

Underlined text has been added. ~~Strikethrough text~~ has been deleted.

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 15

IMPLEMENTATION OF REQUIREMENTS FOR OREGON'S INDOOR CLEAN AIR
ACT, NUTRITIONAL INFORMATION AT CHAIN RESTAURANTS, ~~AND~~
STANDARDS FOR REDUCING THE SALE OF TOBACCO AND INHALANT
DELIVERY SYSTEMS TO MINORS AND PACKAGING AND LABELING
REQUIREMENTS FOR INHALANT DELIVERY SYSTEMS

Packaging and Labeling

333-015-0300

Purpose, Scope and Effective Date

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

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

(3) These rules do not apply to an inhalant delivery system or prefilled inhalant delivery system that contains cannabinoids if that inhalant delivery system or prefilled inhalant delivery system complies with the packaging requirements in OAR 845-025-7000 to 845-025-7060 and the labeling requirements in OAR 333-007-0010 to 333-007-0100.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0305

Definitions

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

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

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

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

(a) The use of 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 packaging that is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) 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.

(10) "Inner package" means the package that must be opened by a consumer in order to have access to the product and that may also be but is not required to be the outer package.

(11) "Liquid nicotine container" means a consumer product that consists of a container that:

(a) Has an opening from which nicotine in a solution or other form is accessible and can flow freely through normal and foreseeable use by a consumer; and

(b) Is used to hold soluble nicotine in any concentration.

(12) "Manufacturer or distributor contact information" means the name, city, state and country of the manufacturer who made the inhalant delivery system.

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

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

(15) "Non-nicotine liquid container" means a container that:

(a) Has an opening from which liquid non-nicotine or liquid non-cannabinoid substances can flow freely through normal and foreseeable use by a consumer; and

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

(16) "Outer package" means the external package visible to a consumer in the retail setting such as, but not limited to, a box or container.

(17) "Outlet" means any location in Oregon which sells at retail or otherwise distributes tobacco products or inhalant delivery systems to consumers including, but not limited to, locations that sell such products over the counter or through vending machines.

(18) "Packaged in a manner attractive to minors" means an inhalant delivery system product where any package, including the outer package or label on the outer package, or the inner package or label on the inner package:

(a) Depicts cartoons;

(b) Depicts celebrities or fictitious characters played by people;

(c) Depicts people using the product;

(d) Depicts food or beverage;

(e) Resembles any product of the type that is typically marketed to minors; or

(f) Resembles the shape of any animal, commercially recognizable toy or candy.

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

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

(21) "Significant scientific agreement" means based on the totality of the publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by evidence as defined by section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)) and 21 CFR 101.14(c).

(22) "These rules" means OAR 333-015-0300 to 333-015-0375.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0310

Labeling Requirements for Liquid Nicotine Containers

(1) A label on a liquid nicotine container must clearly display:

(a) Ingredients in descending order of predominance;

(b) Nicotine concentration expressed in milligrams per milliliter, which may be shortened to read as mg/mL;

(c) Milliliters of liquid contained in the liquid nicotine container;

(d) Milligrams of nicotine contained in the liquid nicotine container;

(e) Manufacturer or distributor contact information; and

(f) Product warnings that read:

(A) Keep out of reach of children;

(B) Nicotine is highly addictive and can be toxic;

(C) It is illegal to sell or distribute this product to minors; and

(D) For accidental exposure, call the Poison Center at 1-800-222-1222.

(2) Labels and product warnings must:

(a) Conform to the general label requirements in OAR 333-015-0330;

(b) Be displayed on the inner package; and

(c) Be displayed on the outer package if the product has both an inner and outer package.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0315

Labeling Requirements for Non-nicotine Liquid Container

(1) A label on a non-nicotine liquid container must clearly display:

(a) Ingredients in descending order of predominance;

(b) Milliliters of liquid contained in the non-nicotine liquid container;

(c) Zero milligrams of nicotine contained in the non-nicotine liquid container;

(d) Manufacturer or distributor contact information; and

(e) Product warnings that read:

(A) Keep out of reach of children; and

(B) It is illegal to sell or distribute this product to minors.

(2) Label and product warnings must:

(a) Conform to general label requirements set forth in OAR 333-015-0330;

(b) Be displayed on the inner package; and

(c) Be displayed on the outer package if the product has both an inner and outer package.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0320

Labeling Requirements for Prefilled Inhalant Delivery Systems

(1) A label on a prefilled inhalant delivery system must clearly display:

(a) Ingredients in descending order of predominance;

(b) Nicotine concentration expressed in milligrams per milliliter, which may be shortened to read as mg/mL;

(c) Milliliters of liquid contained in the liquid nicotine container;

(d) Milligrams of nicotine contained in the liquid nicotine container;

(d) Manufacturer or distributor contact information; and

(e) Product warnings that read:

(A) Keep out of reach of children;

(B) Nicotine is highly addictive and can be toxic;

(C) It is illegal to sell or distribute this product to minors; and

(D) For accidental exposure, call the Poison Center at 1-800-222-1222.

(2) Label and product warnings must:

(a) Conform to general label requirements set forth in OAR 333-015-0330;

(b) Be displayed on the inner package; and

(c) Be displayed on the outer package if the product has both an inner and outer package.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0325

Labeling Requirements for Fillable Inhalant Delivery Systems

(1) A label on a fillable inhalant delivery system that is not packaged with a liquid nicotine container must clearly display:
(a) Manufacturer or distributor contact information; and
(b) Product warnings that read:
(A) Keep out of reach of children; and
(B) It is illegal to sell or distribute this product to minors.
(2) Label and product warnings must:
(a) Conform to general label requirements set forth in OAR 333-015-0330; and
(b) Be displayed on the outer package.
(3) A fillable inhalant delivery system packaged with a liquid nicotine container must comply with OAR 333-015-0340.
Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175

333-015-0330

General Label Requirements; Exceptions

(1) A label required by these rules must:
(a) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2015), Uniform Packaging and Labeling Regulation, incorporated by reference;
(b) Use the Arial or Times New Roman font;
(c) Comprise more than 30 percent of the inner package and more than 30 percent of the outer package;
(d) Be printed using either black ink on a white background or white ink on a black background;
(e) Be smear resistant;
(f) Be in no smaller than 6 point font;
(g) Be in non-capitalized font, other than the first letter of a sentence;
(h) Be in English, but it may be in other languages; and
(i) Be unobstructed and conspicuous.
(2) An inhalant delivery system may have one or more labels affixed to the outer package at the point of sale.
(3) A label may not include health claims or descriptors that:
(a) Imply a product is safer, healthier or less risky than other products;
(b) Represent that a product has curative or therapeutic effects; or
(c) Do not meet the FDA Significant Scientific Agreement standard as defined in section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 343(r)(3)) and 21 CFR 101.14(c).
Stat. Auth.: ORS 431A.175
Stats. Implemented: ORS 431A.175

333-015-0335

Nicotine Content Requirements

(1) In order for a label that is required to contain information about nicotine concentration to be compliant with these rules:
(a) The nicotine content in the product may not exceed a 15 percent variation in:
(A) Mg/mL from the content level on the label; and
(B) Mg from the content level on the label.

(2) A consumer product labeled as having 0 mg nicotine or 0 mg/mL of nicotine may not contain any nicotine.

(3) The Authority may request from a manufacturer, retailer or distributor:

(a) A mixing protocol report for solutions mixed at the point of sale in the retail outlet to verify nicotine content as labeled.

(b) Laboratory testing protocols and dated testing results for quantities not mixed at the time of sale, and not available for point of sale purchase, to verify nicotine content as labeled.

(c) Laboratory testing protocols and dated results for manufacturers of liquid nicotine.

(4) In accordance with ORS 433.870, a county that has assumed the responsibility of the duties and responsibilities under ORS 446.425 and 448.100, or contracted with the authority under ORS 190.110, is responsible for enforcing the provisions of ORS 433.835 to 433.875 and has the same enforcement power as the authority.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

Packaging

333-015-0340

Packaging Requirements for Liquid Nicotine Containers

A liquid nicotine container for sale to a consumer:

(1) Must be:

(a) In child-resistant safety packaging; and

(b) Labeled in accordance with these rules.

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0345

Packaging Requirements for Non-nicotine Liquid Containers

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

(1) Must be:

(a) In child-resistant safety packaging; and

(b) Labeled in accordance with these rules.

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0350

Packaging Requirements for Prefilled Inhalant Delivery Systems

A prefilled inhalant delivery system for sale to a consumer:

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

(2) May not be placed in an inner or outer package that is attractive to minors.

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0355

Packaging Requirements for Fillable Inhalant Delivery Systems

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

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

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

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

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

333-015-0360

Verification of Child-Resistant Packaging

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

Stat. Auth.: ORS 431A.175

Stats. Implemented: ORS 431A.175

Enforcement

333-015-0365

Inspections

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

Stat. Auth.: ORS 431A.183

Stats. Implemented: ORS 431A.183

Violations

333-015-0370

Violations

(1) It is a violation for a manufacturer, retailer or distributor to:

(a) 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.

(b) Fail to respond to a request from the Authority for information or documentation.

(c) 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.

Stat. Auth.: ORS 431A.175, 431A.178

Stats. Implemented: ORS 431A.175, 431A.178

Penalties

333-015-0375

Civil Penalties

(1) The Authority may impose a civil penalty for each violation of OAR 333-015-0310 to 333-015-0030 against a manufacturer, retailer or distributor according to the following schedule:

(a) \$0 together with the issuance of a warning letter to the retailer; for the first violation

(b) Minimum of \$250 for the second violation within a 24-month period of the first violation.

(c) Minimum of \$500 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 \$5000 for the fifth violation within a 36-month period of the fourth violation.

(f) Minimum of \$11,000 for the sixth or subsequent violation within a 48-month period of the fifth violation.

(2) The Authority may impose a civil penalty for each violation of OAR 333-015-0340 to 333-015-0360 against a manufacturer, retailer or distributor according to the following schedule:

(a) \$0 together with the issuance of a warning letter to the retailer; for the first violation

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

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

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

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

(e) 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).

Stat. Auth.: ORS 431A.178

Stats. Implemented: ORS 431A.178