



## CR 102 Memorandum

### **Rules Concerning Marijuana Processor and Marijuana Retailer Compliance with Washington State Board of Health Prohibition of vitamin E acetate.**

Date: May 26, 2021  
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#### **Background**

The Washington State Liquor and Cannabis Board (Board) proposes rule amendments that would allow the Board to take disciplinary action against any licensed marijuana processor or marijuana retailer failing to comply with the provisions of WAC 246-80-021, concerning the sale of vitamin E acetate.

#### *EVALI Outbreak*

In July 2019, the United States Centers for Disease Control and Prevention (CDC), United States 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 two thousand eight hundred seven confirmed cases reported across fifty states, the District of Columbia, Puerto Rico and the US Virgin Islands, including sixty-eight deaths confirmed in twenty-nine 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 forty-eight samples of fluid collected from the lungs of patients with vaping-associated lung disease from ten 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 eighty-two percent of the samples, and nicotine

was identified in sixty-two percent of the samples. A further study found ninety-four percent 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.

### *Washington State Board of Health Response*

Based on these findings, the Washington State Board of Health (SBOH) adopted two emergency rules prohibiting the use of vitamin E acetate by a person licensed under chapter 69.50 or 70.345 RCW. The first was filed on March 19, 2020 as WSR 20-08-007, and the second was filed as WSR 20-15-117 on July 17, 2020. At the same time, the SBOH began rulemaking to make the emergency prohibition permanent on May 6, 2020, and the permanent prohibition of vitamin E acetate became effective November 15, 2020 as WSR 20-23-006, codified as WAC 246-80-021.

### *LCB Response*

Consistent with the statutory authority provided to the Board by House Bill (HB) 2826 (Chapter 133, Laws of 2020) concerning marijuana vapor products, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342, and upon the determination of the SBOH that vitamin E acetate is a drug of concern and should be prohibited, the Board adopted an emergency rule on May 27, 2020 as WAC 314-55-1065 under WSR 20-12-035, prohibiting the sale of vitamin E acetate.

Emergency amendments concerning WAC 314-55-077 and -079 were adopted on May 27, 2020 allowing the Board to take disciplinary action against any licensed marijuana processor or marijuana retailer failing to comply with the provisions of WAC 314-55-1065. These emergency amendments were extended on September 16, 2020 and on January 6, 2021.

On April 28, 2021, the Board rescinded its emergency prohibition of vitamin E acetate. Since the SBOH prohibition was permanent, the emergency rule was no longer needed. The Board also rescinded emergency amendments to WAC 314-55-077 and -079 referencing WAC 314-55-1065.

Following this, the Board filed new emergency amendments to WAC 314-55-077 and -079 referencing the permanent SBOH vitamin E acetate as WSR 21-10-044.

## Stakeholder Engagement

Emergency rules allowing the Board to take action if a licensed marijuana producer or retailer sells a product containing vitamin E acetate have been in place continuously for a year. There have been no petitions to rescind the emergency rules, and no comment has been received regarding these rules. For these reasons, the agency did not host any virtual Listen and Learn sessions regarding the substance of these proposed rules.

## Estimated Costs of Compliance

Agencies are required to consider costs **imposed** on business and costs associated with compliance with proposed rules. Agencies are **not** required under chapter 19.85 RCW to consider indirect costs not associated with compliance. Fines, penalties, or defense costs associated with enforcement actions for failure to comply with the proposed rules are considered to be indirect costs that are not associated with compliance. As a result, these costs were not analyzed. However, an analysis of potential administrative costs was conducted, and is described more fully in the CR 102 form. That analysis indicates that these rules are not anticipated to result in more than minor costs on businesses as defined in RCW 19.85.020(2).

## Rule Necessity

Consistent with RCW 69.50.342(1)(m), the Board is authorized to 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 consultation with the 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.

Emergency rules regarding the Board's ability to take disciplinary action against any licensed marijuana processor or retailer failing to comply with prohibition of the use of vitamin E acetate have been in place continuously since May 27, 2020. The proposed rule amendments are necessary to provide permanent, rather than temporary enforcement continuity of WAC 246-80-021 concerning the permanent prohibition of vitamin E acetate.

## Description of Rule Changes

**Amended section. WAC 314-55-077:** The proposed rule amendment would allow the Board to take disciplinary action against any licensed marijuana processor for failing to comply with the provisions of WAC 246-80-021 concerning the sale of vitamin E acetate.

**Amended section. WAC 314-55-079:** The proposed rule amendment would allow the Board to take disciplinary action against any licensed marijuana processor for failing to comply with the provisions of WAC 246-80-021 concerning the sale of vitamin E acetate.