the effect would be $50-$100 million in total for OLCC licensed retailers. This is a maximum possible effect, and it is highly unlikely that the true effect would be this large, due to affected items having a pathway to come into compliance through proper disclosure and labeling of ingredients. OLCC does not have data on the wholesale price of these products, but if items cannot be sold due to noncompliance with these rules, hemp handler certificate holders and OLCC wholesalers and processors would be negatively affected with lost wholesale revenue. Hemp grower certificate holders, hemp handler certificate holders, and OLCC producers could possibly also be negatively affected due to lower demand for their input materials in the processing of these items.

If processors face negative economic impacts and a loss in sales, employees would likely face negative economic effects as well in the form of lower pay or job loss. The specific magnitude of the effect would be dependent on the degree to which third-party manufacturers are willing to comply with the ingredient disclosure and intended use declaration requirements.

OLCC estimates that inhalable cannabinoid products with non-cannabis additives constitute approximately 5–10% of cannabis sales in the OLCC system. OLCC expects most, if not all, of these products to be able to meet the ingredient disclosure requirements, if third-party manufacturers are willing to disclose those ingredients in the required format. Due to the lack of disclosure requirements currently, OLCC is unable to quantify the number of inhalable cannabinoid products or non-cannabis additives being used that are formulated with any of the banned ingredients (e.g. MCT oil). Items that do contain banned ingredients would be unable to be sold under these rules after July 1, 2021, but the products could be reformulated and comply with these rules on an ongoing basis.

Depending on how licensees and the market adjusts to these rules, there is also a potential positive effect on businesses. Products without non-cannabis additives are sold at a higher price point; if consumers do substitute towards vape products without non-cannabis additives then total sales could remain net neutral or even increase, having a possible positive impact on licensees' revenue. Many of the third-party additives affected by these rules can also be derived from cannabis, meaning that if third-party companies cannot or will not comply with these rules there may be increased demand for OLCC producers' usable marijuana.

The change to the definition of "licensee," in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a fiscal impact because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

(b) Local Government:
The OLCC expects a possible negative fiscal and economic effect on units of local government, depending on how many third-party additive manufacturers and/or OLCC processors are unable or unwilling to comply with the new requirements for disclosure of non-cannabis additive ingredients. If sales from these products decline, and consumers do not substitute towards other cannabis products, tax revenue for units of local government may decline. OLCC estimates that sales of products affected by these rules constitute 5-10% of the OLCC market, or approximately $50-$100 million in the most recent 12 month period. If all of these items were unable to be sold and consumers did not substitute towards other items, the effect on units of local government could be $1.7-$3.4 million in total for their collective share of the statewide marijuana tax distribution, and $1.5-$3 million in total if all jurisdictions collect the 3% local marijuana tax. This is a maximum possible effect, and it is highly unlikely that the true effect would be this large, due to affected items having a pathway to come into compliance through proper disclosure and labeling of ingredients.

Depending on how licensees and the market adjusts to these rules, there is also a potential positive effect on units of local government. Products without non-cannabis additives are sold at a higher price point; if consumers do substitute towards vape products without non-cannabis additives then total sales could remain net neutral or even increase, having a possible positive impact on local governments' tax receipts.

Additional positive benefit may accrue to units of local government in the form of fewer acute and chronic health effects from potentially harmful ingredients and lower public health expenditures associated with these harms. Certain ingredients most likely to cause acute and chronic harms (e.g. Vitamin E Acetate, squalene, squalane, and MCT oil) are being banned. The definition of adulteration, in combination with the increased disclosure and transparency of ingredients, will make OLCC better able to respond if scientific evidence emerges that certain other ingredients are harmful to public health. Finally, the requirement for non-cannabis additive ingredients to be accompanied by a statement of intended use in inhalable products will provide greater clarity to licensees and consumers about which ingredients were manufactured with that intent. All of these changes provide greater clarity, expectations of use, and more robust information with which licensees and consumers may make more informed choices. This should decrease the likelihood of acute EVALI-like events or chronic harm associated with vaporization of additive ingredients.

The change to the definition of “licensee,” in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a fiscal impact because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

(c) State Agencies:
The OLCC does not expect a fiscal or economic impact on state agencies. OLCC has sole enforcement duties and authority over cannabis vaping products and therefore these rules do not expand any other agencies’ role or responsibilities.

The change to the definition of “licensee,” in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a fiscal impact because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

(d) The public (consumers and 3rd party additive manufactures):

Consumers of inhalable cannabinoid products with non-cannabis additives could be negatively economically affected by higher prices on products they consume. However, there would likely be a positive health impact by the removal of the ingredients most likely to cause both acute and chronic harm (e.g. Vitamin E Acetate, squalene, squalane, and MCT oil). These positive health impacts would likely translate to positive long-term economic impacts to consumers due to lower health care spending and decreased risk of hospitalizations. The effect of greater transparency and disclosure of information to consumers would also be positive, in that it would enable them to make more informed choices regarding their own consumption as it relates to their personal health.

If third-party additive manufacturers are unable or unwilling to disclose ingredients and state intended use of the additives in inhalable products, these businesses would be negatively affected by the rules by not being able to sell their additive products to OLCC licensees. The OLCC does not have any data on the price or quantity of the additives currently being used by OLCC processors. OLCC’s rules would not affect third-party additive manufacturers’ ability to sell their additive products in other states or outside of the OLCC’s regulated cannabis supply chain.

Additional positive benefit may accrue to consumers in the form of fewer acute and chronic health effects from potentially harmful ingredients and lower health expenditures associated with these harms. Certain ingredients most likely to cause acute and chronic harms (e.g. Vitamin E Acetate, squalene, squalane, and MCT oil) are being banned. The definition of adulteration, in combination with the increased disclosure and transparency of ingredients, will make OLCC better able to respond if scientific evidence emerges that certain other ingredients are harmful to public health. Finally, the requirement for non-cannabis additive ingredients to be accompanied by a statement of intended use in inhalable products will provide greater clarity to licensees and consumers about which ingredients were manufactured

with that intent. All of these changes provide greater clarity, expectations of use, and more robust information with which licensees and consumers may make more informed choices. This should decrease the likelihood of acute EVALI-like events or chronic harm associated with vaporization of additive ingredients.

The change to the definition of "licensee," in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a fiscal impact because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

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).

(a) Estimate of the number of small businesses subject to the proposed rule and identification of the types of businesses and industries with small businesses subject to the proposed rule:

Based on activity recorded in the OLCC's Cannabis Tracking System, OLCC estimates that approximately 140 processors and wholesalers have manufactured and/or transferred inhalable cannabinoid products with non-cannabis additives. Of those businesses, OLCC estimates that 111 are small businesses.

OLCC estimates that 624 active retailers have made sales of inhalable cannabinoid products with non-cannabis additives since March 2020. Of these, OLCC estimates that 534 are small businesses.

OLCC further estimates that approximately 12 third-party additive companies would be affected by this rule. OLCC does not have information of how many of these businesses qualify as small businesses, or how many are based in Oregon.

In total, OLCC estimates that approximately 657 small businesses may be impacted by this rule.

(b) Brief description of the projected reporting, recordkeeping and other administrative activities required for compliance with the proposed rule, including costs of professional services:

OLCC estimates the following costs of compliance for the new rules:
The ban on certain ingredients such as MCT oil, as well as the possibility that some third-party manufacturers may be unwilling or unable to comply with the new standards for non-cannabis additive ingredients, may result in OLCC processors substituting towards cannabis-derived terpenes and other ingredients for their inhalable products. OLCC estimates that non-cannabis additives are 30% the cost of cannabis-derived terpenes. Licensees typically include these ingredients at a 5-10% rate in the final product. OLCC does not have sufficient data on the full cost of input materials and therefore cannot estimate the increase in total production costs.

Submission of new item labels for approval under the revised rules would cost $100 per item. Under OLCC's rules, multiple "flavors" or variants of the same item could be submitted under a single application. OLCC does not have data indicating how many individual label applications would have to be submitted, but estimates that the cost of compliance would be approximately $1,000 per affected business.

Revisions of new labels and (optional) label inserts to meet ingredient disclosure requirements would also be required, although OLCC estimates that only minor revisions would be required. OLCC estimates that costs of graphic design would range between $50 and $100 per hour. Because the revised rules require a slightly modified product identity, additional information within an already designed and approved ingredient listing, and/or disclosure of the full list of ingredients on an item insert that is likely to be standardized (and/or have fewer design elements than exterior packaging), OLCC expects redesigns to be minimal. OLCC has no way of firmly estimating the average time it will require for design revisions to be made, but a full day of a graphic designer's time would potentially cost between $800 – $1,000.

The revisions may also require licensees to order and/or design new packaging. Existing items that are currently non-compliantly labeled but have compliant labels approved prior to July 1, 2021, will also require staff time to replace old labels with new labels (and possibly also ingredient inserts). OLCC has no way of firmly estimating the average time it will require for these revisions to be made, of the cost of new packaging or labeling, or of the labor cost of applying new labels. OLCC estimates that approximately 344,000 affected inhalable cannabinoid product units are in the inventories of 603 small business licensees, or an average of approximately 571 units per license. OLCC estimates that the labor cost to replace labels for this many units would likely be 40 to 80 hours of total staff hours; at a rate of $25 per hour this would be labor costs of $1,000 to $2,000.

The onset of the rule is February 1, 2021, and the sell-down period for previously approved inhalable cannabinoid products with non-cannabis additives is a further six months. The OLCC estimates that this amount of time will be sufficient for licensees to redesign labels and order/design new packaging. The sell-down period will also provide licensees an opportunity to sell existing stock of items in order to minimize both the number of inhalable cannabinoid product units and excess non-compliant labels that must be disposed of, as well as the amount of staff hours required to relabel items with newly approved labels.

OLCC licensees will be required to re-categorize existing items by February 1, 2021. OLCC expects minimal time or cost impacts to licensees, because licensees will have sufficient lead time to begin categorizing items under the correct category as they are created. OLCC estimates that approximately 603 small business licensees have an inhalable cannabinoid product with non-cannabis additives in inventory as of October 20, 2020, and that there are approximately 22,446 such "packages" in the Cannabis Tracking System in the possession of small business licensees. RFID unique tags are required for all "packages" in the Cannabis Tracking System, and each tag costs $0.25; if all such packages were to be re-categorized, the supply cost per license would be approximately $9.50. Labor cost is more difficult to estimate, but it is likely that staff time of re-categorization would take approximately 8 to 40 staff hours; at $25 per hour this would cost between $200 and $1,000.

For third-party manufacturers, OLCC estimates that the direct cost of compliance would be minimal to negligible. Third-

party manufacturers presumably already have knowledge of their own input ingredients and concentrations. Many, if not most, of these ingredient lists are already provided to OLCC processors under a non-disclosure agreement. The only requirements of these rules would be a prescribed format of these ingredient lists, including full disclosure of ingredients; maximum concentrations of each; and labeling of intended use of the additive including use in an inhalable product. In cases where these ingredient lists already disclose all ingredients and concentrations, the only direct cost would be inclusion of the intended use. For ingredient lists that do not currently disclose all ingredients and/or maximum concentrations, the creation of the ingredient list should be minimal, because the OLCC revised rules would allow electronic documentation to be provided to OLCC licensees and submitted as part of the item label pre-approval application.

For third-party manufacturers, there may be indirect costs of these rules related to increased cost in product liability insurance premiums as a result of being required to state that the additive's intended use is in inhalable products. OLCC has no way of estimating these indirect costs; OLCC rules also do not require that third-party manufacturers hold product liability insurance.
OLCC expects no effect on the cost of compliance due to the change in definition of the term "licensee." The change to the definition of "licensee," in isolation of any other changes to relevant sections of rule, merely clarifies the status quo definition. It is not expected to have a cost of compliance because the persons who qualify as a licensee under the new definition are identical to the persons who qualify as a licensee under the previous definition.

(c) Identification of equipment, supplies, labor and increased administration required for compliance with the proposed rule:

OLCC does not anticipate ongoing equipment, supply, labor, or administrative costs of compliance due to these rules. The costs of compliance described above pertain to the costs to come into compliance and remain in compliance with these rules.

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

OLCC began this rulemaking process by holding a rules advisory committee comprised of subject matter experts and public health officials. OLCC then held two rules advisory committees that included OLCC licensees and third-party additive manufacturers. Discussion from the second rules advisory committee informed revisions to the proposed rules, which significantly scaled back fiscal and economic impacts to licensees. Revisions to the proposed rules were presented to the third rules advisory committee, which was comprised of small businesses that would be directly affected by the proposed rules. Discussion from this third rules advisory committee informed further revisions to the proposed rules to further decrease the fiscal and economic impacts to small businesses as well as dramatically reduce the costs of compliance. The OLCC also developed these rules based on input from Oregon Health Authority and Alcohol and Drug Policy Commission staff related to possible health impacts. This was done by developing and completing an analysis of possible public health impacts.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
845-025-1015, 845-025-2755, 845-025-3220, 845-025-3265, 845-025-3270, 845-025-7000, 845-025-7120, 845-025-7160, 845-025-7190, 845-025-8520

AMEND: 845-025-1015

RULE SUMMARY: A technical fix is being made to extend the adulteration prohibition to hemp items sold in the OLCC system. The rule is also being updated to more closely align the “adulteration” definition with OLCC’s statutory authority to prevent adulterated items from being sold and to protect the public health. This will allow the OLCC to quickly take action, as necessary, to prohibit certain substances that may pose a risk to human health from being included in certain marijuana items. New definitions for “Inhalable cannabinoid product” and “Non-cannabis additive” are added to support the other proposed rule adoptions and amendments.

This rule also incorporates a change in the definition of “licensee” that had been adopted via a temporary rule amendment in October 2020. This change clarified the definition of “licensee” in conjunction with other changes made in the prior temporary rule package. It is of benefit to licensees and streamlines the license application review process. This definition of “licensee” will be reconsidered during an upcoming permanent rule process in 2021 prior to the temporary rule expiring.

CHANGES TO RULE:

845-025-1015
Definitions ¶

For the purposes of OAR 845-025-1000 to 845-025-8590, unless otherwise specified, the following definitions apply:¶
(1) "Added substance" means any component or ingredient added to usable marijuana, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the final cannabinoid product, including but not limited to flavors, non-marijuana derived terpenes, and any substances used to change the viscosity or consistency of the cannabinoid product.¶
(2) "Adulterated" means to make a marijuana or hemp item impure by adding foreign or inferior ingredients or substances. A marijuana or hemp item may be considered to be adulterated if:¶
(a) In the Commission's judgment, it bears or contains any poisonous or deleterious substance in a quantity rendering the marijuana or hemp item injurious ~~to~~in a manner that may pose a risk to human health, including but not limited to tobacco or nicotine;¶
(b) It bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;¶
(c) It consists in whole or in part of any filthy, putrid, or decomposed substance, or otherwise is unfit for human consumption;¶
(d) It is processed, prepared, packaged, or is held under improper time-temperature conditions or under other conditions increasing the probability of contamination with excessive microorganisms or physical contaminants;¶
(e) It is processed, prepared, packaged, or held under insanitary conditions increasing the probability of contamination or cross-contamination;¶
(f) It is held or packaged in containers composed, in whole or in part, of any poisonous or deleterious substance rendering the contents potentially injurious to health;¶
(g) Any substance has been substituted wholly or in part therefor;¶
(h) Damage or inferiority has been concealed in any manner; or¶
(i) Any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.¶
(3) "Assign and affix a UID tag" means to designate a UID number to a marijuana item in CTS and to also physically attach the corresponding UID tag to a marijuana plant or a receptacle holding a marijuana item.¶
(4) "Attractive to minors" means packaging, labeling and advertising 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; or¶
(e) Words that refer to products that are commonly associated with minors or marketed by minors.¶
(5) "Authority" means the Oregon Health Authority.¶
(6) "Business day" means Monday through Friday excluding legal holidays.¶
(7) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana or industrial hemp.¶
(8) "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 or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or¶
(c) A chemical extraction process using the solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure; or¶
(d) Any other process identified by the Commission, in consultation with the Authority, by rule.¶
(9) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate, cannabinoid extract or dried marijuana leaves or flowers have been incorporated.¶
(10) "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;¶
(b) A chemical extraction process using the solvent carbon dioxide, if the process uses high heat or pressure; or¶
(c) Any other process identified by the Commission, in consultation with the authority, by rule.¶
(11) Cannabinoid Product¶
(a) 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, that contains cannabinoids or dried marijuana leaves or flowers;¶
(b) Includes:¶
(A) Usable marijuana, cannabinoid extracts and cannabinoid concentrates that have been combined with an added substance; or¶
(B) Any combination of usable marijuana, cannabinoid extracts and cannabinoid concentrates.¶
(c) Does not include:¶
(A) Usable marijuana by itself;¶
(B) A cannabinoid concentrate by itself;¶
(C) A cannabinoid extract by itself; or¶
(D) Industrial hemp, as defined in ORS 571.300.¶
(12)"Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of 4 fluid ounces or less that consists of either:¶
(a) A non-potable solution consisting of at least 25% 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 comprised of glycerin, plant-based oil, or concentrated syrup; cannabinoid concentrate, extract or usable marijuana; and other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.¶
(13) "Cannabis Tracking System" or "CTS" means the system for tracking the transfer of marijuana items and other information as authorized by ORS 475B.177.¶
(14) "Commission-certified Hemp Grower" means a hemp grower certified by the Commission under OAR 845-025-2700 to deliver industrial hemp to processors or wholesalers.¶
(15) "Commission- certified Hemp Handler" means a hemp handler certified by the Commission under OAR 845-025-2705 to deliver industrial hemp or hemp items to processors, wholesalers, or retailers.¶

(16) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature which may exhibit 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.¶
(17) "Common Ownership"¶
(a) Means any commonality between individuals or legal entities named as applicants or persons with a financial interest in a license or business proposed to be licensed.-¶
(b) Does not mean the leasing of the property to another licensee at a commercially reasonable rate if there is no other financial interest in the other licensed business.¶
(18) "Compliance transaction" means a single covert, on-site visit in which a Commission authorized representative poses as an authorized representative of a licensee or a consumer and attempts to purchase or purchases a marijuana item from a licensee, or attempts to sell or sells a marijuana item to a licensee.¶
(19)"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.¶
(20) "Contractor" means a person, other than a licensee representative, who temporarily visits the licensed premises to perform a service, maintenance or repair.¶
(21)"Commission" means the Oregon Liquor Control Commission.¶
(22) "Commissioner" means a member of the Oregon Liquor Control Commission.¶
(23) "Consumer" means a person who purchases, acquires, owns, holds or uses marijuana items other than for the purpose of resale.¶
(24) "CTS Administrator" means a CTS user who may add, edit or disable access for other CTS users.¶
(25) "CTS User" means an individual with online access to CTS.¶
(26) "Date of Harvest" means the day the last mature marijuana plant in the harvest lot was harvested.¶
(27) "Designated primary caregiver" has the meaning given that term in ORS 475B.791.¶
(28)(a) "Financial consideration" means value that is given or received either directly or indirectly through sales, barter, trade, fees, charges, dues, contributions or donations.¶
(b) "Financial consideration" does not include marijuana, cannabinoid products or cannabinoid concentrates that are delivered within the scope of and in compliance with ORS 475B.301.¶
(29) "Financial interest" means having an interest in the business such that the performance of the business causes, or is capable of causing, an individual, or a legal entity with which the individual is affiliated, to benefit or suffer financially.¶
(a) Financial interest includes but is not limited to:¶
(A) Receiving, as an employee or agent, out-of-the-ordinary compensation, either in the form of overcompensation or under compensation;¶
(B) Lending money, real property or personal property to an applicant,-licensee, or laboratory licensee for use in the business that constitutes a substantial portion of the business cost or is lent at a commercially unreasonable rate;¶
(C) Giving money, real property or personal property to an applicant, licensee, or laboratory licensee for use in the business; or¶
(D) Being the spouse or domestic partner of an applicant, licensee, or laboratory licensee. For purposes of this

subsection, "domestic partners" includes adults who share the same regular and permanent address and would be financially impacted by the success or failure of the business as well as adults who qualify for a "domestic partnership" as defined under ORS 106.310.¶
(b) Financial interest does not include any investment that the investor does not control in nature, amount or timing.¶
(30) "Elementary school"-¶
(a) Means a learning institution containing any combination of grades kindergarten through 8.¶
(b) Does not mean a learning institution that includes only pre-kindergarten, kindergarten, or a combination of pre-kindergarten and kindergarten.¶
(31) "Flowering" means a marijuana plant that has formed a mass of pistils measuring greater than two centimeters wide at its widest point.¶
(32) "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.810.¶
(33)(a) "Harvest" means the physical act of cutting or picking flowers or leaves from a marijuana plant or removing mature marijuana plants from the soil or other growing media.¶
(b) "Harvest" does not include pruning or removing waste material from a marijuana plant remaining in soil or other growing media.¶
(34) "Harvest lot" means a specifically identified quantity of marijuana that is, cultivated utilizing the same growing practices and harvested within a 72 hour period at the same location and cured under uniform conditions.¶
(35) "Harvested industrial hemp"¶
(a) Means industrial hemp that has been harvested, including:¶
(A) Industrial hemp that has not been processed in any form; and¶
(B) Industrial hemp that has been minimally processed, for purposes of transfer or storage including chopping, separating, or drying.¶
(b) Does not mean:¶
(A) Usable hemp as defined in OAR 603-048-2310;¶
(B) An industrial hemp commodity or product as defined in OAR 603-048-0010;¶
(C) Living industrial hemp plants; or¶
(D) Industrial hemp seed:¶
(i) That is part of a crop, as that term is defined in ORS 571.300;¶
(ii) That is retained by a hemp grower for future planting;¶
(iii) That is agricultural hemp seed;¶
(iv) That is for processing into or for use as agricultural hemp seed; or¶
(v) That has been processed in a manner or to an extent that the Cannabis seed is incapable of germination.¶
(36) "Hemp Grower" means a person or entity that is registered with the Oregon Department of Agriculture under ORS 571.305 to produce industrial hemp.¶
(37) "Hemp Handler" means a person or entity that is registered with the Oregon Department of Agriculture under ORS 571.305 to process industrial hemp into commodities, products or agricultural hemp seed.¶
(38) "Hemp item"¶
(a) Means:¶
(A) Usable hemp as defined in OAR 603-048-2310;¶
(B) Hemp stalk as defined in OAR 603-048-2310;¶
(C) A cannabinoid product as defined in OAR 603-048-2310; or¶
(D) A hemp concentrate or extract as defined in OAR 603-048-2310.¶
(b) Does not mean:¶
(A) Industrial hemp processed through retting or other processing such that it is suitable fiber for textiles, rope, paper, hempcrete, or other building or fiber materials;¶
(B) Industrial hemp seed processed such that it is incapable of germination and processed such that is suitable for

human consumption; or¶
(C) Industrial hemp seed pressed or otherwise processed into oil.¶
(39) "Immature marijuana plant" means a marijuana plant that is not flowering.¶
(40)-"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 or human use.¶
(41) "Intended for human use" means intended to be used by applying it to a person's skin or hair, inhalation or otherwise consuming the product except through the mouth.¶
(42) "Inventory Tracking" means activities and documentation processes to track marijuana items from seed to sale, including establishing an accurate record from one marijuana item to another, in the cannabis tracking system.¶
(43) "Industrial hemp":¶
(a) Means all non-seed parts and varieties of the Cannabis plant, whether growing or not, that contain an average tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry weight basis.¶
(b) Means any Cannabis seed:¶
(A) That is part of a crop, as that term is defined in ORS 571.300;¶
(B) That is retained by a hemp grower for future planting;¶
(C) That is agricultural hemp seed;¶
(D) That is for processing into or for use as agricultural hemp seed; or¶
(E) That has been processed in a manner or to an extent that the Cannabis seed is incapable of germination.¶
(c) Does not mean industrial hemp commodities or products or marijuana.¶
(44) "Inhalable cannabinoid product" means a cannabinoid product or hemp cannabinoid product that is intended for human inhalation.¶
(45) "Invited guests" means family member and business associates of the licensee, not members of the general public.¶
(456) "Laboratory" means a laboratory certified by the Authority under ORS 438.605 to 438.620 and authorized to sample or test marijuana items for purposes specified in these rules.¶
(467) "Laboratory licensee" means a laboratory licensed under ORS 475B.560 and includes each applicant listed on an application that the Commission has approved and each individual who the Commission has added to the license.¶
(478) "Licensee" means any person who holds a license issued under ORS 475B.070, 475B.090, 475B.100, or 475B.105 and includes:¶
(a) E each applicant listed on an application that the Commission has approved;¶
(b) Each individual who meets the qualification described in OAR 845-025-1045 and who the Commission has added to the license under OAR 845-025-1030; or¶
(c) Each individual who has a financial interest in the licensed business and and each individual who the Commission has added to the license under OAR 845-025-1030.¶
(489) "Licensee representative" means an owner, director, officer, manager, employee, agent, or other representative of a licensee, to the extent that the person acts in a representative capacity.¶
(4950) "Limited access area" means a building, room, or other contiguous area on a licensed premises where a marijuana item is present, but does not include a consumer sales area on a licensed retailer premises.¶
(501) "Limit of quantification" or "LOQ" 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.¶
(512) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. "Marijuana" does not include:¶
(a) Industrial hemp, as defined in ORS 571.300; or¶
(b) Prescription drugs, as that term is defined in ORS 689.005, including those containing one or more cannabinoids, that are approved by the United State Food and Drug Administration and dispensed by a pharmacy, as defined in ORS 689.005.¶
(523) "Marijuana flowers" means the flowers of the plant genus Cannabis within the plant family Cannabaceae.¶

(5~~3~~4) "Marijuana items" means marijuana, cannabinoid products, cannabinoid concentrates and cannabinoid extracts.¶
(54~~5~~) "Marijuana leaves" means the leaves of the plant genus Cannabis within the plant family Cannabaceae.¶
(5~~5~~6) "Marijuana processor" means a person who processes marijuana items in this state.¶
(5~~6~~7) "Marijuana producer" means a person who produces marijuana in this state.¶
(5~~7~~8) "Marijuana retailer" means a person who sells marijuana items to a consumer in this state.¶
(5~~8~~9) "Marijuana wholesaler" means a person who purchases marijuana items in this state for resale to a person other than a consumer.¶
(~~59~~60) "Mature marijuana plant" means a marijuana plant that is not an immature marijuana plant.¶
(6~~0~~1) "Medical grade cannabinoid product, cannabinoid concentrate or cannabinoid extract" means a cannabinoid product, cannabinoid concentrate or cannabinoid extract that has a concentration of tetrahydrocannabinol that is permitted under ORS 475B.625 for consumers who hold a valid registry identification card issued under ORS 475B.797.¶
(6~~1~~2) "Micro-Wholesaler" means a marijuana wholesaler licensed by the Commission that only purchases or receives seeds, immature plants or usable marijuana from a producer with a micro tier I or tier II canopy.¶
(6~~2~~3) "Minor" means any person under 21 years of age.¶
(6~~3~~4) "Non-cannabis additive" means a substance or group of substances that are derived from a source other than marijuana or industrial hemp.¶
(a) "Non-cannabis additive" includes but is not limited to purified compounds, essential oils, oleoresins, essences or extractives, protein hydrolysates, distillates, or isolates.¶
(b) "Non-cannabis additive" does not include plant material that is in the whole, broken, or ground form.¶
(65) "Non-Toxic" means not causing illness, disability or death to persons who are exposed.¶
(64~~6~~) "Non-profit Dispensary" means a medical marijuana dispensary registered under ORS 475B.858, owned by a nonprofit corporation organized under ORS chapter 65, and that is in compliance with the Authority's rules governing non-profit dispensaries in OAR 333, Division 8.¶
(6~~5~~7) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.¶
(6~~6~~8) "Patient" has the same meaning as "registry identification cardholder."¶
(6~~7~~9) "Permittee" means any person who holds a Marijuana Workers Permit.¶
(~~68~~70) "Person" has the meaning given that term in ORS 174.100.¶
(~~69~~71) "Person Responsible for a Marijuana Grow Site" or "PRMG" has the meaning given that term in OAR 333-008-0010.¶
(7~~0~~2) "Points of ingress and egress" means any point that may be reasonably used by an individual to enter into an area and includes but is not limited to doors, gates, windows, crawlspace access points, and openings whether or not those points are secured by a locked door, window, or means capable of being unlocked or unsealed by a key, code, or other method intended to allow access.¶
(7~~1~~3) "Person responsible for a marijuana grow site" or "PRMG" has the meaning given that term in OAR 333-008-0010.¶
(7~~2~~4) "Premises" or "licensed premises" includes the following areas of a location licensed under sections ORS 475B.010 to 475B.545:¶
(a) All public and private enclosed areas at the location that are used in the business operated at the location, including offices, kitchens, rest rooms and storerooms;¶
(b) All areas outside a building that the Commission has specifically licensed for the production, processing, wholesale sale or retail sale of marijuana items; and¶
(c) "Premises" or "licensed premises" does not include a primary residence.¶
(7~~3~~5) "Primary Residence" means real property inhabited for the majority of a calendar year by an owner, renter or tenant, including manufactured homes and vehicles used as domiciles.¶
(74~~6~~) "Principal Officer" includes the president, any vice president with responsibility over the operation of a licensed business, the secretary, the treasurer, or any other officer designated by the Commission.¶

(7~~5~~7) "Processes"¶
(a) "Processes" means the processing, compounding or conversion of marijuana into cannabinoid products, cannabinoid concentrates or cannabinoid extracts.¶
(b) "Processes" does not include packaging or labeling.¶
(7~~6~~8) "Process lot" means:¶
(a) Any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and batches from the same or different harvest lots; or¶
(b) Any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.¶
(7~~7~~9) "Producer" means a marijuana producer licensed by the Commission.¶
(~~7~~80) "Produces"¶
(a) "Produces" means the manufacture, planting, propagation, cultivation, growing or harvesting of marijuana.¶
(b) "Produces" does not include:¶
(A) The drying of marijuana by a marijuana processor, if the marijuana processor is not otherwise producing marijuana; or¶
(B) The cultivation and growing of an immature marijuana plant by a marijuana wholesaler or marijuana retailer if the marijuana wholesaler or marijuana retailer purchased or otherwise received the plant from a licensed marijuana producer.¶
(~~79~~81) "Propagate" means to grow immature marijuana plants or to breed or produce seeds.¶
(8~~0~~2) "Public place" means a place to which the general public has access and includes, but is not limited to, hallways, lobbies and other parts of apartment houses and hotels not constituting rooms or apartments designed for actual residence, and highways, streets, schools, places of amusement, parks, playgrounds and areas used in connection with public passenger transportation.¶
(8~~1~~3) "Regulatory specialist" means a full-time employee of the Commission who is authorized to act as an agent of the Commission in conducting inspections or investigations, making arrests and seizures, aiding in prosecutions for offenses, issuing citations for violations and otherwise enforcing chapter 471, ORS 474.005 to 474.095, 474.115, 475B.010 to 475B.545, 475B.550 to 475B.590 and 475B.600 to 475B.655, Commission rules and any other statutes the Commission considers related to regulating liquor or marijuana.¶
(8~~2~~4) "Registry identification cardholder" has the meaning given that term in ORS 475B.791.¶
(8~~3~~5) "Retailer" means a marijuana retailer licensed by the Commission.¶
(8~~4~~6) "Safe" means:¶
(a) A metal receptacle with a locking mechanism capable of storing all marijuana items on a licensed premises that:¶
(A) Is rendered immobile by being securely anchored to a permanent structure of an enclosed area; or¶
(B) Weighs more than 750 pounds.¶
(b) A "vault"; or¶
(c) A refrigerator or freezer capable of being locked for storing marijuana items that require cold storage that:¶
(A) Is rendered immobile by being securely anchored to a permanent structure of an enclosed area; or¶
(B) Weighs more than 750 pounds.¶
(8~~5~~7) "Sampling laboratory" means a laboratory that only has an ORELAP accredited scope item for sampling under ORS 438.605 to 438.620 and is not accredited to perform cannabis testing.¶
(8~~6~~8) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes junior high schools that have 9th grade.¶
(8~~7~~9) "Security plan" means a plan as described by OAR 845-025-1030, 845-025-1400 and 845-025-1405 that fully describes how an applicant will comply with applicable laws and rules regarding security.¶
(~~88~~90) "Shipping Container" means any container or wrapping used solely for the transport of a marijuana items in bulk to a marijuana licensee as permitted in these rules.¶
(~~89~~91) "These rules" means OAR 845-025-1000 to 845-025-8750.¶

(90~~2~~2) "Tissue culture plantlet" or "plantlet" means plant cells or tissues introduced into a culture from nodal cutting and cultivated under sterile conditions. A tissue culture plantlet from a marijuana plant is an immature marijuana plant.¶
(91~~3~~3) "UID number" means the 24-digit number on the UID tag.¶
(92~~4~~4) "UID tag" means a unique identification tag ordered and received from the Commission's designated vendor for CTS for the purpose of tracking marijuana items in CTS.¶
(93~~)~~ 5)(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.¶
(94~~6~~6) "Vault" means an enclosed area or room that is constructed of steel-reinforced or block concrete and has a door that contains a multiple-position combination lock or the equivalent, a relocking device or equivalent, and a steel plate with a thickness of at least one-half inch.¶
(95~~7~~7) "Wholesaler" means a marijuana wholesaler licensed by the Commission.
Statutory/Other Authority: ORS 475B.025
Statutes/Other Implemented: ORS 475B.015, 475B.025

AMEND: 845-025-2755

RULE SUMMARY: This rule is being updated to apply the same standards to hemp inhalable products sold by hemp handler certificate holders as the new standards for inhalable marijuana products manufactured by OLCC processors. The rule would also apply the sell-down period of prohibited inhalable products to hemp handler certificate holders.

CHANGES TO RULE:

845-025-2755
Industrial Hemp Handler Certificate Privileges; Prohibitions
(1) A Commission-certified hemp handler may deliver industrial hemp or hemp items to a processor, wholesaler, or retailer that holds a license issued under ORS 475B.090, 475B.100, or 475B.105 in accordance with this rule.¶
(2) If transferring, selling or transporting to a Commission licensee, a Commission-certified hemp handler may only:¶
(a) Transfer, sell, or transport harvested industrial hemp or hemp items to a processor licensed under ORS 475B.090 that holds an industrial hemp endorsement;¶
(b) Transfer, sell, or transport harvested industrial hemp or hemp items to a wholesaler licensed under ORS 475B.100; or¶
(c) Transfer, sell, or transport hemp items to a retailer licensed under ORS 475B.105.¶
(3) When transferring, selling, or transporting pursuant to subsection (2) of this rule a Commission-certified hemp handler:¶
(a) May only transfer, sell, or transport industrial hemp and hemp items that:¶
(A) Have been tested in accordance with the Authority's rules for testing the equivalent marijuana item in OAR 333-007-0300 to 333-007-0500 and OAR 333, division 64;-¶
(B) Have been tested for THC and CBD concentration in accordance with OAR 333-007-0430, notwithstanding whether a test for potency would be required for the equivalent marijuana item; and¶
(C) Otherwise complies with the requirements for marijuana items under ORS 475B.010 to 475B.545, ORS 475B.550 to 475B.590, and 475B.600 to 475B.655 and Commission rules.-¶
(b) May only transfer industrial hemp or hemp items from the location identified in the application under OAR 845-025-2705(2)(c).¶
(c) Must:¶
(A) Hold a valid Industrial Hemp Handler Certificate issued by the Commission.¶
(B) Provide the licensee a copy of any test result conducted on the industrial hemp or hemp items. Test results include, but are not limited to, any pre-harvest test result conducted under OAR 603-048-0600 and any results from research & development testing.-¶
(C) Comply with CTS requirements in accordance with OAR 845-025-2775.¶
(D) Transport industrial hemp or hemp items in compliance with the requirements for a licensee transporting marijuana items under OAR 845-025-7700(2)(a), (2)(b)(A)-(C), (2)(b)(F)-(K), and (2)(d)(A)-(D).¶
(d) May not transfer to a licensee:¶
(A) Any industrial hemp that has failed the testing described in OAR 603-048-0600 to 603-048-0650;¶
(B) Any batch of harvested industrial hemp that exceeds the THC limits specified in OAR 845-025-2760;¶
(C) Any hemp item that exceeds the THC limits specified in OAR 845-025-2760;¶
(D) Any living industrial hemp plants;~~-or~~¶
(E) Industrial hemp seed<u>; or¶</u>
<u>(F) On or after July 1, 2021, any inhalable cannabinoid product that a licensee is prohibited from receiving under OAR 845-025-8520</u>.¶
(4) Failed potency testing; remediation.¶
(a) If a batch of industrial hemp or hemp items tested under OAR 333-007-0430 exceeds the THC limits specified in OAR 845-025-2760 when a compliance test is conducted under OAR 333-007-0430, it fails potency testing for the purposes of these rules.-¶
(b) If a batch of industrial hemp or hemp items fails potency testing, the Commission-certified hemp handler

must:¶
(A) Store and segregate the batch in a secure area until it is transferred or destroyed;¶
(B) Label the batch clearly to indicate it has failed a test and the label must include a test batch number; and¶
(c) For each batch of industrial hemp or hemp items that fails potency testing, the Commission-certified hemp handler must:¶
(A) Process the batch into a hemp item that does not exceed the THC limits specified in OAR 845-025-2760;¶
(B) Transfer the batch to a Commission-certified hemp handler for the purposes of processing the industrial hemp into a hemp item that does not exceed the THC limits specified in OAR 845-025-2760; or¶
(C) Destroy the batch in a manner specified by the Commission.¶
(d) A Commission-certified hemp handler may not transfer, sell, or transport:¶
(A) Any hemp item derived from a batch of industrial hemp or hemp items that failed potency testing except to a licensee or laboratory licensee as provided in these rules.¶
(B) Industrial hemp that fails potency testing other than as provided in these rules.¶
(5) Equivalent marijuana items. For the purposes of this rule:¶
(a) Cannabinoid capsule as defined in OAR 603-048-2310 is equivalent to cannabinoid capsule as defined in OAR 333-007-0310.¶
(b) Cannabinoid product as defined in OAR 603-048-2310 is equivalent to cannabinoid product as defined in OAR 333-007-0310.-¶
(c) Harvested industrial hemp is equivalent to usable marijuana as defined in OAR 333-007-0310.¶
(d) Hemp concentrate or extract as defined in OAR 603-048-2310 is equivalent to cannabinoid concentrate or extract as defined in OAR 333-007-0310.¶
(e) Hemp edible as defined in OAR 603-048-2310 is equivalent to cannabinoid edible as defined in OAR 333-007-0310.¶
(f) Hemp stalk as defined in OAR 603-048-2310 is equivalent to usable marijuana as defined in OAR 333-007-0310.¶
(g) Hemp tincture as defined in OAR 603-048-2310 is equivalent to cannabinoid tincture as defined in OAR 333-007-0310.¶
(h) Hemp topical as defined in OAR 603-048-2310 is equivalent to cannabinoid topical as defined in OAR 333-007-0310.¶
(i) Hemp transdermal patch as defined in OAR 603-048-2310 is equivalent to cannabinoid transdermal patch as defined in OAR 333-007-0310.¶
(j) Usable hemp as defined in OAR 603-048-2310 is equivalent to usable marijuana as defined in OAR 333-007-0310.
Statutory/Other Authority: ORS 475B.025
Statutes/Other Implemented: ORS 571.336

AMEND: 845-025-3220

RULE SUMMARY: The rule is being updated to prohibit processors from manufacturing inhalable cannabinoid products with non-cannabis additives that do not meet the updated requirements of this rule package, but also provides a limited sell-down period of these products that are manufactured prior to February 1, 2021. In an effort to further strengthen OLCC's ability to protect the public health, the rule is being updated to remove the limitation that adulterants can only come from non-cannabis sources, and broadened the applicability beyond "additives" to include substances.

CHANGES TO RULE:

845-025-3220
General Processor Requirements ¶

(1) A processor must:¶
(a) Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.¶
(b) Have counters and surface areas that are constructed in a manner that reduce the potential for development of microbials, molds and fungi and that can be easily cleaned.¶
(c) Maintain the licensed premises in a manner that is free from conditions which may result in contamination and that is suitable to facilitate safe and sanitary operations for product preparation purposes.¶
(d) Store all marijuana or hemp items not in use in a locked area, including products that require refrigeration in accordance with OAR 845-025-1410.¶
(e) Assign every process lot a unique identification number and enter this information into CTS.¶
(2) A processor may not process, transfer or sell a marijuana or hemp items:¶
(a) That by its shape, design or flavor is likely to appeal to minors, including but not limited to:¶
(A) Products that are modeled after non-cannabis products primarily consumed by and marketed to children; or¶
(B) Products in the shape of an animal, vehicle, person or character.¶
(b) That is made by applying cannabinoid concentrates or extracts to commercially available candy or snack food items.¶
(c) That contains Dimethyl Sulfoxide (DMSO).¶
(3d) If such an item is an inhalable cannabinoid product that does not meet the requirements in OAR 845-025-3265, except that a processor may transfer or sell an inhalable cannabinoid product that does not meet the requirements in OAR 845-025-3265 until July 1, 2021, if the non-compliant inhalable cannabinoid product was processed prior to February 1, 2021.¶
(4) A processor may not treat or otherwise adulterate a cannabinoid product, concentrate or extract with any non-cannabinoid additivadditive or substance that would increase potency, toxicity or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives or substances include but are not limited to nicotine, caffeine, polyethylene glycol, or any chemicals that increase carcinogenicity or cardiac effects.¶
(45) A processor must maintain records of industrial hemp test results for 2 years.
Statutory/Other Authority: ORS 475B.025, 475B.090
Statutes/Other Implemented: ORS 475B.090, 2017 OL Ch. 531

ADOPT: 845-025-3265

RULE SUMMARY: The proposed rule creates additional requirements in order to better protect public health and safety by ensuring that all the contents of non-cannabis additives for use in inhalable cannabinoid products are disclosed to regulators. All non-cannabis ingredients must be clearly stated to be intended for human inhalation. Further, the rule sets prohibitions upon certain ingredients being used in inhalable cannabinoid products that are most likely to cause harm when exposed to cannabis vaping conditions and inhaled.

The companies that provide additives to OLCC licensees are not overseen by state or federal regulatory authorities for products meant for inhalation. The additive ingredients may be “Generally Recognized as Safe” (GRAS), but GRAS-certification is scientifically evaluated only based on use in food products that will be ingested. An ingredient’s GRAS status is irrelevant for the question of whether it is safe to vaporize and inhale. Many of the non-cannabis additive products purchased by OLCC licensees have unknown health effects when used in cannabis products that will be vaporized and inhaled.

Currently, many non-cannabis additives used in these products contain ingredients that are not disclosed to OLCC, retailers selling the products, nor consumers purchasing the products. Without full disclosure, regulators cannot begin to assess the safety of these ingredients and consumers cannot make an informed choice about what they are consuming. These rules also require the maximum concentrations of non-cannabis ingredients within additives to be disclosed to OLCC so that if an ingredient is found to be problematic in certain concentrations, the OLCC can take measures to prohibit or limit its use.

As of this rulemaking, most of the manufacturers of non-cannabis additives utilized in inhalable cannabinoid products state that their products are meant for culinary use and make no claims that the ingredients should be inhaled. However, these same additive companies market their products almost exclusively to the cannabis industry for usage in vaporization products. Many companies add disclaimers related to their additives products’ use for inhalation and some go so far as to put the onus on the end-user to conduct safety assessments. The requirement set forth in this rule for the clear labeling of intended use of human inhalation will make explicit to OLCC licensees which ingredients should be used in inhalable products and which cannot be.

In the United States, 2019 saw an unprecedented outbreak of e-cigarette, or vaping product-use associated lung injury (EVALI), which sickened thousands and killed hundreds due to acute lung injury. Oregon had 23 confirmed cases, 2 of which were fatal. Primarily, EVALI patients have been diagnosed with lipoid pneumonia (inhalation of oil) and/or chemical pneumonitis (chemical burns in the lungs). The precise causative agent of EVALI is still unknown and may never be known due to the many variables and complex chemistry that occurs in vaping products. Researchers have speculated that several factors may be responsible, including cutting agents, flavorings, and pesticides. Research has shown that certain substances, when heated under common cannabis vaping conditions and inhaled into the lungs can have serious negative health consequences. Therefore, the OLCC is proposing to explicitly prohibit the most troublesome substances and will take action should more research arise.

CHANGES TO RULE:

845-025-3265
Inhalable Cannabinoid Product Processor Requirements

(1) A processor may only use a non-cannabis additive in an inhalable cannabinoid product if the non-cannabis additive is accompanied by a list of ingredients from the manufacturer of the non-cannabis additive that:¶
(a) In a header section, displays the name of the non-cannabis additive and the business name of the manufacturer of the non-cannabis additive;¶
(b) In clear and legible font, includes a statement that each of the ingredients in the non-cannabis additive is for use in a product intended for human inhalation;¶
(c) Accurately identifies all ingredients in the non-cannabis additive; and¶
(d) For each ingredient of the non-cannabis additive, includes:¶
(A) A Chemical Abstracts Service Reference Number that specifies the ingredient's isomer and, if applicable, enantiomer; and¶
(B) The ingredient's maximum concentration within the non-cannabis additive.¶
(2) A processor may not use a non-cannabis additive in an inhalable cannabinoid product that contains any amount of:¶
(a) Squalene;¶
(b) Squalane;¶
(c) Vitamin E Acetate;¶
(d) Triglycerides, including but not limited to Medium-Chain Triglyceride (MCT) Oil; or¶
(e) Propylene Glycol.¶
(3) On or after February 1, 2021, a processor may not manufacture or process an inhalable cannabinoid product that does not meet the requirements of this rule.¶
(4) On or after July 1, 2021, a processor may not possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not meet the requirements of this rule.¶
(5) Sanction.¶
(a) An intentional violation of this rule is a Category II violation.¶
(b) An unintentional violation of this rule is a Category III violation.
Statutory/Other Authority: ORS 475B.025, 475B.232, 475B.236
Statutes/Other Implemented: ORS 475B.025

ADOPT: 845-025-3270

RULE SUMMARY: This proposed rule requires that licensees possessing inhalable cannabinoid products with non-cannabis additives track these items in the cannabis tracking system (CTS) under a new category. Also, the rule requires that licensees record the additive name(s) and manufacturer(s) in these items in a way that matches the information on the additive's required list of ingredients. These two requirements will provide the OLCC with greater line of sight to which specific non-cannabis additives are on the market and in which items. This enables swifter action by OLCC if information emerges that calls the safety of an additive ingredient into question.

CHANGES TO RULE:

845-025-3270
CTS Requirements for Inhalable Cannabinoid Products with Non-Cannabis Additives
(1) On and after February 1, 2021, any inhalable cannabinoid product possessed by a licensee, research certificate holder, or hemp certificate holder that contains a non-cannabis additive must be recorded in CTS:¶
(a) With the item category of:¶
(A) "Inhalable Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a marijuana item; or¶
(B) "Inhalable Hemp Cannabinoid Product with Non-Cannabis Additives" for an inhalable cannabinoid product that is a hemp item.¶
(b) In the item's ingredients section of CTS, for all non-cannabis additives used in the item, with:¶
(A) The name of the non-cannabis additive; and¶
(B) The business name of the manufacturer of the non-cannabis additive.¶
(2) The ingredients recorded in CTS under (1)(b) of this rule must match the information that is contained in the header section of the non-cannabis additive's list of ingredients as required by OAR 845-025-3265(1)(a).
Statutory/Other Authority: ORS 475B.025, 475B.070, 475B.090, 475B.100, 475B.560, 475B.105
Statutes/Other Implemented: ORS 475B.177

AMEND: 845-025-7000

RULE SUMMARY: The amendments to this rule further define what is included in a generic label.

CHANGES TO RULE:

845-025-7000
Packaging and Labeling - Definitions ¶

For the purposes of OAR 845-025-7000 through 845-025-7190, 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 or hemp item.¶
(2) "Added substances" means any component or ingredient added to usable marijuana, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the final cannabinoid product including but not limited to added flavors, non-marijuana derived terpenes, and any substances used to change viscosity or consistency of the cannabinoid product.¶
(3) "Attractive to minors" means packaging, receptacles, inhalant delivery devices, 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.¶
(4) "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. For the purposes of labeling, cannabinoid concentrate or extract also includes concentrates and extracts derived from industrial hemp.¶
(8)(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; 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) "Cannabinoid product" means:¶
(a) 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; or¶
(b) Usable marijuana, cannabinoid extracts and cannabinoid concentrates that have been combined with an added substance.¶
(c) "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.¶
(10) "Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of 4 fluid ounces or less that consists of either:¶
(a) A non-potable solution consisting of at least 25% 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 comprised of glycerin, plant-based oil, or concentrated syrup; cannabinoid concentrate, extract or usable marijuana; and other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.¶
(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.¶
(13) "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.¶
(15) "Commission" means the Oregon Liquor Control Commission.¶
(16) "Consumer," for the purposes of these rules, has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.¶
(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, patient, or designated primary caregiver.¶
(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 day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media.¶
(19) "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 receptacle 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 and includes beverages.¶
(23) "Generic label"~~ m~~¶
(a) Means a label that ~~contains only the information required by rule.~~¶
~~(a) A generic label may not contain~~does not have any graphics, pictures, or logos, other than symbols required by these rules~~.~~ and has:¶
(~~b~~A) ~~A generic label may include a~~Only the information required by rule;¶
(B) Additional test information not required by rule; or ~~a~~¶
(C) Additional information described in OAR 845-025-7160(7)(c).¶

(b) Does not mean a label for an inhalable cannabinoid product with a non-cannabis additive that is processed or manufactured on or after February 1, 2021.¶
(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, inhalation or otherwise consuming the product except through the mouth.¶
(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.¶
(31) "Licensee" has the meaning given that term in ORS 475B.015.¶
(32) "Major 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.¶
(34) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product, or a cannabinoid concentrate 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 Commission 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) "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.¶
(b) "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;-¶
(b) Licensed by the Commission under ORS 475B.070 who produces kief;¶
(c) Registered with the Oregon Department of Agriculture under ORS 571.305 who manufactures hemp items; or¶
(d) 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.785 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.¶
(54) "UID number" for the purpose of labeling, means the unique identification number generated by CTS 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.605
Statutes/Other Implemented: ORS 475B.605

AMEND: 845-025-7120

RULE SUMMARY: The amendments to this rule describe how inhalable cannabinoid products that contain non-cannabis additives must list and label ingredients.

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) Name of the lab that performed any test and any test analysis date;-¶
(11) Universal symbol;-¶
(12) Activation time expressed in words or through a pictogram;-¶
(13) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";-¶
(14) 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.¶
(15) 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) "Do not drive a motor vehicle while under the influence of marijuana."-¶
(c) "DO NOT EAT" in bold, capital letters.¶
(16) For inhalable cannabinoid products that contain non-cannabis additives:¶
(a) The product identity must clearly identify that the product contains non-cannabis additives and, in addition to the other requirements of OAR 845-025-7000 through 845-025-7190, must include the words "non-cannabis additive."¶
(b) In addition to the other ingredients in the inhalable cannabinoid product, for each non-cannabis additive used, at minimum the ingredient listing must contain the words "non-cannabis additive," and the name of the non-cannabis additive and business name of the manufacturer of the non-cannabis additive as contained in the list of ingredients required by OAR 845-025-3265(1).¶
(c) All of the ingredients in the non-cannabis additive:¶
(A) Must match the ingredients identified on the list of ingredients required by OAR 845-025-3265(1);¶
(B) Must be listed in descending order of predominance by weight or volume; and¶
(C) Must be listed on:¶
(i) The label's ingredient list as sub-ingredients of the ingredient term "non-cannabis additive"; or¶
(ii) An insert within the product's package that clearly indicates that the ingredients listed are contained within the inhalable cannabinoid product.

Statutory/Other Authority: ORS 475B.605, 475B.232, 475B.236
Statutes/Other Implemented: ORS 475B.605

AMEND: 845-025-7160

RULE SUMMARY: These rule changes require inhalable cannabinoid products that contain non-cannabis additives to have pre-approved labels compliant with these rules prior to being sold to consumers.

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, patient, or designated primary caregiver, 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~~C) For label applications for inhalable cannabinoid products that contain non-cannabis additives:¶
(i) The non-cannabis additive's list of ingredients as required by 845-025-3265(1); and¶
(ii) In a form and manner prescribed by the Commission, information regarding the manufacturer of the non-cannabis additive, the additive or additives being used by the licensee, and attestation by the licensee of the accuracy of the information submitted for label pre-approval.¶
(3) If a licensee submits a list of ingredients to the Commission in order to comply with (2)(b)(C) of these rules, and that the licensee believes the list of ingredients is a trade secret, the licensee must mark the information "confidential - trade secret."¶
(a) If the Commission receives a public records request for information submitted by a licensee, it will review all documents submitted to determine whether the documents contain trade secrets that would be exempt from disclosure under Oregon's Public Records Act, ORS 192.345.¶
(b) For purposes of this rule "trade secret" has the meaning given that term in ORS 192.345.¶
(4) 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~~5) 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~~6) 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 application will be denied and the licensee or registrant must resubmit the packaging or labeling in accordance with section (1) of this rule.¶
(~~6~~7) 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~~8) 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 place of address 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~~9) Prior to a licensee transferring a package or label approval from one licensee to another, the licensee requesting to transfer the label must submit a form prescribed by the Commission and pay the applicable fee as described in OAR 845-025-1060.¶
(~~9~~10) 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 package approval if the packaging is identical to the previously-approved package.¶
(1~~0~~1) The Commission may publish a list of licensees and registrants who have approved label applications.¶
(1~~1~~2) 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~~.¶
(1~~2~~3) 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).¶
(1~~3~~4) 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, ORS 475B.620, 475B.236, 475B.605
Statutes/Other Implemented: ORS 475B.610, ORS 475B.620

AMEND: 845-025-7190

RULE SUMMARY: These rules require inhalable cannabinoid products manufactured on or after February 1, 2021, and that contain non-cannabis additives to have pre-approved labels compliant with these rules prior to being sold to consumers. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

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 for sale to a consumer on or after April 1, 2019 must be labeled and packaged according to these rules.¶
(3) On and after January 1, 2020, 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.¶
(4) For inhalable cannabinoid products that contain a non-cannabis additive and are processed or manufactured on or after February 1, all labels must be pre-approved by the Commission in accordance with these rules.¶
(a) An inhalable cannabinoid product with a label approved by the Commission prior to February 1, 2021; that contains a non-cannabis additive; and that does not meet the requirements of OAR 845-25-3265 or 845-025-7120 may not be possessed, sold, delivered, transferred, transported, purchased, or received on or after July 1, 2021.¶
(b) An inhalable cannabinoid product that contains a non-cannabis additive; that is manufactured prior to February 1, 2021; and that has a compliant generic label may be possessed, sold, delivered, transferred, transported, purchased, or received prior to July 1, 2021.
Statutory/Other Authority: 475B.236, 475B.620, ORS 475B.605, ORS 475B.615
Statutes/Other Implemented: ORS 475B.605

AMEND: 845-025-8520

RULE SUMMARY: Amendments to this rule apply the prohibition to possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not comply with OAR 845-025-3265 on or after July 1, 2021, to all license types. For inhalable cannabinoid products that contain non-cannabis additives and that are manufactured prior to February 1, 2021, licensees have until July 1, 2021 to do the following: sell the items in inventory, bring any remaining inhalable cannabinoid products with non-cannabis additives into compliance with revised and pre-approved labels, and/or destroy the items.

CHANGES TO RULE:

845-025-8520
Prohibited Conduct ¶

(1) Sale to a Minor. A licensee or permittee may not sell, deliver, transfer or make available any marijuana item or hemp item to a person under 21 years of age unless the individual holds a valid OMMP patient or designated primary caregiver card.¶
(a) Violation of this section for an intentional sale to a minor by licensee or permittee or licensee representative is a Category II violation.¶
(b) Violation of this section for other than intentional sales is a Category II(b) violation.¶
(2) Identification. A licensee or licensee representative must require a person to produce identification as required by ORS 475B.216 before selling or providing a marijuana item or hemp item to that person. Violation of this section is a Category IV violation.¶
(3) Access to Premises.¶
(a) A licensee, laboratory licensee, or permittee may not:¶
(A) During regular business hours for the licensed premises, refuse to admit or fail to promptly admit a Commission regulatory specialist who identifies him or herself and who enters or wants to enter a licensed premises to conduct an inspection to ensure compliance with ORS 475B affecting the licensed privileges; or these rules;¶
(B) Outside of regular business hours or when the premises appear closed, refuse to admit or fail to promptly admit a Commission regulatory specialist who identifies him or herself and requests entry on the basis that there is a reason to believe a violation of ORS 475B affecting the licensed privileges; or these rules is occurring; or¶
(C) Once a regulatory specialist is on the licensed premises, ask the regulatory specialist to leave until the specialist has had an opportunity to conduct an inspection to ensure compliance with ORS 475B affecting the licensed privileges; or these rules.¶
(b) Violation of this section is a Category II violation.¶
(c) A licensee or laboratory licensee must at all times retain control of, or the right of access to, all or any part of the licensed premises. Except as provided in OAR 845-025-1160(5), failure to retain such control or right of access is a Category I violation and may be grounds for immediate suspension or cancellation of the license.¶
(4) Use or Consumption of Intoxicants on Duty and Under the Influence on Duty.¶
(a) No licensee, licensee representative, laboratory licensee, laboratory licensee representative, or permittee may consume any intoxicating substances while on duty, except for employees as permitted under OAR 845-025-1230(6)(b). Violation of this subsection is a Category III violation.¶
(b) No licensee, licensee representative, laboratory licensee, laboratory licensee representative, or permittee may be under the influence of intoxicating substances while on duty. Violation of this subsection is a Category II violation.¶
(c) Whether a person is paid or scheduled for a work shift is not determinative of whether the person is considered "on duty."¶
(d) As used in this section:¶
(A) "On duty" means:¶

(i) From the beginning to the end of a work shift for the licensed business, including any and all coffee, rest or meal breaks; or¶
(ii) Performing any acts on behalf of the licensee or the licensed business outside of a work shift if the individual has the authority to put himself or herself on duty.¶
(B) "Intoxicants" means any substance that is known to have or does have intoxicating effects, and includes alcohol, marijuana, or any other controlled substances.¶
(5) Permitting Use of Marijuana at Licensed Premises. A licensee, laboratory licensee, or permittee may not permit the use or consumption of marijuana, hemp items, or any other intoxicating substance, anywhere in or on the licensed premises, or in surrounding areas under the control of the licensee, except for employees as permitted under OAR 845-025-1230(6)(b). Violation of this section is a Category III violation.¶
(6) Import and Export. A licensee, laboratory licensee, or permittee may not import marijuana items into this state or export marijuana items out of this state. Violation of this section is a Category I violation and could result in license or permit revocation.¶
(7) Permitting, Disorderly or Unlawful Conduct. A licensee, laboratory licensee, or permittee may not permit disorderly activity or activity that is unlawful under Oregon state law on the licensed premises or in areas adjacent to or outside the licensed premises under the control of the licensee.¶
(a) If the prohibited activity under this section results in death or serious physical injury, or involves unlawful use or attempted use of a deadly weapon against another person, or results in a sexual offense which is a Class A felony such as first degree rape, sodomy, or unlawful sexual penetration, the violation is a Category I violation and could result in license or permit revocation.¶
(b) If the prohibited activity under this section involves use of a dangerous weapon against another person with intent to cause death or serious physical injury, it is a Category II violation.¶
(c) As used in this section:¶
(A) "Disorderly activities" means activities that harass, threaten or physically harm oneself or another person.¶
(B) "Unlawful activity" means activities that violate the laws of this state, including but not limited to any activity that violates a state criminal statute.¶
(d) The Commission does not require a conviction to establish a violation of this section except as required in ORS 475B.045.¶
(8) Marijuana as a Prize, Premium or Consideration. No licensee or permittee may give or permit the giving of any marijuana item as a prize, premium, or consideration for any lottery, contest, game of chance or skill, exhibition, or any competition of any kind on the licensed premises.¶
(9) Visibly Intoxicated Persons. No licensee or permittee may sell, give, or otherwise make available any marijuana item to any person who is visibly intoxicated. Violation of this section is a Category III violation.¶
(10) Prohibited inhalable cannabinoid products.¶
(a) For purposes of this rule, a "prohibited inhalable cannabinoid product" is an inhalable cannabinoid product that does not meet the requirements of OAR 845-025-3265.¶
(b) No licensee or permittee may:¶
(A) Process or manufacture a prohibited inhalable cannabinoid product on or after February 1, 2021; ¶
(B) Possess, sell, deliver, transfer, transport, purchase, or receive the prohibited inhalable cannabinoid product on or after July 1, 2021, if the prohibited inhalable cannabinoid product was processed or manufactured prior to February 1, 2021; or¶
(C) Possess, sell, deliver, transfer, transport, purchase, or receive a prohibited inhalable cannabinoid product that was processed or manufactured on or after February 1, 2021.¶
(c) An intentional violation of this section is a Category II violation.¶
(d) An unintentional violation of this section is a Category III violation.¶
(11) Additional Prohibitions. A licensee or permittee may not:¶
(a) Sell or deliver any marijuana item or hemp item through a drive-up or walk-up window.¶
(b) Use any device or machine that both verifies the age of the consumer and delivers marijuana or hemp items to the consumer.¶

(c) Deliver marijuana or hemp items to a consumer off the licensed premises, except that retail licensees may provide delivery as set forth in OAR 845-025-2880.¶
(d) Violation of this subsection is a Category III violation.¶
(e) Permit industrial hemp or a hemp item to be present on the licensed premises, except as allowed by these rules. Violation of this subsection is a Category I violation.
Statutory/Other Authority: ORS 475B.025, ORS 475B.070, 475B.090, 475B.100
Statutes/Other Implemented: ORS 475B.070, 475B.090, 475B.100, 475B.105, 475B.227, 475B.329, 475B.333, 475B.119