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CHERYL MYERS DEPUTY SECRETARY OF STATE AND TRIBAL LIAISON



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NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333 OREGON HEALTH AUTHORITY PUBLIC HEALTH DIVISION

FILED 08/10/2023 12:00 PM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Regulating sale of tobacco products and inhalant delivery systems (IDS), including minor attractive IDS packaging

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/22/2023 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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HEARING(S)

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

DATE: 09/18/2023 TIME: 10:30 AM OFFICER: Staff

HEARING LOCATION ADDRESS: Remote via Zoom, Video/teleconference call, Portland, OR 97232

REMOTE MEETING DETAILS MEETING URL: Click here to join the meeting PHONE NUMBER: 1-669-254-5252 CONFERENCE ID: 1602750406 SPECIAL INSTRUCTIONS: This rulemaking hearing is being held remotely via Zoom.

Join ZoomGov Meeting: https://www.zoomgov.com/meeting/register/vJItde6trj8qHKxwSWGc3Ze0kG_gb1JvDvk

Meeting ID: 160 275 0406

Passcode: 030379

One tap mobile +16692545252,1602750406# US (San Jose) You may also send an email to publichealth.rules@odhsoha.oregon.gov to register for the hearing and receive the link for the meeting via calendar appointment.

The hearing will close no later than 12:00PM (noon) but may close early if everyone who has signed up to testify has had a chance to enter their comments into the record.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

In this rulemaking, the Oregon Health Authority (OHA) is proposing revised rules to clarify the overall language for the Tobacco Retail License (TRL) Program. The program has been conducting inspections and administering penalties for a year and has identified revisions needed to ensure consistent language and clarity throughout the administrative rules. Additionally, OHA is proposing 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 333-015-0360. This revision is to clarify the rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

• ORS 431A.175, 431A.178 & 431A.183, ORS 431A.190-220:

https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html

- ORS 413.042: https://www.oregonlegislature.gov/bills_laws/ors/ors413.html
- ORS 431.110, 431.141-.144: https://www.oregonlegislature.gov/bills_laws/ors/ors431.html
- ORS 167.755, 167.765, 167.770 & 167.780: https://www.oregonlegislature.gov/bills_laws/ors/ors167.html
- OAR 333-015-0202 to 333-015-0360

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

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

In 2021, the Oregon Legislature passed Senate Bill 587 (OL 2021, ch. 586), establishing a new statewide tobacco retail license (TRL) program. TRL requires retailers to have a license to sell tobacco products and inhalant delivery systems in Oregon. Rulemaking took place in 2021 to establish the program. These rules describe how OHA administers the program and enforces state laws and rules and federal laws and regulations that govern the retail sale of tobacco products and inhalant delivery systems, including not selling tobacco products or inhalant delivery systems to people under 21 years of age. The current rulemaking makes minor revisions to the rules to ensure consistency and clarity throughout.

Rates of youth tobacco use are highest among youth who are in lower income, Native American, African American, and/or LGBT communities. Tobacco industry marketing is concentrated in communities of color, both because of higher concentrations of retailers and industry price promotions and advertising (https://www.cdc.gov/tobacco/health-equity/index.htm). TRL has the greatest benefit for youth targeted by the tobacco industry by conducting statewide inspections to test compliance with laws prohibiting the sale of tobacco products and inhalant delivery systems to people under 21 years of age. A strong, consistent enforcement program that holds retailers accountable can decrease

youth tobacco use in combination with other tobacco prevention strategies.

These rules will have an impact on these communities at greater risk through the regulatory compliance of tobacco retailers. As part of the Rules Advisory Committee (RAC) recruitment process, OHA verbally and electronically communicated to tobacco retailers, Local Public Health Authorities and community-based organizations located throughout Oregon, youth, health care professionals, and other affected parties located throughout Oregon, asking them to consider being part of the RAC. Communication was in both English and Spanish. Multiple businesses affected by rules participated in the RAC, including tobacco product and inhalant delivery system stores and a distributor. Public comment opportunities will be shared electronically with all tobacco retailers located in Oregon, allowing all businesses affected by the rule to provide feedback on the rules that they will have to follow. The TRL program will continue to communicate rule changes with tobacco retailers during their inspections of the stores, answering any questions they have and providing retailer educational materials in multiple languages, as needed. Materials are currently available in English, Spanish, Korean, Russian, Simplified Chinese, Arabic and Vietnamese. These are some of the most common languages spoken by tobacco retailers in Oregon, as identified during the original TRL rulemaking process, and from inspections conducted on over 1,000 tobacco retailers in Oregon in the first several months of the program's operation. Educational materials support retailer compliance with tobacco retailers allers by clearly communicating program expectations and thus benefit the retailers' communities.

FISCAL AND ECONOMIC IMPACT:

The proposed revisions to the administrative rules could minimally increase costs for OHA 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 OHA and/or local public health authorities if they chose to take on certain responsibilities for administering TRL locally. OHA currently conducts inspections to ensure that retailers comply with tobacco retail sales laws. Inspectors will incorporate mechanisms to verify that inhalant delivery systems available in stores are compliant with revised packaging requirements. The Oregon Department of Revenue may have minimally increased enforcement costs, as they are responsible for suspending or revoking tobacco retail licenses if violations reach a certain threshold, as described in OAR 150-323-0520.

OHA may have increased costs associated with education and awareness efforts to help businesses comply with the revised inhalant delivery system packaging requirements. 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) There are approximately 1,800 small businesses with around 2,000 locations that would be subject to these rules. These include mini-marts, bodegas, restaurants and bars, drug stores, and other locations where tobacco products or inhalant delivery systems are sold at retail not subject to a local tobacco retail license.

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

Specifically, if retailers of tobacco products or inhalant delivery systems have their license suspended or revoked, they may seek counsel if they decide to appeal the suspension or revocation.

(c) The rule revisions may require inhalant delivery system packaging that differs from what businesses currently use. 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 Rules Advisory Committee included representatives from:

- the Northwest Grocery Association, which represents small businesses that sell tobacco products and may sell inhalant delivery systems;
- stores that sell tobacco products and/or inhalant delivery systems; and
- a distributor of tobacco products and inhalant delivery systems.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-015-0202, 333-015-0207, 333-015-0212, 333-015-0237, 333-015-0242, 333-015-0247, 333-015-0252, 333-015-0257, 333-015-0262, 333-015-0300, 333-015-0305, 333-015-0310, 333-015-0355, 333-015-0357, 333-015-0360

AMEND: 333-015-0202

RULE SUMMARY: Amend OAR 333-015-0202: The Purpose and Effective Date portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to remove the date enforcement will begin, as this date has passed.

CHANGES TO RULE:

333-015-0202

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Purpose and Effective Date (1) The purpose of licensing tobacco retailers is to promote compliance and improve enforcement of local ordinances and rules, state laws and rules and federal laws and regulations that govern the retail sale of tobacco products and inhalant delivery systems. (2) Enforcement of these rules will begin on July 1, 2022. Statutory/Other Authority: ORS 431A.192, ORS 431A.218, <u>ORS 413.042</u> Statutes/Other Implemented: ORS 431A.190-431A.220, <u>ORS 431.110</u>, <u>ORS 431.141-431.144</u>

RULE SUMMARY: Amend OAR 333-015-0207: The Definitions portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to clarify the definitions of "Local Public Health Authority" and "Vending Machine.".

CHANGES TO RULE:

333-015-0207

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Definitions

The following definitions apply to these rules unless the context indicates otherwise:¶

(1) "Annual Oregon Health Authority license application fee" or "annual Authority license application fee" means the fee adopted by the Authority in OAR 333-015-0227 to be paid by a retailer of tobacco products or inhalant delivery systems at the time that the retailer submits an application under OAR 150-323-0500.¶

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

(3) "Department" means the Oregon Department of Revenue.¶

(4) "Department of Revenue fee" means the annual fee adopted by the Department to be paid by a retailer at the same time the annual Authority license application fee is paid.¶

(5) "Designee" means the agent, or employee of the retailer. \P

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

(b) Inhalant delivery system does not include:¶

(A) 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, as defined in ORS 431A.175 and set out in the definitions below. \P

(7) "Local fee" means a fee adopted by a city or governing body of a Local Public Health Authority adopted by an ordinance to be paid by a retailer.-¶

(8) "Local Public Health Authority" or "LPHA" means a county government; a health district formed under ORS 431.443; or an intergovernmental entity that provides public health services pursuant to an agreement entered into under ORS 190.010. This does not include LPHAs with a tobacco retail license authorized pursuant to an ordinance approved under requiring a license or other authorization as described in ORS 431A.220.¶

(9) "Misbranded and adulterated tobacco product" has the meaning defined in Section 902 and 903 of the Federal Food, Drug, and Cosmetic Act.¶

(10) "Premises" means the real property, as designated by a unique address, on which a business that makes retail sales of tobacco products or inhalant delivery systems is located. When used in these rules, "premises" includes "establishments", as used in ORS 431A.183.¶

(11) "Retailer" means a person or entity, as that term is defined in ORS 60.001, that sells for consideration, offers for retail sale, holds for sale, or exchanges or offers to exchange tobacco products or inhalant delivery systems or that distributes free or low-cost samples of tobacco products or inhalant delivery systems from a premises.-¶ (12) "These rules" means OAR 333-015-0202 to 333-015-0272.¶

(13) "Tobacco product" means bidis, cigars, cheroots, stogies, periques, granulated, plug cut, crimp cut, ready rubbed and other smoking tobacco, snuff, snuff flour, cavendish, shisha, hookah tobacco, plug and twist tobacco, fine-cut and other chewing tobaccos, shorts, refuse scraps, clippings, cutting and sweepings of tobacco prepared in such a manner as to be suitable for chewing or smoking in a pipe or otherwise, or both for chewing and smoking, cigarettes, or a device that can be used to deliver tobacco products to a person using the device that has not been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose as defined in ORS 431A.175.¶

(14) "Tobacco retail license" means a license issued by the Department to a retailer for the sale of tobacco products or inhalant delivery systems.¶

(15) "Tobacco retail license fee" means the fee adopted by the Department in OAR 150-323-0500, the fee adopted by the Authority in OAR 333-015-0227, and any local fee adopted by a city or governing body of a LPHA where a retailer is located.¶

(16) "Unique address" means the physical location of the premises where tobacco products or inhalant delivery

systems are sold and may be designated by a street number and name, unit, rural route number, or other designation as recognized by the Unites States Postal Office.¶

(17) "Vending machine" means a device that, upon the insertion of tokens, money or another form of payment, dispense tobacco product(s) or inhalant delivery system(s) as defined in ORS 167.402.

Statutory/Other Authority: ORS 431A.218, ORS 167.780, ORS 431A.175, ORS 431A.183, <u>ORS 413.042</u> Statutes/Other Implemented: ORS 167.780, ORS 431A.175, ORS 431A.183, ORS 431A.190-431A.220, <u>ORS 431.110, ORS 431.141-431.144</u>

RULE SUMMARY: Amend OAR 333-015-0212: The Oregon Health Authority Responsibilities portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to include ORS 413.042 in the statutory authority associated with the rule.

CHANGES TO RULE:

333-015-0212

Retail Sale of Tobacco Products and Inhalant Delivery Systems: <u>Oregon Health</u> Authority Responsibilities The <u>Oregon Health</u> Authority shall:¶

(1) Ensure that state standards established by state laws or rules, and federal standards established by federal laws or regulations, regarding regulation of the retail sale of tobacco products and inhalant delivery systems, are administered and enforced consistently throughout the state;¶

(2) Maintain a system for receiving and responding to public complaints, providing educational materials, conducting inspections, and issuing notices of violation;-¶

(3) Provide technical assistance to LPHAs regarding the regulation of the retail sale of tobacco products and inhalant delivery systems; and \P

(4) Assess the effectiveness of state and local programs for regulating the retail sale of tobacco products and inhalant delivery systems.

Statutory/Other Authority: ORS 431A.218, ORS 413.042

Statutes/Other Implemented: ORS 431A.190-431A.220, ORS 431.110, ORS 431.141-431.144

RULE SUMMARY: Amend OAR 333-015-0237: The Identification for Purchasing Tobacco Products or IDS portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to clarify that the retailer is responsible for ensuring that photo identification is verified for anyone under 30 years of age.

CHANGES TO RULE:

333-015-0237

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Identification for Purchasing Tobacco Products or Inhalant Delivery Systems

A retailer, or their designee, before selling is responsible for ensuring that all sales of tobacco products or inhalant delivery systems to any person about whom there is an under 30 years of age are verified by rmeasonable doubt of the person's having reached 21 years of age, shall require such person to producens of photographic identification containing the bearer's date of birth by verifying their age by means of one of the following pieces of photo identification:

(1) The person's passport issued by the United States or a foreign government;¶

(2) The person's motor vehicle operator's license issued by this state or another state of the United States;¶

(3) An identification card issued under ORS 807.400;¶

(4) A United States military identification card;¶

(5) An identification card issued by a federally recognized Indian tribe; or \P

(6) Any other identification card issued by a state or territory of the United States that bears a picture of the person, the name of the person, the person's date of birth and a physical description of the person.

Statutory/Other Authority: ORS 431A.218, ORS 167.755, ORS 431A.175, ORS 431A.183, <u>ORS 413.042, ORS 431.110, ORS 431.141-431.144, ORS 167.750, 21 CFR IPart 1100, 1140, 21 USC 387, 387a, 387f</u>

Statutes/Other Implemented: ORS 167.755, ORS 431A.175, ORS 431A.183, ORS 431A.190-431A.220

RULE SUMMARY: Amend OAR 333-015-0242: The Compliance Inspections portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to clarify when a retailer is eligible for a remediation plan.

CHANGES TO RULE:

333-015-0242

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Compliance Inspections

(1) The Authority or the Oregon Health Authority (Authority) or the local public health authority (LPHA) shall conduct annual unannounced inspections of retailers to ensure compliance with, and to enforce, state laws and rules and federal laws and regulations that govern the retail sale of tobacco products or inhalant delivery systems for purposes related to public health and safety. Inspections shall check compliance for any of the violations listed in OAR 333-015-0257 other than subsection (1)(a).¶

(2) Inspections may take place:¶

(a) Only in areas open to the public; \P

(b) Only during the hours that tobacco products or inhalant delivery systems are distributed or sold; and \P

(c) No more frequently than once a month in any single premises unless a compliance problem exists or is suspected. If there is more than one location on the premises where tobacco products or inhalant delivery systems

are sold, the Authority or the LPHA may conduct inspections at each location. \P

(3) The retailer, or their designee, shall permit the Authority or the LPHA access to the business, in order to determine com<u>Remediation plan:</u>

(a) The Authority or the LPHA may develop a remediation pliance with these rules.¶

(4) Remediation plan:¶

(a) If, during an inspection, the Authority or the LPHA finds violations of these rules, the retailer, or their designee, shall cooperate with the Authority or the LPHA to develop a remediation plan to correct violations a retailer, or their designee, to correct violations discovered during an inspection under this rule as an alternative to a civil penalty. If the retailer, or their designee, refuses to develop a remediation plan, the Authority or the LPHA may impose a civil penalty, as determined by OAR 333-015-0262. Compliance with the remediation plan must be completed within 15 calendar days of the inspection.¶

(b) Post-remediation plan fEollow-up inspection:¶

(A) The Authority or the LPHA shallmay make an unannounced follow-up inspection no sooner than 15 calendar days after the initial inspection.¶

(B) If a violation of these rules is found during the follow-up <u>inspection or post-remediation plan</u> inspection, the Authority or the LPHA may impose a civil penalty, as determined by OAR 333-015-0262.-¶

(c) Post-remediation plan violations. If additional<u>A retailer is eligible for a remediation plan described in this rule if either the Authority or the LPHA has discovered a violations are observed within five years of the date the remediation plan was entered into, the Authority or the LPHA may impose a civil penalty as determined by OAR 333-015-0262 of this rule by the retailer and a follow-up inspection has not been conducted within the review period as defined in OAR 333-015-0262.¶</u>

(4) Cooperation with inspection. The retailer, or their designee, shall permit the Authority or the LPHA access to the business, in order to determine compliance with these rules.

Statutory/Other Authority: ORS 431A.218, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, <u>ORS 413.042</u>

Statutes/Other Implemented: ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 431A.190-431A.220, ORS 431.110, ORS 431.141-431.144

RULE SUMMARY: Amend OAR 333-015-0247: The Minimum Legal Sales Age (MLSA) Inspections portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to clarify that MLSA inspections ensure compliance with rules, in addition to laws. The amended rule also states that OHA may impose a civil penalty for any rule violation.

CHANGES TO RULE:

333-015-0247

Retail Sales of Tobacco Products and Inhalant Delivery Systems: Minimum Legal Sales Age Inspections (1) The Authority or the Oregon Health Authority (Authority) or the local public health authority (LPHA) shall conduct annual random, unannounced inspections of retailers to ensure compliance with, and to enforce, the laws of this stateand rules designed to discourage the sale of tobacco products and inhalant delivery systems to persons under 21 years of age.-¶

(2) Inspections may take place:¶

(a) Only in areas open to the public;¶

(b) Only during the hours that tobacco products or inhalant delivery systems are distributed or sold; and ¶ (c) No more frequently than once a month in any single premises unless a compliance problem exists or is suspected. If there is more than one location on the premises where tobacco products or inhalant delivery systems are sold, the Authority or the LPHA may conduct inspections at each location.¶

(3) The Authority or the LPHA may use persons under 21 years of age to complete inspections to determine compliance with these rules.¶

(4) If a retailer, or their designee, illegally sells a tobacco product or inhalant delivery system during a minimum legal sales age inspection, the Authority or The Authority or the LPHA may impose a civil penaltyies as determinscribed by in OAR 333-015-0262 for any violations of these rules.

Statutory/Other Authority: ORS 431A.218, ORS 167.755, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 413.042

Statutes/Other Implemented: ORS 167.755, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 431A.190-431A.220, ORS 431.110, ORS 431.141-431.144

RULE SUMMARY: Amend OAR 333-015-0252: The Complaint Inspections portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to remove redundancy and instead refer to other parts of the rule that contain this information, specifically OAR 333-015-0242 and -0247.

CHANGES TO RULE:

333-015-0252

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Complaint Inspections

The Authority or the LPHA shall respond to valid complaints received against retailers to ensure compliance with these rules.¶

(1) Initial complaint:¶

(a) The Authority or the LPHA shall assess whether the retailer in question is selling tobacco products or inhalant delivery systems.¶

(b) If the (1) The Oregon Health Authority (Authority) or the LPHA determines that the retailer sells tobacco products or inhalant delivery systems, the Authority or the LPHA shall conduct an unannounced inspection within 60 days of complaint receipt to determine whether the retailer is in violation of these rules.¶

(A) If the complaint is for a retailer illegally selling a tobacco product or inhalant delivery system, a minimum legal sales age inspection shall be conducted. If the retailer, or their designee, illegally sells a tobacco product or inhalant delivery system, the Authority or LPHA may impose a civil penalty as determined by OAR 333-015-0262.¶

(B) If the complaint is for any other violation of these rules and a violation is found, the retailer, or their designee, shall enter into a remediation plan, as outlined in section (2) of this rule.¶

(2) Remediation plan:¶

(a) If, during an inspection, the Authority or the LPHA finds violations of these rules, the retailer, or their designee, shall cooperate with the Authority or the LPHA to develop a remediation plan to correct violations. Compliance with the remediation plan shall be completed within 15 calendar days of the inspection.¶

(b) Post-remediation plan follow-up inspection:¶

(A) The Authority or the LPHA shall make a follow-up inspection no sooner than 15 calendar days after the initial inspection.¶

(B) If a violation of these rules is found during the follow-up inspection, the Authority or the LPHA may impose a civil penalty as determined by OAR 333-015-0262.¶

(3) Post-remediation plan complaints and subsequent minimum legal sales age violation complaints. If an additional complaint is received within five years of the date the remediation plan was entered into or within five years of the first violation of a minimum legal sales age complaint inspection, the Authority or the LPHA shall conduct an unannounced inspection within 60 calendar days of complaint receipt. If a violation is found, the Authority or the LPHA may impose a civil penalty as determined by OAR 333-015-0262.¶

(4) Cooperation with inspection. The retailer, or their designee, shall permit local public health authority (LPHA) may also conduct inspections described in OAR 333-015-0242 and OAR 333-015-0247 upon receipt of a valid complaint.

(2) Cooperation with inspection. The retailer, or their designee, shall permit the Authority or the LPHA access to the business, in order to determine compliance with these rules.

Statutory/Other Authority: ORS 431A.218, ORS 167.755, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, <u>ORS 413.042</u>

Statutes/Other Implemented: ORS 167.755, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 431A.190-431A.220, <u>ORS 431.110</u>, <u>ORS 431.141-431.144</u>

RULE SUMMARY: Amend OAR 333-015-0257: The Violations portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to ensure that all portions of statutory requirements are reflected in the rule language. These clarifications include (see italics):

- (c) Selling, distributing, or allowing to be sold an inhalant delivery system that does not comply with a labeling requirement in OAR 333-015-0310 to 333-015-0320;
- (d) Selling, distributing, or allowing to be sold an inhalant delivery system that does not comply with packaging requirements in OAR 333-015-0340 to 333-015-0360 to be child -resistant and not attractive to minors;
- (e) Selling, distributing, or allowing to be sold cigarettes in any form other than a sealed package that contains at least 20 cigarettes;
- (h) Selling or distributing any quantity of smokeless tobacco or cigarette tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use;
- Offering, or causing to offer, gifts with a cigarette or smokeless tobacco purchase.

Additionally, the amended rule clarifies that it is a violation to sell tobacco products or IDS to a person under 21 whether or not they know the buyer is under 21. The amended rule adds two possible retail violations: 1) failing to comply with OAR 333-015-0237 before selling a tobacco product or IDS to a person, and 2) any other violation of a retail sales law, rule or regulation for tobacco products or IDS. The amended rule also incorporates requirements from ORS 180.441(2) as they relate to selling or dispensing cigarettes, smokeless tobacco or IDS from a vending machine.

CHANGES TO RULE:

333-015-0257

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Violations of OAR 333-015-0202 through 333-015-0360

(1) Violations for a retailer include the following acts or omissions by the retailer or their designee:¶ (a) Selling <u>or allowing to be sold</u> tobacco products or inhalant delivery systems to a person under 21 years of age: <u>in violation of ORS 431A.175(2)(a) or 21 USC 387f(d)(5). A violation of this subsection occurs regardless of</u> <u>whether the retailer or their designee knows the buyer was under the age of 21:</u>¶

(b) Failing to post a notice substantially similar to the following notice: The sale of tobacco products and inhalant delivery systems to persons under 21 years of age is prohibited by law. Any person who sells, or allows to be sold, a tobacco product or inhalant delivery system to a person under 21 years of age is in violation of Oregon law. Such notice shall be posted in a location that is clearly visible to the seller and the purchaser;¶

(c) Selling, <u>distributing</u>, <u>or allowing to be sold</u> an inhalant delivery system that does not comply with a labeling requirement in OAR 333-015-0310 to 333-015-0320;¶

(d) Selling<u>, distributing</u>, or allowing to be sold an inhalant delivery devicesystem that does not comply with packaging requirements in OAR 333-015-0340 to 333-015-0360 to be child-<u>resistant and not attractive to minors</u>.

(e) Selling<u>, distributing</u>, or allowing to be sold cigarettes in any form other than a sealed package that contains at least 20 cigarettes;¶

(f) Locating tobacco products or inhalant delivery systems where they are accessible by store customers without assistance by a store employee; \P

(g) Selling tobacco products, unless persons under 21 years of age are prohibited from entering the premises. Vending machines selling cigarettes, smokeless tobacco or inhalant delivery systems, whether or not they are only accessible to individuals over the age of 21, are prohibited;¶

(g) Selling or dispensing cigarettes, smokeless tobacco or inhalant delivery systems infrom a vending machine in an area accessible to a, per ORS 180.441(2), regardless of whether persons under 21 years of age;¶ (h) Sell are prohibited from entering the premises;¶

(h) Selling or distributing any quantity of smokeless tobacco or cigarette tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use;¶

(i) Selling flavored cigarettes, other than menthol;¶

(j) Offering, or causing to offer, gifts with a cigarette or smokeless tobacco purchase;¶

(k) Distributing free samples of tobacco products or inhalant delivery systems, except smokeless tobacco may be distributed in an area where persons under the age of 21 are prohibited, as described in ORS 180.486. ¶ (I) Selling "light", "low tar" or "mild" cigarettes;¶

(m) Selling misbranded or adulterated tobacco products or inhalant delivery systems;¶

(n) Failing to display a tobacco retail license;¶

(o) Operating without a license;¶

(p) Failing to cooperate with an inspection, which includes, but is not limited to, refusing access to the premises, interference, a threat, or harassment that delays, impairs or obstructs the <u>Authority or the Oregon Health</u> <u>Authority (Authority) or the local public health authority (LPHA)</u> from carrying out its inspection or other duties under these rules:

(q) Failing to comply with the requirement of OAR 333-015-0237 before selling or allowing to be sold a tobacco product or inhalant delivery system to a person;¶

(r) Any other violation of state law or rule or federal law or regulation that governs the wholesale or retail sale of tobacco products or inhalant delivery systems for purposes related to public health and safety.

(2) Each product not in compliance with OAR 333-015-0340 to 333-015-0360 or sold in violation of these rules may be considered a separate violation. For example, if 10 liquid nicotine containers are sold without child-resistant packaging that may be considered a total of 10 violations.

Statutory/Other Authority: ORS 431A.218, ORS 167.755, ORS 167.765, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 180.486, <u>ORS 413.042</u>

Statutes/Other Implemented: ORS 167.755, ORS 167.765, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 180.486, ORS 431A.190-431A.220, <u>ORS 431.110</u>, <u>ORS 431.141-431.144</u>

RULE SUMMARY: Amend OAR 333-015-0262: The Civil Penalties portion of the Retail Sale of Tobacco Products and IDS rule needs to be amended to clarify the 60-month review period. Additionally, the amended rule clarifies that each instance of a violation of a different requirement is a separate violation that is subject to the increasing penalty schedule.

CHANGES TO RULE:

333-015-0262

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Civil Penalties for Violations of OAR 331-015-0202 through 333-015-0360

(1) The AuthorityOregon Health Authority (Authority) may impose a civil penalty not exceeding \$5000 for each violation described in OAR 333-015-0257. A retailer may be subject to multiple civil penalties at a single inspection if the Authority or <u>the local public health authority (LPHA)</u> finds multiple violations. For example, if an inspector finds a first of different rules or multiple instances of violations of selling cigarettes from an unsealed package and a second violation of locating tobacco products where they are accessible to customers without a store employee, that may result in a civil penalty of \$3000 (\$1000 plus \$2000). the same rule. Each instance of a violation of a different requirement, obligation, prohibition, rule, statute, or regulation is a separate and distinct violation subject to the increasing penalty schedule described in section (2) of this rule.¶

(2) The Authority may impose civil penalties against a retailer according to the following schedule:¶
 (a) \$1000 for the first violation in the review period. In addition to issuing a civil penalty for the first violation, within 90 days the retailer shall read the retailer manual available from the Authority.¶

(b) \$2000 for the second violation of the same subsection of OAR 333-015-0257 within a 60-month period of the first violation the review period.¶

(c) \$3500 for the third violation of the same subsection of OAR 333-015-0257 within a 60-month period of the first violat the review periond.¶

(d) \$5000 for the fourth or any subsequent violation of the same subsection of OAR 333-015-0257 within a 60-month period of the first violation. the review period. \P

(3) For the purposes of this rule, "review period" means the 60-month period from the date the first violation is discovered. A new 60-month review period begins on the date the first violation is discovered after the prior review period ends. ¶

(34) If the Authority imposes a penalty under this section, the penalty imposition may be appealed as a contested case under ORS chapter 183 within 21 days of the date the notice of intent to impose a civil penalty is mailed by certified mail to the retailer is served on the retailer.¶

(5) For purposes of determining the applicable civil penalty amount for violation(s) as described in section (2) of this rule, the Authority does not consider violations discovered during an inspection where the retailer and the Authority or the LPHA develop a remediation plan.

Statutory/Other Authority: ORS 431A.218, ORS 431A.178, ORS 413.042

Statutes/Other Implemented: ORS 431A.178, ORS 431A.190-431A.220, ORS 431.110, ORS 431.141-431.144

RULE SUMMARY: Amend OAR 333-015-0300: The Purpose, Scope and Effective Date portion of the Packaging and Labeling rule needs to be amended to remove the date the standards apply, as this date has passed.

CHANGES TO RULE:

333-015-0300

Packaging and Labeling: Purpose, Scope and Effective Date \P

(1) The purpose of OAR 333-015-03050 to 333-015-0360 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 and labeling requirements in OAR 845-025-7000 to 845-025-7190.

Statutory/Other Authority: ORS 431A.175

Statutes/Other Implemented: ORS 431A.175

RULE SUMMARY: Amend OAR 333-015-0305: The Definitions portion of the Packaging and Labeling rule needs to be amended to remove the definition of "Cartoon" as it is not used in the rules.

CHANGES TO RULE:

333-015-0305 Packaging and Labeling: Definitions ¶

For the purposes of OAR 333-015-0300 to 333-015-0360:¶

(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; \P

(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 \P

(c) Re-sealable for any product intended for more than a single use, such as a fillable inhalant delivery system. (54) "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. \P

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

(7<u>6</u>) "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.¶

(87) "Inhalant" means nicotine, or any other substance that: \P

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

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

(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.

(98)(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 \P

(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.¶

(109) "Inner 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.¶

(110) "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. \P

(121) "Manufacturer or distributor contact information" means the name, city, state and country of the

manufacturer who made the inhalant delivery system. \P

(132) "Minor" means an individual under 18 years of age.¶

(14<u>3</u>) "Nicotine" means any form of the chemical nicotine, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived.¶

(154) "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 \P

(b) Is not used to hold liquid nicotine or cannabinoids.¶

(165) "Outer 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.¶

(176) "Packaging" means any of the materials used to wrap or protect an inhalant delivery system and includes but is not limited to the inner packaging and outer packaging.

(187) "Prefilled inhalant delivery system" means an inhalant delivery system that is permanently sealed, prefilled, disposable and not intended to be disassembled by the consumer.¶

(198) "Retail setting" means a place of business in which merchandise is primarily sold directly to an ultimate consumer.¶

(2019) "Retailer" means a person or entity, as that term is defined in ORS 60.001, that sells for consideration, offers for retail sale, holds for sale, or exchanges or offers to exchange tobacco products or inhalant delivery systems or that distributes free or low-cost samples of tobacco products or inhalant delivery systems from a premises.-¶

(210) "These rules" means OAR 333-015-0300 to 333-015-0360.

Statutory/Other Authority: ORS 431A.175, ORS 431A.218 Statutes/Other Implemented: ORS 431A.175, ORS 431A.190-431A.220

RULE SUMMARY: Amend OAR 333-015-0310: The Labeling Requirements for the Liquid Nicotine Containers portion of the Packaging and Labeling rule needs to be amended to correct a reference to a "liquid nicotine container," as the original rule omitted "liquid."

CHANGES TO RULE:

333-015-0310

Labeling Requirements for Liquid Nicotine Containers \P

A label on a liquid nicotine container must conform to the labeling standards set forth in 21 CFR Part 1143.3, including but not limited to:

(1) The label bears the following required warning statement on the package label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."¶

(2) The required warning statement must appear directly on the label and must be clearly visible underneath any cellophane or other clear wrapping as follows:-¶

(a) Be located in a conspicuous and prominent place on the two principal display panels of the container and the warning area must comprise at least 30 percent of each of the principal display panels;-¶

(b) Be printed in at least 12-point font size and ensures that the required warning statement occupies the greatest possible proportion of the warning area set aside for the required text;-¶

(c) Be printed in conspicuous and legible Helvetica bold or Arial bold type (or other sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the label;-¶

(d) Be capitalized and punctuated as indicated in section (1) of this rule; and-¶

(e) Be centered in the warning area in which the text is required to be printed and positioned such that the text of the required warning statement and the other information on the principal display panel have the same orientation.¶

(3) A <u>liquid</u> nicotine container that would otherwise be required to bear the warning in section (1) of this rule but is too small or otherwise unable to accommodate a label with sufficient space to bear such information is exempt from compliance with the requirement provided that the information and specifications required under sections (1) and (2) of this rule appear on the carton or other outer container or wrapper if the carton, outer container, or wrapper has sufficient space to bear the information, or appear on a tag otherwise firmly and permanently affixed to the tobacco product package. In such cases, the carton, outer container, wrapper, or tag will serve as the location of the principal display panel.

Statutory/Other Authority: ORS 431A.175, ORS 431A.218, 21 CFR Part 1143.3 Statutes/Other Implemented: ORS 431A.175, ORS 431A.190-431A.220

RULE SUMMARY: Amend OAR 333-015-0355: The Packaging Requirements for the Fillable IDS portion of the Packaging and Labeling rule needs to be amended to reflect the requirements more clearly.

CHANGES TO RULE:

333-015-0355

Packaging Requirements for Fillable Inhalant Delivery Systems \P

(1) A fillable inhalant delivery system that is not packaged without a liquid nicotine container for sale to a consumer shall not be packaged in a 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 shall comply with OAR 333-015-0310 and OAR 333-015-0340.
Statutory/Other Authority: ORS 431A.175
Statutes/Other Implemented: ORS 431A.175

RULE SUMMARY: Amend OAR 333-015-0357: The Packaging Attractive to Minors portion of the Packaging and Labeling rule needs to be amended to more clearly state what features of the packaging may reasonably appear to be attractive to minors.

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; it is packaged in a manner that is designed, intended, or reasonably appears to be attractive to minors. Features of the packaging that may reasonably appear be attractive to minors include but are not limited to the following: ¶

(d<u>1</u>) Terms or descriptive words for flavors that are likely to appeal to minhe shape of any animal, commercially recognizable toy, sports such as tart, tangy, sweet, cool, fire, ice, lit, spiked, poppin', juicy, candy, desserts, soda, sweet flavors including fruit, or alcohol flavequipment, commercially recognizable candy, or images of minors; or **(**(e<u>2</u>) The shape of any animal,<u>A</u> commercially recognizable toy, sports equipment, or commercially recognizable candy attached to the package.

Statutory/Other Authority: ORS 431A.175 Statutes/Other Implemented: ORS 431A.175

RULE SUMMARY: Amend OAR 333-015-0360: The Verification of Packaging that is Child-Resistant portion of the Packaging and Labeling rule needs to be amended to change "must" to "shall" for consistency in rule language.

CHANGES TO RULE:

333-015-0360 Verification of Packaging that is Child-Resistant \P

Retailers mustshall provide verification of a manufacturer's written laboratory testing report describing the results of whether packaging is child-resistant based on the protocol set forth in 16 CFR 1700.20 (1995) to the AuthorityOregon Health Authority (Authority) upon the Authority's request. Statutory/Other Authority: ORS 431A.175.<u>ORS 413.042</u> Statutes/Other Implemented: ORS 431A.175