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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
06/26/2018 8:03 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Inhalant delivery systems packaged in a manner attractive to minors

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/31/2018 5:00 PM

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

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Filed By:
Brittany Hall
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HEARING(S)

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

DATE: 07/17/2018

TIME: 1:00 PM

OFFICER: Jana Fussell

ADDRESS: Portland State Office

Building

800 NE Oregon St. Room 1C

Portland, OR 97232

NEED FOR THE RULE(S):

In this rulemaking, the Oregon Health Authority (Authority) is proposing revised rules to refine the meaning of "packaged in a manner attractive to minors" as it relates to inhalant delivery systems (IDS) (also known as e-cigarettes), as used in Oregon Administrative Rules (OAR) 333-015-0300 to 333-015-0375.

The proposed rulemaking:

1. Refines the meaning of "packaged in a manner attractive to minors" as it relates to IDS to reflect the purpose of the statute, and to clarify the rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS 431A.175 & 431A.178 (https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html)

OAR 333-015-0300 to 333-015-0375

(<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1230>)

FISCAL AND ECONOMIC IMPACT:

The proposed administrative rules are predicted to minimally increase costs for the Oregon Health Authority and local

public health authorities. There could be minimal cost increases for small businesses. See below for further explanation.

COST OF COMPLIANCE:

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

(1) The implementation of these administrative rules is predicted to minimally increase enforcement costs for the Oregon Health Authority and/or local public health authorities, if they chose to enforce this rule locally. The Oregon Health Authority currently conducts inspections in collaboration with the Oregon State Police to ensure that retailers comply with laws prohibiting sales of tobacco to people under 21 years of age. Inspectors will incorporate mechanisms to verify that inhalant delivery systems available in stores are compliant with packaging requirements.

The Oregon Health Authority may have increased costs associated with education and awareness efforts to help businesses comply with the law. Staff time to investigate complaints and, if appropriate, to issue citations may also increase costs.

There is no anticipated cost of compliance impact on the public.

(2)(a) As of March 4, 2018, prior to the Rules Advisory Committee meeting, it is estimated that there are over 100 retailers that sell only inhalant delivery systems in Oregon.

Inhalant delivery systems are also sold in retail establishments such as in some grocery stores, convenience stores and gas stations. Using the Oregon Health Authority's tobacco retailer database, there are an estimated 4,000 retailers that currently sell tobacco products in Oregon. It is likely that most of these also sell inhalant delivery systems, although there are no data to confirm exact numbers. The number of retail establishments that sell inhalant delivery systems and are classified as small businesses cannot be estimated using available information.

(b) Minimal additional reporting, recordkeeping or other administrative activities by private businesses are projected.

(c) The rule revisions may require packaging that differs from what businesses currently use for inhalant delivery systems. The cost differential for various types of products meeting packaging requirements is unknown and cannot be estimated with available information.

Complying with revised requirements for packaging may increase the amount of personnel time spent on identifying and sourcing compliant products.

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

The 2018 Inhalant Delivery Systems Packaged in a Manner Attractive to Minors Rules Advisory Committee included

representatives from the Northwest Grocery Association, which represents small businesses, and an inhalant delivery system representative.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-015-0300, 333-015-0305, 333-015-0340, 333-015-0345, 333-015-0350, 333-015-0355, 333-015-0357, 333-015-0360, 333-015-0375

AMEND: 333-015-0300

RULE SUMMARY: Amend OAR 333-015-0300: The Oregon Liquor Control Commission (OLCC) recently revised Oregon Administrative Rules (OAR) related to packaging and labeling requirements for recreational marijuana. The Purpose portion of the OHA rules needs to be amended to refer to OLCC's revised OARs.

CHANGES TO RULE:

333-015-0300

Packaging and Labeling: Purpose, Scope and Effective Date ¶¶

(1) The purpose of OAR 333-015-0305 to 333-015-0375 is to set the minimum standards for the labeling and packaging of inhalant delivery systems that are sold to a consumer.¶

(2) These minimum standards are applicable on and after July 1, 2016.¶

(3) These rules do not apply to an inhalant delivery system or prefilled inhalant delivery system that contains cannabinoids if that inhalant delivery system or prefilled inhalant delivery system complies with the packaging requirements in OAR 845-025-7000 to 845-025-7060 and the and labeling requirements in OAR ~~333-007-845-025-70040 to 333-007-010845-025-7190.~~

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0305

RULE SUMMARY: Amend OAR 333-015-0305: The Definitions portion of the rules needs be amended to refine the meaning of "packaged in a manner attractive to minors" as it relates to inhalant delivery systems. Specifically, "packaging" will be defined, and "packaged in a manner attractive to minors" will be removed from definition and moved into a separate rule. Additional definitions need to be amended slightly to ensure consistent language throughout the rules.

CHANGES TO RULE:

333-015-0305

Packaging and Labeling: Definitions ¶¶

For the purposes of OAR 333-015-0300 to 333-015-0375:¶¶

(1) "Authority" means the Oregon Health Authority.¶¶

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

(3) "Cartoon" means any drawing or other depiction of an object, person, animal or 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.¶¶

(4) "Child-resistant" means having inner or outer packaging that is:¶¶

(a) Intended to protect children from nicotine exposure in the household environment or other environment where the product is used;¶¶

(b) Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly, as defined by 16 CFR 1700.20 (1995); and¶¶

(c) Re-sealable for any product intended for more than a single use, such as a fillable inhalant delivery system.¶¶

(5) "Consumer product" means any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.¶¶

(6) "Distributor" means a person or company that supplies stores or businesses with goods.¶¶

(7) "Fillable inhalant delivery system" means a product that is sold without nicotine or non-nicotine inhalants, not permanently sealed and can be opened and filled with any inhalant.¶¶

(8) "Inhalant" means nicotine, or any other substance that:¶¶

(a) Is in a form that allows the nicotine, cannabinoid or substance to be delivered into a person's respiratory system;¶¶

(b) Is inhaled for the purpose of delivering the nicotine, cannabinoid or other substance into a person's respiratory system; and¶¶

(c)(A) Is not approved by, or emitted by a device approved by, the United States Food and Drug Administration (FDA) for a therapeutic purpose; or¶¶

(B) If approved by, or emitted by a device approved by, the United States Food and Drug Administration for a therapeutic purpose, is not marketed and sold solely for that purpose.¶¶

(9)(a) "Inhalant delivery system" means:¶¶

(A) A device that can be used to deliver nicotine or cannabinoids in the form of a vapor or aerosol to a person inhaling from the device; or¶¶

(B) A component of a device described in this section or a substance in any form sold for the purpose of being vaporized or aerosolized by a device described in this section, whether the component or substance is sold separately or is not sold separately.¶¶

- (b)(A) Inhalant delivery system does not include any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose; and¶
- (B) Tobacco products.¶
- (10) "~~Inner package~~" ~~means the package~~ or "inner packaging" means the materials used to wrap or protect a product that must be opened by a consumer in order to have access to the product and that may also be but is not required to be the outer package.¶
- (11) "Liquid nicotine container" means a consumer product that consists of a container that:¶
- (a) Has an opening from which nicotine in a solution or other form is accessible and can flow freely through normal and foreseeable use by a consumer; and¶
- (b) Is used to hold soluble nicotine in any concentration.¶
- (12) "Manufacturer or distributor contact information" means the name, city, state and country of the manufacturer who made the inhalant delivery system.¶
- (13) "Minor" means an individual under 18 years of age.¶
- (14) "Nicotine" means any form of the chemical nicotine, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived.¶
- (15) "Non-nicotine liquid container" means a container that:¶
- (a) Has an opening from which liquid non-nicotine or liquid non-cannabinoid substances can flow freely through normal and foreseeable use by a consumer; and¶
- (b) Is not used to hold liquid nicotine or cannabinoids.¶
- (16) "~~Outer package~~" ~~means the external package~~ or "outer packaging" means the external material used to wrap or protect a product that is visible to a consumer in the retail setting such as, but not limited to, a box or container.¶
- (17) "Outlet" means any location in Oregon which sells at retail or otherwise distributes tobacco products or inhalant delivery systems to consumers including, but not limited to, locations that sell such products over the counter or through vending machines.¶
- (18) "~~Packaged in a manner attractive to minors~~" ~~means~~ any of the materials used to wrap or protect an inhalant delivery system product where any package, including the outer package or label on the outer package, or the inner package or label on the inner package:¶
- (a) ~~Depicts cartoons;~~¶
- (b) ~~Depicts celebrities or fictitious characters played by people;~~¶
- (c) ~~Depicts people using the product;~~¶
- (d) ~~Depicts food or beverage;~~¶
- (e) ~~Resembles any product of the type that is typically marketed to minors; or~~¶
- (f) Resembles the shape of any animal, commercially recognizable toy or candy and includes but is not limited to the inner packaging and outer packaging.¶
- (19) "Prefilled inhalant delivery system" means an inhalant delivery system that is permanently sealed, prefilled, disposable and not intended to be disassembled by the consumer.¶
- (20) "Retail setting" means a place of business in which merchandise is primarily sold directly to an ultimate consumer.¶
- (21) "These rules" means OAR 333-015-0300 to 333-015-0375.
- Statutory/Other Authority: ORS 431A.175
- Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0340

RULE SUMMARY: Amend OAR 333-015-0340: The Packaging Requirements for Liquid Nicotine Containers portion of the rules needs to be amended to ensure consistent language throughout the rules. Specifically, "child-resistant safety packaging" will be amended to "child-resistant" and "may not be placed in an inner or outer package" will be changed to "may not be packaged in a manner that is attractive to minors."

CHANGES TO RULE:

333-015-0340

Packaging Requirements for Liquid Nicotine Containers ¶

A liquid nicotine container for sale to a consumer:¶

(1) Must be:¶

(a) ~~In child-resistant safety packaging;~~ and¶

(b) Labeled in accordance with these rules.¶

(2) May not be packaged in ~~an inner or outer package~~ a manner that is attractive to minors.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0345

RULE SUMMARY: Amend OAR 333-015-0345: The Packaging Requirements for Non-nicotine Liquid Containers portion of the rules needs to be amended to ensure consistent language throughout the rules. Specifically, "child-resistant safety packaging" will be amended to "child-resistant" and "may not be placed in an inner or outer package" will be changed to "may not be packaged in a manner that is attractive to minors."

CHANGES TO RULE:

333-015-0345

Packaging Requirements for Non-nicotine Liquid Containers ¶

A non-nicotine liquid container for sale to a consumer:¶

(1) Must be:¶

~~(a) In child-resistant safety packaging; and.¶~~

(2) May not be packaged in a manner or outer package that is attractive to minors.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0350

RULE SUMMARY: Amend OAR 333-015-0350: The Packaging Requirements for Prefilled Inhalant Delivery Systems portion of the rules needs to be amended to ensure consistent language throughout the rules. Specifically, "placed in an inner or outer package" will be changed to "packaged in a manner" that is attractive to minors.

CHANGES TO RULE:

333-015-0350

Packaging Requirements for Prefilled Inhalant Delivery Systems ¶

A prefilled inhalant delivery system for sale to a consumer:¶

(1) Must be labeled in accordance with these rules.¶

(2) May not be ~~packaged in an i~~manner ~~or outer package~~ that is attractive to minors.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0355

RULE SUMMARY: Amend OAR 333-015-0355: The Packaging Requirements for Fillable Inhalant Delivery Systems portion of the rules needs to be amended to ensure consistent language throughout the rules. Specifically, "placed in an inner or outer package" will be changed to "packaged in a manner" that is attractive to minors.

CHANGES TO RULE:

333-015-0355

Packaging Requirements for Fillable Inhalant Delivery Systems ¶¶

(1) A fillable inhalant delivery system that is not packaged with a liquid nicotine container for sale to a consumer:¶¶

(a) Must be labeled in accordance with these rules.¶¶

(b) May not be packaged in ~~any packaging, including an inner or outer package,~~manner that is attractive to minors.¶¶

(2) A fillable inhalant delivery system that is packaged with a liquid nicotine container for sale to a consumer must comply with OAR 333-015-0340.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

ADOPT: 333-015-0357

RULE SUMMARY: Adopt OAR 333-015-0357: The Packaging Attractive to Minors section will be adopted as a separate rule.

CHANGES TO RULE:

333-015-0357

Packaging Attractive to Minors

(1) An inhalant delivery system is packaged in a manner that is attractive to minors if because of the packaging's presentation, shape, graphics, coloring or writing, it is likely to appeal to minors.¶

(2) The Authority considers the following non-exclusive list to be likely to appeal to minors: ¶

(a) Cartoons;¶

(b) Celebrities, athletes, mascots, fictitious characters played by people, or other people likely to appeal to minors;¶

(c) Food or beverages likely to appeal to minors such as candy, desserts, soda, food or beverages with sweet flavors including fruit or alcohol;¶

(d) Terms or descriptive words for flavors that are likely to appeal to minors such as tart, tangy, sweet, candy, desserts, soda, sweet flavors including fruit, or alcohol flavors; or¶

(e) The shape of any animal, commercially recognizable toy, sports equipment, or commercially recognizable candy.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0360

RULE SUMMARY: Amend OAR 333-015-0360: The Verification of Packaging that is Child-Resistant portion needs to be amended to ensure consistent language throughout the rules. Specifically, "child-resistant packaging results" will be changed to "results of whether packaging is child-resistant".

CHANGES TO RULE:

333-015-0360

Verification of Packaging that is Child-Resistant Packaging ¶

Oregon-based outlets must provide verification of a manufacturer's written laboratory testing report describing ~~child-resistant~~ the results of whether packaging results is child-resistant based on using the protocol set forth in 16 CFR 1700.20 (1995) to the Authority upon the Authority's request.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

AMEND: 333-015-0375

RULE SUMMARY: Amend OAR 333-015-0375: The Civil Penalties portion needs to be amended to include language stating that prior to issuing a civil penalty, OHA will issue a warning letter to a manufacturer, retailer or distributor for a product that is in violation of these rules.

CHANGES TO RULE:

333-015-0375

Civil Penalties ¶

~~(1) The Authority may impose a civil penalty~~Prior to issuing a civil penalty the Authority will issue a warning letter to the manufacturer, retailer or distributor for a product that is in violation of these rules. ¶

~~(2) Civil penalties may be imposed~~ for each violation of OAR 333-015-0340 to 333-015-0360 against a manufacturer, retailer or distributor according to the following schedule:¶

(a) \$0 together with the issuance of a warning letter to the ~~retailer for the first violation~~manufacturer, retailer or distributor for the first violation related to each product. ¶

(b) Minimum of \$500 for the second violation within a 24-month period of the first violation.¶

(c) Minimum of \$800 for the third violation within a 24-month period of the second violation.¶

(d) Minimum of \$2000 for the fourth violation within a 24-month period of the third violation.¶

(e) Minimum of \$8000 for the fifth violation within a 36-month period of the fourth violation.¶

(f) Minimum of \$15,000 for the sixth or subsequent violation within a 48-month period of the fifth violation.¶

~~(23)~~ A civil penalty may not to exceed \$15,000 for each violation or \$1,050,000 for all violations found in a single inspection.¶

~~(34)~~ Each product that does not comply with these rules or that is distributed, sold, or allowed to be sold in violation of these rules is a separate violation. For example, if 10 liquid nicotine containers are distributed, sold, or allowed to be sold without child-resistant packaging the civil penalty could be \$5000 (10 x \$500).

Statutory/Other Authority: ORS 431A.178

Statutes/Other Implemented: ORS 431A.178