



CR103 Memorandum

Regarding WAC 314-55-010 – Definitions; New Section WAC 314-55-550 – Marijuana vapor products; New Section WAC 314-55-1055 – Ingredient disclosure

Date: February 17, 2021
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Background

On September 27, 2019, Governor Inslee issued Executive Order 19-03 to address an outbreak of lung injuries emerging in previously healthy individuals who had vaped THC or nicotine vapor products.

Under direction of Executive Order 19-03, on October 10, 2019, the Washington State Board of Health (SBOH) issued emergency rules prohibiting the sale of flavored vapor products by persons licensed under chapter 69.50 RCW or chapter 70.345 RCW.

On October 16, 2019, the Washington State Liquor and Cannabis Board (Board) adopted an emergency rule as WSR 19-21-100 creating new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03.

On November 20, 2019, the SBOH adopted an emergency rule as WSR 19-24-001 on November 20, 2019, prohibiting the sale of vapor products containing vitamin E acetate. The SBOH found that the outbreak of lung disease continued to grow, and that the adoption of an emergency rule prohibiting the sale of vapor products containing vitamin E acetate was necessary for the preservation of the public health, safety, and general welfare. The SBOH relied on the following to support its finding:

- 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 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 multistate outbreak.
- As of November 13, 2019, there have been two thousand one hundred seventy-two confirmed cases reported across forty-nine states, the District of Columbia, Puerto Rico and the United States Virgin Islands, including forty-two deaths confirmed in twenty-four states. Fourteen cases of lung injury 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, the CDC conducted laboratory tests of twenty-nine 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. 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 stated that, until the relationship of vitamin E acetate and lung health is better characterized, it is important that vitamin E acetate not be added to vapor products.

On February 5, 2020, the Board extended its emergency rule originally filed as WSR 19-21-100 that created new WAC 314-55-1055 requiring manufacturers of THC vapor products to disclose all compounds, including ingredients, solvents, additives, etc. used in the production and processing as well as the source of all vapor products as directed by Executive Order 19-03 as WSR 20-05-004.

The SBOH emergency flavor ban expired on or about February 7, 2020.

On March 19, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-08-007.

On March 25, 2020, House Bill (HB) 2826 (Chapter 133, Laws of 2020), now codified in RCW 69.50.101, RCW 69,50.327, RCW 69.50.342, was enacted in

response to concerns related to marijuana vapor product and vapor related lung illnesses. The legislation contained an emergency clause, and in its intent section, found that “recent reports of lung illnesses associated with vapor products” demanded “serious attention by the state in the interest of protecting public health and preventing youth access. While state law grants the liquor and cannabis board broad authority to regulate vapor products containing marijuana, the legislature finds that risks to public health and youth access can be mitigated by clarifying that the board is granted specific authority to prohibit the use of any additive, solvent, ingredient, or compound in marijuana vapor product production and processing and to prohibit any device used in conjunction with a marijuana vapor product.”

On May 27, 2020, the Board issued its own emergency rule as WSR 20-12-035 as new WAC 314-55-1065 prohibiting the sale of vapor products containing vitamin E acetate consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

Also on May 27, 2020, the Board rescinded WSR 20-05-004, and replaced it with WSR 20-12-039, extending the requirements for disclosure of all ingredients used in the production of marijuana concentrates for inhalation and marijuana extracts for inhalation as described in WAC 314-55-105, and consistent with the authority granted by HB 2826, now codified in RCW 69.50.101, RCW 69.50.327, RCW 69.50.342.

On July 17, 2020, the SBOH extended its emergency rule concerning the prohibition of the sale of vapor products containing vitamin E acetate as WSR 20-15-117.

On September 16, 2020, the Board extended emergency rule WAC 314-55-1055 as WSR 20-19-083, and emergency rule WAC 314-55-1065 as WSR 20-19-080. Each of these rules will expire on January 14, 2021.

On November 15, 2020, the SBOH adopted WAC 246-80-012 as WSR 20-23-006, permanently prohibiting the sale of vapor products containing vitamin E acetate. The prohibition applies to any person licensed under chapter 69.50 or 70.345 RCW. The rule went into effect immediately upon filing.

On January 6, 2021, the Board again extended emergency rule WAC 314-55-1055 as WSR 21-02-095, and emergency rule WAC 314-55-1065 as WSR 21-02-092. Each of these rules will expire on May 6, 2021.

Rule Necessity

Consistent with HB 2826, new rule sections and amendment to existing rule is necessary to allow the Board to accomplish the following:

- Prohibit any type of device used in conjunction with a marijuana vapor product, and prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products one the Board has determined, following consultation with the Department of Health (DOH) or other authority the WSLCB deems appropriate, that the device, additive, solvent, ingredient or compound may pose a risk to public health or youth access;
- Establish definitions for terms including, but not limited to “characterizing flavor,” botanical terpenes,” and others; and
- Require marijuana processors to submit, under oath, to the DOH, a complete list of all constituent substances and the amount and sources of all constituent substances 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.

Description of Rule Changes

Amended section. WAC 314-55-010 – Definitions. Adds definitions for “characterizing flavor” and “terpenes.” Additionally, existing subsections were renumbered to accommodate this amendment.

New section. WAC 314-55-550 – Marijuana products. Establishes a procedure for the Board to monitor, evaluate and prohibit devices or additives used in conjunction with marijuana vapor products.

New section. WAC 314-55-1055 – Ingredient disclosure. Requires marijuana processors and producers to 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

Variance between proposed rule (CR102) and final rule:

There is no variance between the proposed rule and the final rule.

Rule Implementation

Informing and Educating Persons Impacted by the Rule

To help inform and educate persons impacted by the rule, the WSLCB will:

- Email notice with the adoption materials to persons who commented on the rules, the rule making and licensee distribution lists, and the general WSLCB GovDelivery list;
- Post rule adoption materials, including final rule language, response to comments, final analysis (Concise Explanatory Statement), and any other relevant documents on the rulemaking webpage for public access.
- Provide information and training on request.

Promoting and Assisting Voluntary Compliance

WSLCB will promote and assist voluntary compliance through technical assistance.

- WSLCB staff are available to respond to phone and email inquiries about the rules.
- Licensing and Enforcement/Education leadership and staff have participated in rule revisions, and are familiar with the final product. Internal and external education efforts to share knowledge and assure consistent application of rule will be supported.
- Rule and guidance documents will be available on the WSLCB website.
- WSLCB will use available and customary resources to disseminate materials and information to all persons impacted by the rules.

These actions are designed to inform and educate all persons impacted by the rules to support and promote voluntary compliance.

Training and Informing WSLCB Staff

Several WSLCB staff responsible for implementing these adopted rules work directly with impacted parties and are already familiar with the nuances of the rule changes. Additional internal guidance documents may be prepared as necessary. The WSLCB will also consider:

- Provision of internal and external training and education, as needed, potentially including webinars, training, and videos if appropriate;
- Coordinating and centrally locating decisions to assure consistency between agency, staff, and industry.

Rule Effectiveness Evaluation

The WSLCB will evaluate the effectiveness of these rules in the following ways, including but not limited to:

- Monitoring questions received after the effective date of these rules, and adjusting training and guidance accordingly;
- Monitoring the number of enforcement actions, including type, resolution, and final outcome;
- Monitoring the number of requests for rule language revisions or changes;

- Monitoring the number of requests for rule interpretation;
- Monitoring licensee feedback including, but not limited to, the number of requests for assistance.