

Date: September 16, 2020

To: Jane Rushford, Board Chair

Ollie Garrett, Board Member Russ Hauge, Board Member

From: Casey Schaufler, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director

Megan Duffy, Deputy Director

Justin Nordhorn, Chief of Enforcement

Becky Smith, Licensing Director

Subject: Approval to extend an emergency rule (CR 103E) regarding

establishment new section - WAC 314-55-1065 - Prohibition -

Vitamin E Acetate

House Bill (HB) 2826 concerning marijuana vapor products went into effect on March 25, 2020. Among other things, HB 2826 amended RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (m), providing that the Board may, by rule, prohibit any device used in conjunction with a marijuana vapor product and the prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products, when the Board determines, following a determination by the Washington State Department of Health or any other authority the Board deems appropriate, that the device, additive, solvent, ingredient, or compound may pose a risk to public health or youth access.

This emergency rule extension provides that no person including, but not limited to, a person licensed under chapter 69.50 RCW, may sell, offer for sale, or possess with intent to sell, or offer for sale vapor products containing vitamin E acetate.

Process

The Policy and Rules Manager requests that the Board extend the emergency rule described above, and requests approval to file the emergency rule described above. A CR 103E Memorandum on this rule was presented at the Board meeting on September 16, 2020, and is attached to this request.

If adopted, the timeline for the rule making process is outlined below:

September 16, 2020	Board is asked to adopt the emergency rulemaking order (CR 103E) as described above.		
September 16, 2020	Emergency rule becomes effective.		
Approve	Disapprove	Jane Rushford, Chair	Date
Approve	Disapprove		
		Ollie Garrett, Board Member	Date
Approve	Disapprove	Russ Hauge, Board Member	 Date
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Attachment: CR 103E Memorandum



CR 103E Memorandum

Emergency Rule Extension Regarding WAC 314-55-1065 – Prohibition – Vitamin E Acetate

Date: September 16, 2020

Presented by: Casey Schaufler, Policy and Rules Coordinator

Issue:

The standards in this emergency rule have not changed from the previous emergency rule. House Bill (HB) 2826 (Chapter 133, Laws of 2020) concerning marijuana vapor products went into effect on March 25, 2020. Among other things, HB 2826 amended RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (m), providing that the Board may, by rule, prohibit any device used in conjunction with a marijuana vapor product and the prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products, when the Board determines, following a determination by the Washington State Department of Health or any other authority the Board deems appropriate, that the device, additive, solvent, ingredient, or compound may pose a risk to public health or youth access.

On November 19, 2019, March 19, 2020, and July 17, 2020, the Washington State board of Health (SBOH) offered the following background and reasoning for its ban of vitamin E acetate:

- In July 2019 the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration, state and local health jurisdictions and other clinical and public health partners began investigation [of] outbreaks of lung injury associated with e-cigarette product use, or vaping. In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multi-state outbreak. As of February 18, 2020, CDC reported a total of two thousand eight hundred seven cases of hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases, and sixty-eight deaths in twenty-nine states and the District of Columbia. Twenty-seven cases of lung injury, including two deaths have been reported in Washington State.
- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, a recent study cited by the CDC conducted laboratory tests of fifty-one samples of fluid collected from the lungs of patients with vaping-associated lung disease from sixteen

states. Forty-nine samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of the injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. THC was identified in forty-seven of fifty samples and nicotine was identified in thirty of forty-seven samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and recommends that vitamin E acetate not be added to any vapor products.

 During the 2020 legislative session, the governor submitted request legislation (SB 6254) aimed at increasing regulation of vapor products in Washington. The bill included a ban of vitamin E acetate, however the legislature failed to pass SB 6254. Due to the clear association of vitamin E acetate with EVALI and absent legislative action to ban vitamin E acetate the SBOH determined that continuing a ban is necessary to protect the public health, safety and welfare.

Consistent with the statutory authority provided to the Board by HB 2826, and upon the determination of the SBOH that vitamin E acetate is a drug of concern and should be banned, the Board should consider extension of WAC 314-55-1065 prohibiting the use of vitamin E acetate.

WAC 314-55-1065(2) provides that:

No person, including, but not limited to, a person licensed under chapter 69.50 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.

Reasons why rules are needed:

The extension of this emergency rule allows the Board to take disciplinary action, without interruption, against any licensed marijuana processor that fails to comply with the provisions of it emergency rule WAC 314-55-1065 prohibiting the use of vitamin E acetate consistent with the authority of chapter 69.50 RCW.

The immediate extension of rule that provides for both the enforcement of WAC 314-55-1065, and preservation of public health, safety and general welfare is necessary. Therefore, the immediate adoption of a rule establishing provisions for the enforcement of WAC 314-55-1065 that prohibits the use of vitamin E acetate is necessary.

Process:

Consistent with RCW 34.05.350, any agency may find that the immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule change is exempt from the filing of a CR 101, analytical, and public hearing requirements.

An emergency rule adopted under RCW 34.05.350 takes effect upon filing with the code reviser, unless a later date is specified in the order of adoption, and may not remain in effect for longer than one hundred twenty days after filing.

Notice will be sent to all who have indicated that they want to receive notice of rule activity, and posted to the Board's website.

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RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103F (December 2017)

Agency: Washington State Liquor and Cannabis Board

or room (becomine to 11)	
(Implements RCW 34.05.350	
and 34.05.360)	

	ve date of rule:
	ergency Rules
	Immediately upon filing.
Ш	Later (specify)
Any ot □ Y	her findings required by other provisions of law as precondition to adoption or effectiveness of rule? ✓es ⊠ No If Yes, explain:
Purpos	se: WAC 314-55-1065 - Prohibition - Vitamin E Acetate. The Washington State Liquor and Cannabis Board (Board)
acetate vitamin any oth	opted an emergency rule to extend WAC 314-55-1065 that prohibits the sale of vapor products containing vitamin E. This applies to the sale, offer for sale, or possession with intent to sell or offer for sale vapor products containing E acetate at any location or by any means including by telephone or other method of voice transmission, the mail or ner delivery service, or the internet or other online service. This filing supersedes and replaces emergency rules filed R 20-12-035 on May 27, 2020.
	n of rules affected by this order:
Nev	•
Ame	pealed: ended: WAC 314-55-1065 pended:
Statuto 69.50.3	ory authority for adoption: HB 2826 (Chapter 133, Laws of 2020), effective March 25, 2020; RCW 69.50.342; RCW 345.
Other a	authority:
Und ⊠	Jer RCW 34.05.350 the agency for good cause finds: That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.
Bill (HB amend Board r type of marijua Health	ns for this finding: The standards in this emergency rule have not changed from the previous emergency rule. House 3) 2826 concerning marijuana vapor products went into effect on March 25, 2020. Among other things, HB 2826 ed RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (m), providing that the may, by rule, prohibit any device used in conjunction with a marijuana vapor product and the prohibit the use of any additive, solvent, ingredient, or compound in the production and processing of marijuana products, including ana vapor products, when the Board determines, following a determination by the Washington State Department of or any other authority the Board deems appropriate, that the device, additive, solvent, ingredient, or compound may risk to public health or youth access.
	vember 19, 2019, March 19, 2020, and July 17, 2020, the Washington State board of Health (SBOH) offered the ng background and reasoning for its ban of vitamin E acetate:
•	In July 2019 the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration, state and local health jurisdictions and other clinical and public health partners began investigation [of] outbreaks of lung injury associated with e-cigarette product use, or vaping. In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multi-state outbreak. As of February 18, 2020, CDC reported a total of two thousand eight hundred seven cases of hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases, and sixty-eight deaths in twenty-nine states and the District of Columbia.

Twenty-seven cases of lung injury, including two deaths have been reported in Washington state.

- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, a recent study cited by the CDC conducted laboratory tests of fifty-one samples of fluid collected from the lungs of patients with vaping-associated lung disease from sixteen states. Forty-nine samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of the injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. THC was identified in forty-seven of fifty samples and nicotine was identified in thirty of forty-seven samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and recommends that vitamin E acetate not be added to any vapor products.
- During the 2020 legislative session, the governor submitted request legislation (SB 6254) aimed at increasing regulation of vapor products in Washington. The bill included a ban of vitamin E acetate, however the legislature failed to pass SB 6254. Due to the clear association of vitamin E acetate with EVALI and absent legislative action to ban vitamin E acetate the SBOH determined that continuing a ban is necessary to protect the public health, safety and welfare.

Consistent with the statutory authority provided to the Board by HB 2826, and upon the determination of the SBOH that vitamin E acetate is a drug of concern and should be banned, the Board adopted an emergency rule on May 27, 2020 as WAC 314-55-1065 prohibiting the use of vitamin E acetate. That emergency rule has been extended.

The extension of this emergency rule provides that no person including, but not limited to, a person licensed under chapter 69.50 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.

The Board has the authority and responsibility to adopt rules for the preservation of public health. The immediate extension of rule that prohibits the use of vitamin E acetate and preserves of public health, safety and general welfare is necessary. Therefore, the immediate extension of a rule prohibiting the use of vitamin E acetate is necessary.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note.

A section may be counted in more than one category.

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The number of sections adopted in order to compl	y with:					
Federal statute:	New		Amended		Repealed	
Federal rules or standards:	New		Amended		Repealed	
Recently enacted state statutes:	New		Amended		Repealed	
The number of sections adopted at the request of a	a nongov	vernment	al entity:			
	New		Amended		Repealed	
The number of sections adopted on the agency's o	own initia	ative:				
	New		Amended	1	Repealed	
The number of sections adopted in order to clarify	, stream	line, or re	form agency	procedu	res:	
	New		Amended		Repealed	
The number of sections adopted using:						
Negotiated rule making:	New		Amended		Repealed	
Pilot rule making:	New		Amended		Repealed	
Other alternative rule making:	New		Amended	1	Repealed	

Date Adopted: September 16, 2020	Signature:
Name: Jane Rushford	and helps of
Title: Chair	

WAC 314-55-1065 Prohibition—Vitamin E acetate. (1) Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, the Centers for Disease Control (CDC) conducted laboratory tests of twenty-nine samples of fluid collected from the lungs of patients with vaping-associated lung disease from ten states. All of the samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of injury in the lungs. The CDC did not determine that vitamin E acetate was present in only THC vapor products or only non-THC vapor products. THC was identified in eighty-two percent of the samples, and nicotine was identified in sixty-two percent of the samples.

Subsequently, tests of fifty-one samples of fluid collected from the lungs of patients with vaping-associated lung disease in sixteen states identified vitamin E acetate in forty-eight of the samples. THC was identified in forty-seven of fifty samples and nicotine was identified in thirty of forty-seven samples. Evidence is not yet sufficient to rule out the contribution of other chemicals, substances, or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and stated that it is important that vitamin E acetate not be added to any vapor products. Adoption of a rule prohibiting the sale of vapor products containing vitamin E acetate is necessary for the preservation of the public health, safety, and general welfare.

(2) No person including, but not limited to, a person licensed under chapter 69.50 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.

[1] OTS-2295.1