OFFICE OF THE SECRETARY OF STATE

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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

12/23/2021 8:33 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Regulating the retail sale of tobacco products and inhalant delivery systems

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/24/2022 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:

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Portland, OR 97232

Public Health Division

Rules Coordinator

HEARING(S)

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

DATE: 01/21/2022 TIME: 9:00 AM OFFICER: Staff

ADDRESS: Remotely via Zoom

N/A

Portland, OR 97232

SPECIAL INSTRUCTIONS:

Due to COVID-19, public meetings are

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Join ZoomGov Meeting:

https://www.zoomgov.com/j/1615278348?pwd=YmVwaE9uT2JpMmVrRjlrYTNGK3djdz09

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in order to register for the hearing and receive the link for the meeting via calendar appointment.

The hearing will close no later than 11:00 AM but may close early if everyone who has signed up to testify has had a chance to enter their comments into the record.

NEED FOR THE RULE(S)

In 2021, the Oregon Legislature passed Senate Bill 587, also known as Oregon Laws 2021, Chapter 586. This bill

requires the Oregon Health Authority (OHA), in partnership with the Department of Revenue (DOR), to establish a new statewide tobacco retail license program, requiring retailers to get a license to sell tobacco products and inhalant delivery systems starting in 2022. These rules describe how OHA will administer a tobacco retail license program and enforce state laws and rules and federal laws and regulations that govern the retail sale of tobacco products and inhalant delivery systems.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

- Oregon Laws 2021, Chapter 586 (SB 587 Enrolled): https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB587/Enrolled
- ORS 431A.175, 431A.178 & 431A.183: https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html
- ORS 167.755, 167.765, 167.770 & 167.780: https://www.oregonlegislature.gov/bills_laws/ors/ors167.html

FISCAL AND ECONOMIC IMPACT:

The proposed administrative rules are predicted to increase costs for OHA and Local Public Health Authorities (LPHAs), if LPHAs choose to take on certain responsibilities for administering the program in their local jurisdictions. However, SB 587 requires OHA to adopt a fee that will cover the costs of administering and enforcing tobacco sales laws. The revenue generated by the tobacco and inhalant delivery system retailer license fee is estimated to cover the cost OHA will incur for running the tobacco retail license program. Similarly, SB 587 allows LPHAs to adopt a fee that will cover costs associated with local enforcement and education activities. See below for further explanation.

There will be minimal cost increases for small businesses, as they will have to pay the annual license fee to continue selling tobacco products and inhalant delivery systems. 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) Implementation of these administrative rules is predicted to significantly impact OHA. OHA must:
- Ensure consistent administration and enforcement throughout the state of regulations regarding the retail sale of tobacco products and inhalant delivery systems. This includes state standards established by state laws and rules and federal standards established by federal laws and regulations;
- Maintain a system for receiving complaints, providing educational materials, conducting inspections, and issuing notices of violation;
- Provide technical assistance to local public health authorities regarding the regulation of the retail sale of tobacco products and inhalant delivery systems; and
- Assess the effectiveness of state and local programs for regulating the retail sale of tobacco products and inhalant delivery systems.

Implementation of these rules will impact DOR, as they are responsible for suspending or revoking licenses if retailers reach a certain threshold for violating tax or retail sales laws. OHA and DOR will communicate regularly to ensure coordination and consistent tracking of retailer violations.

LPHAs, if they choose to take on certain responsibilities for administering the program in their local jurisdictions, as laid out below, may be impacted. Specifically, LPHAs may:

• Enforce an ordinance adopted by the local jurisdiction regulating the retail sale of tobacco products and inhalant

delivery systems for purposes related to public health and safety;

- Administer and enforce standards established by state law or rule regulating the retail sale of tobacco products and inhalant delivery systems;
- Educate tobacco retailers on local, state and federal laws and standards regulating the retail sale of tobacco products and inhalant delivery systems.

There is no anticipated impact to the public as a result of these rules.

- (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, retailers of tobacco products or inhalant delivery systems will be required to physically post their license and, if they have their license suspended or revoked, they may seek counsel if they decide to appeal the suspension or revocation.
- (c) Minimal equipment, supplies, labor and increased administration are projected for compliance with these proposed rules. The expectation for tobacco product or inhalant delivery system retailers to follow local, state, and federal tobacco retail sales laws and rules is not new. Rather, the creation of a tobacco retail licensing program establishes a mechanism for ensuring retailers comply with existing laws and rules and provides resources for them to do so.

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

The Rules Advisory Committee reviewed the proposed rule text and the Statement of Need and Fiscal Impact, and included representatives from:

- the Northwest Grocery Association, which represents small businesses that sell tobacco products and may sell inhalant delivery systems;
- the Oregon Vapor Trade Association, which represents small businesses that sell inhalant delivery systems; and
- a store that sells inhalant delivery systems.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-015-0200, 333-015-0202, 333-015-0205, 333-015-0207, 333-015-0210, 333-015-0212, 333-015-0215, 333-015-0217, 333-015-0222, 333-015-0227, 333-015-0232, 333-015-0237, 333-015-0242, 333-015-0247, 333-015-0252, 333-015-0257, 333-015-0262, 333-015-0267, 333-015-0272, 333-015-0300, 333-015-0305, 333-015-0310, 333-015-0320, 333-015-0325, 333-015-0340, 333-015-0345, 333-015-0350, 333-015-0355, 333-015-0360, 333-015-0365, 333-015-0370, 333-015-0375

REPEAL: 333-015-0200

RULE SUMMARY: Repeal OAR 333-015-0200: The Authority repeals the Definitions portion of the Tobacco and Inhalant Delivery Systems Sales to Persons under 21 Years of Age rule because proposed rule changes incorporate the definitions in other portions of the rules (see OAR 333-015-0207).

CHANGES TO RULE:

333-015-0200

Tobacco and Inhalant Delivery Systems Sales to Persons Under 21 Years of Age: Definitions ¶

- (1) "Authority" means the Oregon Health Authority. ¶
- (2) "Block grant" means the Substance Abuse Prevention and Treatment Block Grant pursuant to 42 USC 300x21e et seq. ¶
- (3)(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. ¶
- (4) "Outlet" means any location 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. ¶
- (5) "Secretary" means the Secretary of the United States Department of Health and Human Services. ¶
 (6) "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. ¶
- (7) "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.175, 431A.183, OL 2017, Ch. 701 Statutes/Other Implemented: ORS 431A.175, 431A.183, OL 2017, Ch. 701

RULE SUMMARY: Adopt OAR 333-015-0202: In this rule, the Authority states the purpose of licensing tobacco retailers- to promote compliance and improve enforcement of local ordinances and rules, state laws and rules and federal laws and regulations. The proposed language aligns with Oregon Laws 2021, Chapter 586, section 2. Additionally, rule indicates the specific date of July 1, 2022 for the beginning of enforcement of these rules.

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: Oregon Laws 2021, Chapter 586 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586

RULE SUMMARY: Repeal OAR 333-015-0205: The Authority repeals the Notice Posting Requirement portion of the Tobacco and Inhalant Delivery Systems Sales to Persons under 21 Years of Age rule because proposed rule changes incorporate the language in other portions of the rules.

CHANGES TO RULE:

333-015-0205

Tobacco and Inhalant Delivery Systems Sales to Persons Under 21 Years of Age: Notice Posting Requirement ¶

- (1) An outlet must post a notice substantially similar to the notice described in section (2) of this rule in a location that is clearly visible to the seller and the purchaser. ¶
- (2) Content of the Notice: 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. ¶
- (3) The Authority may impose a civil penalty for each violation of this rule that is not less than \$250 or more than \$1.000.

Statutory/Other Authority: ORS 431A.175, 431A.183

Statutes/Other Implemented: ORS 431A.175, 431A.183, OL 2017, Ch. 701

RULE SUMMARY: Adopt OAR 333-015-0207: The Definitions portion of the Retail Sale of Tobacco Products and Inhalant Delivery Systems rules needs to be adopted in order to add definitions that are used in rule and to update statutory references. Some of these definitions were previously in OAR 333-015-0200, which is being repealed due to the adoption of this rule. Definitions include:

- "Annual Oregon Health Authority license application fee" or "annual Authority license application fee" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Authority" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Department" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0500.
- "Department of Revenue fee" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Designee" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Inhalant delivery system" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in ORS 431A.175
- "Local fee" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0500.
- "Local Public Health Authority" or "LPHA" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Misbranded and adulterated tobacco products" is added to be used in rules in order to clarify processes, procedures, authorities.
- "Premises" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0510.
- "Retailer" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0500.
- "These rules" is added to clarify which rules are being referred to.
- "Tobacco product" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in ORS 431A.175.
- "Tobacco retail license" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0500.
- "Tobacco retail license fee" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0500.
- "Unique address" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in OAR 150-323-0510.
- "Vending machine" is added to be used in rules in order to clarify processes, procedures, authorities. The definition has the same meaning as in ORS 167.402.

CHANGES TO RULE:

333-015-0207

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Definitions

(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.¶

(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.
- (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 Oregon Laws 2021, Chapter 586.¶
- (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: Oregon Laws 2021, Chapter 586, ORS 167.780, ORS 431A.175, ORS 431A.183 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.780, ORS 431A.175, ORS 431A.183

RULE SUMMARY: Repeal OAR 333-015-0210: The Authority repeals the Location of Tobacco Products Within a Retail Store portion of the Tobacco and Inhalant Delivery Systems Sales to Persons under 21 Years of Age rule because proposed rule changes incorporate the language in other portions of the rules.

CHANGES TO RULE:

333-015-0210

Tobacco and Inhalant Delivery Systems Sales to Persons Under 21 Years of Age: Location of Tobacco Products Within a Retail Store ¶

(1) A person having authority over the location of tobacco products or inhalant delivery systems in a retail store may not locate the tobacco products or inhalant delivery systems in a location where the tobacco products or inhalant delivery systems are accessible by store customers without assistance by a store employee. ¶
(2) This rule does not apply to a person if the location at which the tobacco products or inhalant delivery systems are sold is a store or other establishment at which persons under 21 years of age are prohibited.
Statutory/Other Authority: ORS 163.575, 167.400, 167.402, 167.407, 431A.175, 431A.183
Statutes/Other Implemented: 431A.183, OL 2017, Ch. 701

RULE SUMMARY: Adopt OAR 333-015-0212: In this rule, the Authority lays out their responsibilities under Oregon Laws 2021, Chapter 586. Specifically, the Authority shall ensure that state standards for regulation of the retail sale of tobacco products and inhalant delivery systems are administered and enforced consistently throughout the state. The proposed rule also indicates that while administering and enforcing the standards, the Authority shall maintain a complaint system, provide educational materials for retailers, conduct inspections, issue notices of violation, provide technical assistance to Local Public Health Authorities (LPHA) and assess the effectiveness of state and local programs. The responsibilities of the Authority are listed in the rule to better separate them from DOR responsibilities.

CHANGES TO RULE:

333-015-0212

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Authority Responsibilities The 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; ¶
- $(3) \ Provide \ technical \ assistance \ to \ LPHAs \ regarding \ the \ regulation \ of \ the \ retail \ sale \ of \ to bacco \ products \ and \ inhalant \ delivery \ systems; \ and \P$
- (4) Assess the effectiveness of state and local programs for regulating the retail sale of tobacco products and inhalant delivery systems.

<u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586</u> <u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586</u>

RULE SUMMARY: Repeal OAR 333-015-0215: The Authority repeals the Enforcement portion of the Tobacco and Inhalant Delivery Systems Sales to Persons under 21 Years of Age rule because proposed rule changes incorporate the language in other portions of the rules.

CHANGES TO RULE:

333-015-0215

Tobacco and Inhalant Delivery Systems Sales to Persons Under 21 Years of Age: Enforcement ¶

- (1) The Authority shall coordinate with law enforcement agencies to conduct random, unannounced inspections of wholesalers and retailers of tobacco products or inhalant delivery systems to ensure compliance with, and to enforce, the laws of this state designed to discourage the sale of tobacco products and inhalant delivery systems to persons under 21 years of age. Nothing in these rules shall preempt local jurisdictions from passing ordinances to conduct unannounced inspections. ¶
- (2) Random Sample Procedures: Random, unannounced inspections will be based on the following methodological procedures ¶
- (a) Cover a range of outlets, not to be preselected on the basis of prior violations, to measure overall levels of compliance as well as to identify violations; ¶
- (b) Be conducted in such a way as to provide a probability sample of outlets in order to estimate the success of enforcement actions being taken throughout the state; ¶
- (c) Use reliable methodological design and adequate sample design to reflect: ¶
- (A) Distribution of the population of those under 21 throughout the state; and ¶
- (B) Distribution of outlets throughout the state that are accessible to persons under 21 years of age; and ¶
- (d) Be conducted at times when persons under 21 years of age are likely to purchase tobacco products or inhalant delivery systems. ¶
- (3) Targeted Inspections: The Authority may conduct targeted inspections of outlets where a compliance problem exists or is suspected. Information gained in targeted inspection will not be included in data used to determine rate of offense in random inspections. ¶
- (4) Conducting Inspections: 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 sold; and ¶
- (c) No more frequently than once a month in any single outlet unless a compliance problem exists or is suspected. For purposes of this rule, a "single outlet" refers to a specific address location of an outlet, regardless of ownership. ¶
- (5) The Authority may use persons under 21 years of age to complete inspections to determine compliance with these rules.

Statutory/Other Authority: ORS 431A.178, 431A.180, 431A.183

Statutes/Other Implemented: ORS 431A.178, 431A.180, 431A.183, OL 2017, Ch. 701

RULE SUMMARY: Adopt OAR 333-015-0217: In this rule, the Authority lays out optional responsibilities for LPHAs. Specifically, the rule states that that they may enforce an ordinance adopted by the local jurisdiction regulating the retail sale of tobacco products and inhalant delivery systems and administer and enforce standards established by the state laws and rules. The LPHA may also educate tobacco retailers on laws and standards regulating the retail sale of tobacco products and inhalant delivery systems. The Authority also proposes to include language to align with Oregon Laws 2021, Chapter 586, sections 13 and 17 to state that an LPHA may adopt a local fee to conduct activities listed above and shall enter into an Intergovernmental Agreement with the Authority for information sharing purposes.

CHANGES TO RULE:

333-015-0217

Retail Sale of Tobacco Products and Inhalant Delivery Systems: LPHA Responsibilities (1) An LHPA may:¶

(a) Enforce an ordinance adopted by the local jurisdiction regulating the retail sale of tobacco products and inhalant delivery systems for purposes related to public health and safety;¶

(b) Administer and enforce standards established by state laws or rules regarding regulating the retail sale of tobacco products and inhalant delivery systems;¶

(c) Educate tobacco retailers on local, state, and federal laws and standards regulating the retail sale of tobacco products and inhalant delivery systems.¶

(2) If an LPHA assumes one or more of the responsibilities listed in section (1) of this rule, they: ¶

(a) May adopt a local fee to conduct these activities; and \P

(b) Shall enter into an Intergovernmental Agreement with the Authority to ensure information sharing necessary for the effective administration and enforcement of regulations and standards regulating the retail sale of tobacco products and inhalant delivery systems.

Statutory/Other Authority: Oregon Laws 2021, Chapter 586 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586

RULE SUMMARY: Adopt OAR 333-015-0222: In this rule, the Authority proposes to clarify the DOR authority to issue an annual tobacco retail license and clarify that retailers that have obtained a license from a city or county do not need to obtain a state license. This rule aligns with Oregon Laws 2021, Chapter 586, section 5.

CHANGES TO RULE:

333-015-0222

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Licensing Procedures

 $(1) A \ retailer \ shall \ obtain \ a \ to bacco \ retail \ license \ annually \ from \ the \ Department, \ per \ processes \ laid \ out \ in \ OAR \ 150-323-0500. \P$

(2) This does not include retailers that have obtained a license from a city or county authorized pursuant to an ordinance approved under Oregon Laws 2021, Chapter 586.

Statutory/Other Authority: Oregon Laws 2021, Chapter 586

Statutes/Other Implemented: Oregon Laws 2021, Chapter 586

RULE SUMMARY: Adopt OAR 333-015-0227: In this rule, the Authority states that the annual Authority license fee shall pay expenses of license administration and enforcement, as required by Oregon Laws 2021, Chapter 586, section 12. The application fee of \$723 will be required for tobacco retail applications effective on or after January 1, 2022. Please note that temporary OAR 333-015-0201 (Temporary Administrative Order PH 80-2021) establishing the annual Oregon Health Authority Tobacco Product and Inhalant Delivery System Retailer License application fee, effective December 1, 2021 through May 29, 2022, will be suspended when OAR 333-015-0227 goes into effect.

CHANGES TO RULE:

333-015-0227

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Annual Oregon Health Authority License Application Fee

- (1) The annual Authority license application fee shall be reasonably calculated to pay the expenses of license administration and enforcement, including but not limited to retailer education, inspection and compliance checks, investigation of violations and enforcement actions against violators. ¶
- (2) The annual Authority license application fee for applications effective on or after January 1, 2022, is \$723. The Authority shall review the fee amount annually. \P
- (3) Upon issuance by the Department of a tobacco retail license to a retailer, the annual Authority license application fee is nonrefundable. If the Department denies an initial or renewal application for a tobacco retail license, and that denial becomes final, then the Department will refund the annual Authority license application fee.

<u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586</u> <u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586</u>

RULE SUMMARY: Adopt OAR 333-015-0232: In this rule, the Authority clarifies that either the Authority or the LPHA shall provide educational resources to retailers to support compliance with state and federal laws and rules.

CHANGES TO RULE:

333-015-0232

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Education and Outreach

(1) As part of program administration, the Authority or the LPHA shall provide educational resources to retailers to support compliance with state and federal laws, rules and regulations regulating the retail sale of tobacco products and inhalant delivery systems. ¶

(2) Educational materials may be made available in a retailer's preferred language upon request.

Statutory/Other Authority: Oregon Laws 2021, Chapter 586

Statutes/Other Implemented: Oregon Laws 2021, Chapter 586

RULE SUMMARY: Adopt OAR 333-015-0237: In this rule, the Authority clarifies and streamlines the identification of age process for purchasing tobacco products or inhalant delivery systems. The Authority proposes to use valid photo identification documents similar to the Oregon Liquor Control Commission requirements for acceptable ID when purchasing alcohol.

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 tobacco products or inhalant delivery systems to any person about whom there is any reasonable doubt of the person's having reached 21 years of age, shall require such person to produce 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 ¶
- (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: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 431A.175, ORS 431A.183 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 431A.175, ORS 431A.183

RULE SUMMARY: Adopt OAR 333-015-0242: In this rule, the Authority lays out a process for how annual unannounced inspections of retailers will be conducted by the Authority or LPHA, as required in Oregon Laws 2021, Chapter 586, section 16. Specifically, inspectors will check for compliance with laws regulating the retail sale of tobacco products an inhalant delivery systems. Additionally, rule clarifies when and where such inspections may take place and streamlines the process for inspections.

CHANGES TO RULE:

333-015-0242

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

(1) The Authority or the 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;¶

(b) Only during the hours that tobacco products or inhalant delivery systems are distributed or sold; and \(\begin{align*} \) (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 system.

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 retailer, or their designee, shall permit the Authority or the LPHA access to the business, in order to determine compliance 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. Compliance with the remediation plan must be completed within 15 calendar days of the inspection.¶

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

(A) The Authority or the LPHA shall 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 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 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.

<u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

<u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

RULE SUMMARY: Adopt OAR 333-015-0247: In this rule, the Authority lays out a process for how minimum legal sales age inspections will be conducted by the Authority or LPHA. Specifically, inspectors will check to see if retailers sell tobacco products or inhalant delivery systems to people under the age of 21.

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 LPHA shall conduct annual random, unannounced inspections of retailers to ensure compliance with, and to enforce, the laws of this state 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 LPHA may impose a civil penalty as determined by OAR 333-015-0262.

<u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

<u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

RULE SUMMARY: Adopt OAR 333-015-0252: In this rule, the Authority lays out a streamlined process for how the Authority will respond to valid complaints from the public about a person or business violating laws regulating the retail sale of tobacco products or inhalant delivery systems.

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 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 access to the business, in order to determine compliance with these rules.

<u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

<u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 167.765, ORS 167.770, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183</u>

RULE SUMMARY: Adopt OAR 333-015-0257: In this rule, the Authority outlines all possible violations of the rules in order to help retailers clearly identify which laws and regulations they need to follow to comply with license requirements.

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 tobacco products or inhalant delivery systems to a person under 21 years of age; ¶
- (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 an inhalant delivery system that does not comply with a labeling requirement in OAR 333-015-0310 to $333-015-0320\P$
- (d) Selling an inhalant delivery device 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 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;¶
- (g) Selling tobacco products or inhalant delivery systems in a vending machine in an area accessible to a person under 21 years of age;¶
- (h) Selling 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;¶
- (i) Offering 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 Authority or the LPHA from carrying out its inspection or other duties under these rules.¶
- (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.
- <u>Statutory/Other Authority: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 167.765, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 180.486</u>
- <u>Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 167.755, ORS 167.765, ORS 167.780, ORS 431A.175, ORS 431A.178, ORS 431A.183, ORS 180.486</u>

RULE SUMMARY: Adopt OAR 333-015-0262: In this rule, the Authority outlines the civil penalty amounts associated with violations listed in OAR 333-015-0257. The rule states that the Authority may issue a civil penalty not exceeding \$5000 for each violation, as required by Oregon Laws 2021, Chapter 586, section 15. Specifically, the rule explains that a retailer may be subject to multiple civil penalties at a single inspection if multiple violations are found and provides civil penalty amounts for the first through fourth and subsequent violations. The rule also requires retailers to read the retailer manual within 90 days after the Authority issues a first violation.

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 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 LPHA finds multiple violations. For example, if an inspector finds a first violation 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). ¶
- (2) The Authority may impose civil penalties against a retailer according to the following schedule:¶
 (a) \$1000 for the first violation. 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.¶
- (c) \$3500 for the third violation of the same subsection of OAR 333-015-0257 within a 60-month period of the first violation. \P
- (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.
- (3) 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.

Statutory/Other Authority: Oregon Laws 2021, Chapter 586, ORS 431A.178 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586, ORS 431A.178

RULE SUMMARY: Adopt OAR 333-015-0267: In this rule, the Authority clarifies that, in addition to a civil penalty, a tobacco retail license may be suspended or revoked by DOR as described in OAR 150-323-0520.

CHANGES TO RULE:

333-015-0267

Retail Sale of Tobacco Products and Inhalant Delivery Systems: Suspension and Revocation for Violations of OAR 333-015-0001 through 333-015-0360

<u>In addition to a civil penalty, a license may be suspended or revoked by the Department, as described in OAR 150-323-0520.</u>

Statutory/Other Authority: Oregon Laws 2021, Chapter 586 Statutes/Other Implemented: Oregon Laws 2021, Chapter 586

RULE SUMMARY: Amend OAR 333-015-0272 (formerly OAR 333-015-0220): The Biennial Report portion of the Retail Sale of Tobacco Products and Inhalant Delivery Systems rule was renumbered from OAR 333-015-0220 to OAR 333-015-0272. The amendment removes the requirement for public comment and expands the scope of the report to include all laws described in ORS 431A.175.

CHANGES TO RULE:

333-015-0272

Tobacco and Inhalant Delivery Systems Sales to Persons Under 21 Years of Age Retail Sale of Tobacco Products and Inhalant Delivery Systems: Biennial Report ¶

- (1) Contents of Report: The Authority shall biennially submit a report to the Governor and to the appropriate committee or interim committee of the Legislative Assembly to which matters of public health are assigned. The report shall include:-¶
- (a1) A description of the state's activities to enforce the laws described in OAR 333-015-0200 through OAR 333-015-021RS 431A.175 during the biennium; and \P
- ($\frac{b2}{2}$) A description outlining the overall success the state has achieved during the previous biennium in reducing the availability of tobacco products and inhalant delivery systems to persons under 21 years of age. \P
- (2) Public Comment Required: The biennial report shall be made public and public comment shall be obtained and considered before submitting the report to the Governor and Legislative Assembly.

Statutory/Other Authority: ORS 431A.183, <u>Oregon Laws 2021, Chapter 586</u> Statutes/Other Implemented: ORS 431A.183, <u>Oregon Laws 2021, Chapter 586</u>

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 correct the Administrative Rules being referred to, as some sections of rule are being repealed and incorporated into other portions of the rules.

CHANGES TO RULE:

333-015-0300

Packaging and Labeling: Purpose, Scope and Effective Date ¶

- (1) The purpose of OAR 333-015-0305 to 333-015-03 $\frac{7560}{1}$ is to set the minimum standards for the labeling and packaging of inhalant delivery systems that are sold to a consumer. \P
- (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.

RULE SUMMARY: Amend OAR 333-015-0305: The Definitions portion of the Packaging and Labeling rule needs to be amended to correct the Administrative Rules being referred to, as some sections of rule are being repealed and incorporated into other portions of the rules. Additionally, the definition of "Outlet" is removed as it is not used in the rules. The definition of "Retailer" is added and used in rules to align with definitions provided in the Retail Sale of Tobacco Products and Inhalant Delivery Systems rule (OAR 333-015-0207).

CHANGES TO RULE:

333-015-0305

Packaging and Labeling: Definitions ¶

For the purposes of OAR 333-015-0300 to 333-015-037560:¶

- (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 \P
- (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 \P
- (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" 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 \P
- (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 \P
- (b) Is not used to hold liquid nicotine or cannabinoids.¶
- (16) "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.¶
- (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) "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.
- (198) "Prefilled inhalant delivery system" means an inhalant delivery system that is permanently sealed, prefilled, disposable and not intended to be disassembled by the consumer.¶
- (2019) "Retail setting" means a place of business in which merchandise is primarily sold directly to an ultimate consumer.¶
- (20) "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. ¶ (21) "These rules" means OAR 333-015-0300 to 333-015-037560.

Statutory/Other Authority: ORS 431A.175, <u>Oregon Laws 2021, Chapter 586</u> Statutes/Other Implemented: ORS 431A.175, <u>Oregon Laws 2021, Chapter 586</u>

RULE SUMMARY: Amend OAR 333-015-0310: The Labeling Requirements for Liquid Nicotine Containers portion of the Packaging and Labeling rule needs to be amended to more clearly reflect the labeling requirements for liquid nicotine containers.

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 Parts 1100, 1140 and 114343.3:¶

- (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 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, <u>Oregon Laws 2021, Chapter 586, 21 CFR Part 1143.3</u> Statutes/Other Implemented: ORS 431A.175, Oregon Laws 2021, Chapter 586

RULE SUMMARY: Amend OAR 333-015-0320: The Labeling Requirements for Prefilled Inhalant Delivery Systems portion of the Packaging and labeling rule needs to be amended to refer to the labeling requirements outlined in OAR 333-015-0310.

CHANGES TO RULE:

333-015-0320

Labeling Requirements for Prefilled Inhalant Delivery Systems ¶

A label on a prefilled inhalant delivery system must conform to the labeling standards set forth in 21 CFR Parts 1100, 1140 and 1143 in OAR 333-015-0310, if the prefilled inhalant delivery system contains nicotine.

Statutory/Other Authority: ORS 431A.175, 21 CFR Part 1143.3

Statutes/Other Implemented: ORS 431A.175

RULE SUMMARY: Repeal OAR 333-015-0325: The Authority repeals the Labeling Requirements for Fillable Inhalant Delivery Systems portion of the Packaging and Labeling rule because these labeling requirements do not apply to inhalant delivery systems that do not contain nicotine.

CHANGES TO RULE:

333-015-0325

Labeling Requirements for Fillable Inhalant Delivery Systems

A label on a fillable inhalant delivery system must conform to the labeling standards set forth in 21 CFR Parts 1100, 1140 and 1143.

RULE SUMMARY: Amend OAR 333-015-0340: The Packaging Requirements for Fillable Inhalant Delivery Systems portion of the Packaging and Labeling rule needs to be amended to refer to the labeling requirements outlined in OAR 333-015-0310.

CHANGES TO RULE:

333-015-0340

Packaging Requirements for Liquid Nicotine Containers ¶

A liquid nicotine container for sale to a consumer: ¶

- (1) MustShall be:¶
- (a) Child-resistant; and ¶
- (b) Labeled in accordance with these rules OAR 333-015-0310.¶
- (2) MayShall not be packaged in a manner that is attractive to minors.

RULE SUMMARY: Amend OAR 333-015-0345: The Packaging Requirements for Non-nicotine Liquid Containers portion of the Packaging and Labeling rule needs to be amended to more clearly reflect that these containers "shall" be child-resistant and 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) MustShall be child-resistant.¶
- (2) MayShall not be packaged in a manner that is attractive to minors.

RULE SUMMARY: Amend OAR 333-015-0350: The Packaging Requirements for Prefilled Inhalant Delivery Systems portion of the Packaging and Labeling rule needs to be amended to more clearly reflect that these containers "shall" not be 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 shall not be packaged in a manner that is attractive to minors.

RULE SUMMARY: Amend OAR 333-015-0355: The Packaging Requirements for Fillable Inhalant Delivery Systems portion of the Packaging and Labeling rule needs to be amended to more clearly reflect that these containers "shall" not be packaged in a manner that is attractive to minors. Additionally, the labeling requirement is removed because labeling requirements do not apply to inhalant delivery systems that do not contain nicotine.

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 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 must shall comply with OAR 333-015-0310 and OAR 333-015-0340.

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 in order to remove reference to the "Outlet" definition when referring to the retailer.

CHANGES TO RULE:

333-015-0360

Verification of Packaging that is Child-Resistant ¶

Oregon-based out<u>Retailetrs</u> must 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 Authority upon the Authority's request.

RULE SUMMARY: Repeal OAR 333-015-0365: The Authority repeals the Inspections portion of the Packaging and Labeling rule because proposed rule changes incorporate the inspection language in other portions of the rules.

CHANGES TO RULE:

333-015-0365

Enforcement: Inspections

The Authority shall coordinate random, unannounced inspections of Oregon-based outlets of inhalant delivery systems to ensure compliance with these rules.

RULE SUMMARY: Repeal OAR 333-015-0370: The Authority repeals the Violations portion of the Packaging and Labeling rule because proposed rule changes incorporate the violation language in other portions of the rules.

CHANGES TO RULE:

333-015-0370

Enforcement: Violations

It is a violation for a manufacturer, retailer or distributor to:¶

(1) Distribute, sell or allow to be sold an inhalant delivery device that does not comply with a labeling requirement in OAR 333-015-0310 to 333-015-0030. \P

(2) Distribute, sell or allow to be sold an inhalant delivery device that does not comply with a packaging requirement in OAR 333-015-0340 to 333-015-0360.

Statutory/Other Authority: ORS 431A.175, 431A.178 Statutes/Other Implemented: ORS 431A.175, 431A.178

RULE SUMMARY: Repeal OAR 333-015-0375: The Authority repeals the Civil Penalties rule because proposed rule changes incorporate the revocation language in other portions of the rules.

CHANGES TO RULE:

333-015-0375

Civil Penalties ¶

- (1) 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 described in section (1) of this rule to the 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.¶
- (3) A civil penalty may not to exceed \$15,000 for each violation or \$1,050,000 for all violations found in a single inspection.¶
- (4) 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).