



# PROPOSED RULE MAKING

## CR-102 (December 2017) (Implements RCW 34.05.320)

Do NOT use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: August 21, 2020

TIME: 1:25 PM

WSR 20-18-012

Agency: State Board of Health

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 20-10-113 ; or

Expedited Rule Making--Proposed notice was filed as WSR ; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

Proposal is exempt under RCW .

**Title of rule and other identifying information:** (describe subject) WAC 246-80-021 - Prohibition vitamin E acetate. The State Board of Health is proposing rules to permanently adopt existing emergency rules which ban the sale of vapor products containing vitamin E acetate This applies to the sale, offer for sale, or possession with intent to sell or offer for sale vapor products containing vitamin E acetate at any location or by means including by telephone or other method of voice transmission, the mail or any other delivery service or the internet or other online service.

**Hearing location(s):**

Date:	Time:	Location: (be specific)	Comment:
10/13/2020	2:30 PM	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the state board of health will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. Board members, presenters, and staff will all participate remotely. The public may login using a computer or device, or call-in using a phone, to listen to the meeting through the GoTo Webinar application. The public may submit verbal comments during the specified public comment and rules hearing segments.  1. To access the meeting online and register: <a href="https://attendee.gotowebinar.com/register/4735583794817723406">https://attendee.gotowebinar.com/register/4735583794817723406</a> 2. You can also dial-in and listen/observe only using your phone: Call in: +1 (562) 247-8422; Access Code: 521-354-641	

**Date of intended adoption:** 10/13/2020 (Note: This is **NOT** the **effective** date)

**Submit written comments to:**

Name: Samantha Pskowski  
Address: P.O. Box 47990  
Olympia, WA 98504-7990  
Email: <https://fortress.wa.gov/doh/policyreview>  
Fax: N/A  
Other: None  
By (date) 10/01/2020

**Assistance for persons with disabilities:**

Contact Samantha Pskowski  
Phone: (360) 789-2358  
Fax:  
TTY: 711  
Email: [samantha.pskowski@sboh.wa.gov](mailto:samantha.pskowski@sboh.wa.gov)  
Other:  
By (date) 10/06/2020

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The purpose of this proposal is to create a new section of rule to prohibit the inclusion of vitamin E acetate in vapor products. This proposal would make permanent an existing emergency rule that prohibits the sale of vapor products containing vitamin E acetate. This includes the sale, offer for sale, or possession with intent to sell or offer for sale vapor products containing vitamin E acetate at any location or by means including telephone or other method of voice transmission, the mail or other delivery service, or the internet or other online service.

**Reasons supporting proposal:** In July 2019, the U.S. Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners began investigating outbreaks of e-cigarette or vaping associated lung injury (EVALI). In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multi-state outbreak. As of its final update on February 18, 2020, the CDC has identified 2,807 confirmed cases reported across 50 states, the District of Columbia, Puerto Rico and the US Virgin Islands, including 68 deaths confirmed in 29 states and the District of Columbia. Twenty-seven cases of EVALI, including two deaths, have been reported in Washington State.

As part of the investigation into the multistate outbreak of EVALI, the CDC conducted laboratory tests of 48 samples of fluid collected from the lungs of patients with vaping-associated lung disease from 10 states. An article released on November 8, 2019 showed that all of the samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. The CDC has not determined that vitamin E acetate is present in only THC vapor products or only non-THC vapor products. THC was identified in 82% of the samples, and nicotine was identified in 62% of the samples. A further study found 94% of EVALI patients tested had vitamin E acetate in the bronchoalveolar lavage but no samples from a health comparison group indicated evidence of vitamin E. Two samples showed presence of other toxicants (one each) in the EVALI group but did not provide sufficient evidence to identify another toxicant as the source of disease. The CDC has identified vitamin E acetate as a chemical strongly linked to EVALI and recommends that vitamin E acetate not be added to vapor products.

Based on these findings, the Board is proposing to adopt rules that institute a permanent ban of vitamin E acetate in vapor products.

**Statutory authority for adoption:** RCW 43.20.050(2)(f)

**Statute being implemented:** RCW 43.20.050(2)(f)

**Is rule necessary because of a:**

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None

**Name of proponent:** (person or organization) Washington State Board of Health  Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

	Name	Office Location	Phone
Drafting:	Samantha Pskowski	101 Israel Road SE, Tumwater, WA, 98504-7990	(360) 789-2358
Implementation:	Justin Nordhorn	1025 Union Avenue SE, Olympia, WA 98504	(360) 664-1726
Enforcement:	Justin Nordhorn	1025 Union Avenue SE, Olympia, WA 98504	(360) 664-1726

**Is a school district fiscal impact statement required under RCW 28A.305.135?**  Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Samantha Pskowski

Address: P.O. Box 47990, Olympia, WA 98504-7990

Phone: (360) 789-2358

Fax: N/A

TTY: 711

Email: samantha.pskowski@sboh.wa.gov

Other:

No: Please explain:

**Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- RCW 34.05.310 (4)(b) (Internal government operations)
- RCW 34.05.310 (4)(c) (Incorporation by reference)
- RCW 34.05.310 (4)(d) (Correct or clarify language)
- RCW 34.05.310 (4)(e) (Dictated by statute)
- RCW 34.05.310 (4)(f) (Set or adjust fees)
- RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's analysis showing how costs were calculated. The cost threshold for the industry of Beverage and Tobacco Product Manufacturing and Miscellaneous Store Retailers is \$5,641.52 and \$2,503.84 respectively.

The cost of removing vitamin E acetate from vapor products has been determined to be \$0.27 per 5mL of product. The thickening agent is used in some vapor products and is not considered to be an essential product.

Cost of thickening agent per product = Total cost of total thickening agent / (Total volume of product \* amount of thickening agent per product)

To estimate the total cost to industry, an estimate of the total product sold is needed. Given the lack of publicly available information on the vapor product industry, an estimate was calculated using other available information. The Washington State Department of Revenue estimated revenue of \$19 million from the state's vapor product tax. The tax is structured as a \$0.27 / mL for pod devices under 5 mL and \$0.09 for products over 5 mL. Assuming 50% of revenue comes from pod devices and 50% from products of 5 mL, it can be estimated that there will be 28,148,148 products of 5 mL sold annually. Therefore, the total cost of the rule would be \$7,599,999. We do not have a way of knowing the distribution of this cost across individual retailers, so therefore the cost of the rule spread evenly among all licensed vapor product retailers would be an estimated \$1,900 per establishment.

Therefore, the average cost of the rule per establishment does not exceed the average cost threshold for the industry and does not require a SBEIS.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:

Address:  
Phone:  
Fax:  
TTY:  
Email:  
Other:

**Date:** 08/21/2020

**Name:** Michelle A. Davis

**Title:** Executive Director

**Signature:**

A handwritten signature in black ink that reads "Michelle A. Davis". The signature is written in a cursive style with a large, looped initial "M".

NEW SECTION

**WAC 246-80-021 Prohibition—Vitamin E acetate.** No person including, but not limited to, a person licensed under chapter 69.50 or 70.345 RCW, may sell, offer for sale, or possess with intent to sell, or offer for sale vapor products containing vitamin E acetate. The foregoing prohibition applies to the sale, offer for sale, or possession with intent to sell, or offer for sale vapor products containing vitamin E acetate at any location or by any means in this state including, but not limited to, by means of a telephonic or other method of voice transmission, the mail or any other delivery service, or the internet or other online service.