



CR 103E Memorandum

Emergency Rule Regarding New Section WAC 314-55-1055 – Ingredient Disclosure

Date: January 6, 2021
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 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.

HB 2826 further amended RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (n), providing that the Board may establish, by rule, requirements for processors to submit under oath to the department of health a complete list of all constituent substances and the amount and sources thereof in each marijuana vapor product, including all additives, thickening agents, preservatives, compounds, and any other substance used in the production and processing of each marijuana vapor product.

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 adopted an emergency rule on May 27, 2020 as WAC 314-55-1065 as WSR 20-12-035 prohibiting the sale of vitamin E acetate. That emergency rule has been extended.

Reasons why rules are needed:

The extension of this emergency rule requires that marijuana licensees disclose all compounds, including but not limited to ingredients, solvents, additives, preservatives, thickening agents, terpenes, and other substances used to produce or added to marijuana concentrates for inhalation or marijuana-infused extracts for inhalation at any point during production and processing, regardless of source or origin. Disclosure must be made to the board on forms provided by the board, and submitted to an email address or other platform provided or maintained by the board until permanent rules are established to create a framework for submission of such forms to the department of health consistent with HB 2826.

The immediate extension of rule requiring disclosure of compounds and other substances, including but not limited to vitamin E acetate added to marijuana

concentrates for inhalation or marijuana-infused extracts for inhalation is necessary for the preservation of public health, safety and general welfare. Extension of this emergency rule provides continuity of existing efforts to assist public health officials in isolating the compounds and products that may be connected to lung disease.

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 CR101, 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.