

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing accompanies this form.

FILED
3-15-16 10:48 AM
ARCHIVES DIVISION
SECRETARY OF STATE

Oregon Health Authority, Public Health Division
Agency and Division

333
Administrative Rules Chapter Number

Packaging and Labeling Requirements for Inhalant Delivery Systems

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Permanently adopting administrative rules in chapter 333, division 15, relating to the implementation of HB 2546 (OL 2015, ch. 158).

Statutory Authority:

ORS 431A.175, 431A.178, 431A.183

Other Authority:

Statutes Implemented:

ORS 431A.175, 431A.178, 431A.183

Need for the Rule(s):

In this rulemaking, the Oregon Health Authority (Authority) is proposing new rules to comply with statutory changes from the passage of House Bill 2546 (OL 2015, ch. 158), specifically those sections of HB 2546 requiring inhalant delivery systems sold in Oregon to have child-resistant packaging, packaging that is not attractive to minors and to meet certain labeling specifications.

The proposed rulemaking:

1. Creates definitions in rules to reflect the purpose of the statute, and add clarity to the rules.
2. Requires child-resistant packaging for liquid nicotine containers and non-nicotine liquid containers.
 - a. Provides an exemption for pre-filled inhalant delivery systems.
 - b. Provide an exemption for fillable inhalant delivery systems.
3. Requires that inhalant delivery systems are not "Packaged in a manner attractive to minors," as defined in rules.
4. Requires that inhalant delivery systems display labels that conform to design criteria (e.g., size and font) and contain certain language intended to inform consumers about the content of these products and their health risks.
5. Prohibits certain language on labels of inhalant delivery systems sold in Oregon.
6. Establishes civil penalty amounts and enforcement schedule for violations of the rules.

Documents Relied Upon, and where they are available:

HB 2546 (Oregon Laws 2015, chapter 158): <https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB2546/Enrolled>

Fiscal and Economic Impact:

The U.S. Government Accountability Office estimates that the U.S. market for "e-cigarettes" was approximately \$2.5 billion in 2014* , but the amount of revenue from this industry in Oregon is unknown.

Much of the business in Oregon is in the retail sector, rather than the manufacturing sector. Industry experts believe that most inhalant delivery system products are manufactured abroad, with upwards of 90% of imports coming from China**.

New labeling requirements in these rules mean that inhalant delivery systems will clearly communicate the amounts and concentration levels of nicotine, as well as warnings about the toxic effects of nicotine. This may deter some users and reduce sales of inhalant delivery systems.

Requirements that inhalant delivery systems meet standards to not be "Packaged in a manner attractive to minors" may also deter some users and reduce sales.

Businesses wholly or partially dependent on sales of inhalant delivery systems may be affected to varying degrees by any reductions in sales due to these packaging and labeling requirements.

Because these rules require that liquid nicotine containers and liquid inhalant containers meet standards for child-resistant packaging, there

may be additional costs to businesses for procuring products that meet this standard.

*U.S. GAO Report accessed October 22, 2015 at <http://www.gao.gov/products/GAO-15-491R>

**Communication from Senator Ron Wyden, October 20, 2015, accessed October 22, 2015 at <http://www.finance.senate.gov/newsroom/ranking/release/?id=8b81c645-652f-4d04-84f5-0c2dc6f1a8d7>

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

The implementation of these administrative rules is predicted to minimally increase enforcement costs for the Oregon Health Authority and/or local public health authorities. The Oregon Health Authority currently conducts inspections in collaboration with the Oregon State Police to ensure the retailers are in compliance with laws prohibiting sales of tobacco to minors. Inspectors will incorporate mechanisms to verify that inhalant delivery systems available in stores are compliant with packaging and labeling requirements.

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

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

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:

As of February 19, 2016 there are approximately 284 inhalant delivery system retailers in Oregon. This estimate is based on a search of the Secretary of State's online business registry using the following search criteria: "vape, vapor, electronic cigarette and e-cig."

Inhalant delivery systems are also sold in retail establishments that have a primary business other than selling inhalant delivery systems. These include grocery stores, convenience stores, gas stations and other businesses. Using Synar data and the Oregon Health Authority's assessment of the tobacco retail environment, there are an estimated 2,878 retailers that currently sell tobacco in Oregon. It is likely that many of these also sell inhalant delivery systems, although there are no data to confirm exact numbers. The number of retail establishments that sell inhalant delivery systems and are classified as small businesses cannot be estimated with available information.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

Businesses selling inhalant delivery systems will need to perform additional recordkeeping and other administrative activities to be compliant with these packaging and labeling rules. For example, these rules (333-015-0360) require that any business claiming to be compliant with child-resistant packaging requirements must be prepared to verify this by producing a laboratory testing report, usually obtained through the manufacturer. The amount of time and cost per business is unknown and cannot be estimated with available information.

c. Equipment, supplies, labor and increased administration required for compliance:

These rules require packaging and labeling that may differ from what businesses currently source for inhalant delivery systems. The cost differential for various types of packaging and labeling is unknown and cannot be estimated with available information.

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

How were small businesses involved in the development of this rule?

The 2015 Packaging and Labeling Rules Advisory Committee included representatives from the North West Vapor Association and the North West Grocery Association.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

04-29-2016 5:00 p.m.	Brittany Sande	brittany.a.sande@state.or.us
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address