

Date: April 28, 2021

To: David Postman, Board Chair

Ollie Garrett, Board Member Russ Hauge, Board Member

From: Kathy Hoffman, Policy and Rules Manager

Copy: Rick Garza, Agency Director

Chandra Brady, Director of Enforcement and Education Justin Nordhorn, Policy and External Affairs Director

Becky Smith, Licensing Director

Subject: Approval of emergency rules (CR 103E) amending WAC 314-55-077 – Marijuana processor license – Privileges, requirements and fees and WAC 314-55-079 – Marijuana retailer license – Privileges, requirements and fees.

The Washington State Board of Health adopted a permanent prohibition of vitamin E acetate, effective November 15, 2020 as WSR 20-23-006, codified as WAC 246-80-021. This emergency rule allows the Board to take disciplinary action against any processor or retailer failing to comply with the provisions of WAC 246-80-012 under the authority of chapter 69.50 RCW.

Process

The Policy and Rules Manager requests that the Board adopt the emergency rules described above, and requests approval to file the emergency rules described above. A CR 103E Memorandum on this rule was presented at the Board meeting on April 28, 2021, and is attached to this request.

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

April 28, 2021	Board is asked to adopt the emergency rulemaking order (CR 103E) as described above.
April 28, 2021	Emergency rule becomes effective.

Approve	Disapprove		
Approve	Disapprove	David Postman, Chair	Date
		Ollie Garrett, Board Member	Date
Approve _	Disapprove	Russ Hauge, Board Member	Date

Attachment: CR 103E Memorandum



CR 103E Memorandum

Emergency Rules Regarding Enforcement of WAC 246-80-021 – Adding New Sections to WAC 314-55-077 – Marijuana processor license – Privileges, requirements, and fees and WAC 314-55-079 – Marijuana retailer license – Privileges, requirements and fees.

Date: April 28, 2021

Presented by: Kathy Hoffman, Policy and Rules Manager

Background:

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 ninetyfour 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.

Based on these findings, the Washington State Board of Health adopted a permanent prohibition of vitamin E acetate, effective November 15, 2020 as WSR 20-23-006, codified as WAC 246-80-021.

WAC 246-80-021 provides that:

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.

These emergency rules replace emergency rules filed on January 6, 2021 as WSR 21-02-093 and WSR 21-02-094 that allowed the Board to take disciplinary action, without interruption, against any licensed marijuana processor or retailer failing to comply with the provisions of WAC 314-55-1065 prohibiting the use of vitamin E acetate consistent with its regulatory authority.

However, since the SBOH has permanently adopted WAC 246-80-021 to prohibit the use of vitamin E acetate, and the Board can rely on this authority to enforce compliance, the Board's emergency prohibition under WAC 314-55-1065 is no longer necessary. These emergency rules provide enforcement continuity while the permanent the rule development process takes place, consistent with the CR 101 filed on March 31, 2021 as WSR 21-08-035.

Reasons why rules are needed:

These emergency rules allow the Board to take disciplinary action, without interruption, against any licensed marijuana processor or retailer that fails to comply with the provisions of WAC 246-80-021, prohibiting the use of vitamin E acetate consistent with the authority of chapter 69.50 RCW.

The Board has the authority and responsibility to adopt rules for the preservation of public health. The immediate filing these emergency rules provides for the enforcement of WAC 246-80-021, and preserves public health, safety and general welfare. Therefore, the immediate adoption of these emergency rules concerning enforcement provisions for WAC 246-80-021 prohibiting the sale 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 CR 103E Memo – Emergency rule re

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.

CODE REVISER USE ONLY



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

Agency: washington State Liquor and Cannabis Board
Effective date of rule:
Emergency Rules
□ Later (specify)
Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule? ☐ Yes ☑ No If Yes, explain:
Purpose: WAC 314-55-077 – Marijuana processor license- Privileges, requirements and fees; WAC 314-55-079 – Marijuana retailer license – Privileges, requirements and fees. The Washington State Liquor and Cannabis Board (Board) has adopted rule amendments as WAC 314—55-077(16) and WAC 314-55-079(14) that allows the board to take disciplinary action against any licensed marijuana processor or retailer for failure to comply with the provisions of WAC 246-80-021, concerning the sale of vitamin E acetate. These emergency rules replace and supersede emergency rules filed on January 6, 2021 as WSR 21-02-093 and WSR 21-02-094.
Citation of rules affected by this order:
New:
Repealed:
Amended: WAC 314-55-077, WAC 314-55-079
Suspended:
Statutory authority for adoption: RCW 69.50.101, RCW 69.50.327, RCW 69.50.342; RCW 69.50.345.
Other authority:
EMERGENCY RULE
Under 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.
Reasons for this 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 e-cigarette or vaping associated lung injury (EVALI). In September 2019, the CDC activated its

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 bronchoalveloar 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.

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.

Based on these findings, the Washington State Board of Health adopted a permanent prohibition of vitamin E acetate, effective November 15, 2020 as WSR 20-23-006, codified as WAC 246-80-021.

These emergency rules replace and supersede emergency rules filed on January 6, 2021 as WSR 21-02-093 and WSR 21-02-094 that allowed the Board to take disciplinary action, without interruption, against any licensed marijuana processor or retailer failing to comply with the provisions of WAC 314-55-1065 prohibiting the use of vitamin E acetate consistent with its regulatory authority.

However, since the SBOH has permanently adopted WAC 246-80-021 to prohibit the use of vitamin E acetate, and the Board can rely on this authority to enforce compliance, the Board's emergency prohibition under WAC 314-55-1065 is no longer necessary. These emergency rules provide enforcement continuity while the permanent the rule development process takes place, consistent with the CR 101 filed on March 31, 2021 as WSR 21-08-035.

The Board has the authority and responsibility to adopt rules for the preservation of public health. The immediate adoption of this rule provides uninterrupted enforcement of WAC 246-80-021, and preserves public health, safety and general welfare is necessary. Therefore, continuity of these emergency rules concerning enforcement provisions for WAC 246-80-021 prohibiting the use or sale of vitamin E acetate are 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.								
The number of sections adopted in order to comply	with:							
Federal statute:	New	<i></i>	Amended		Repealed			
Federal rules or standards:	New	<i></i>	Amended		Repealed			
Recently enacted state statutes:	New	<i></i>	Amended		Repealed			
The number of sections adopted at the request of a nongovernmental entity:								
	New	<i></i>	Amended		Repealed			
The number of sections adopted on the agency's own initiative:								
	New		Amended	2	Repealed			
The number of sections adopted in order to clarify, streamline, or reform agency procedures:								
	New	<i></i>	Amended		Repealed			
The number of sections adopted using:								
Negotiated rule making:	New	<i></i>	Amended		Repealed			
Pilot rule making:	New	<i></i>	Amended		Repealed			
Other alternative rule making:	New	<i></i>	Amended	2	Repealed			
Date Adopted: April 28, 2021		Signature:	Plac	o signati	ıra hara			
Name: David Postman			Place signature here					
Title: Chair								

- WAC 314-55-079 Marijuana retailer license—Privileges, requirements, and fees. (1) A marijuana retailer license allows the licensee to sell only useable marijuana, marijuana concentrates, marijuana-infused products, marijuana paraphernalia, and lockable boxes to store marijuana at retail in licensed retail outlets to persons twenty-one years of age and older, except as allowed for persons under twenty-one years of age consistent with RCW 69.50.357 and WAC 314-55-080.
- (2) The WSLCB may accept applications for marijuana retail licenses at time frames published on its website at www.lcb.wa.gov. Using estimated consumption data and population data obtained from the office of financial management (OFM) population data, the WSLCB will determine the maximum number of marijuana retail locations per county.
- (a) The number of retail locations will be determined using a method that distributes the number of locations proportionate to the most populous cities within each county and to accommodate the medical needs of qualifying patients and designated providers. Locations not assigned to a specific city will be at large. At large locations can be used for unincorporated areas in the county or in cities within the county that have no retail licenses designated.
- (b) The number of retail licenses determined by the board can be found on the WSLCB website at www.lcb.wa.gov.
- (3) Any entity and/or principals within any entity are limited to no more than five retail marijuana licenses.
 - (4) Application and license fees.
- (a) The application fee for a marijuana retailer's license is two hundred fifty dollars. The applicant is responsible for fees required by the approved vendor for fingerprint evaluation.
- (b) The annual fee for issuance and renewal of a marijuana retailer license is one thousand three hundred eighty-one dollars. The WSLCB will conduct random criminal history checks at the time of renewal that will require the licensee to submit fingerprints for evaluation from the approved vendor. The licensee is responsible for all fees required for the criminal history checks.
- (5) Internet sales and delivery of product to customers are prohibited.
- (6) Sales of marijuana-infused products not permissible under WAC 314-55-077 are prohibited.
- (7) Marijuana retailers may not sell marijuana products below the current acquisition cost.
- (8) All marijuana products must be stored behind a counter or other barrier to ensure a customer does not have direct access to the product.
- (9) A marijuana retailer may not sell lockable boxes for less than the cost of acquisition or sell boxes received as a donation. The donation of lockable boxes must come from a person or entity that is not a licensed marijuana producer, processor, or retailer.
- (10) Marijuana retailer licensees are allowed to have a maximum of four months of their average inventory on their licensed premises at any given time.
- (11) A marijuana retailer may transport product to other locations operated by the licensee or to return product to a marijuana processor as outlined in WAC 314-55-085.

- (12) A marijuana retailer may accept returns of open marijuana products. Products must be returned in their original packaging with the lot, batch, or inventory ID number fully legible.
- the lot, batch, or inventory ID number fully legible.

 (13) A marijuana retailer may dispose of marijuana products as provided in WAC 314-55-097.
- (14) The board may take disciplinary action against any marijuana retailer that fails to comply with the provisions of WAC 246-80-021.

[2] OTS-1798.3

- WAC 314-55-077 Marijuana processor license—Privileges, requirements, and fees. (1) A marijuana processor license allows the licensee to process, dry, cure, package, and label useable marijuana, marijuana concentrates, and marijuana-infused products for sale at wholesale to marijuana processors and marijuana retailers.
 - (2) Application and license fees.
- (a) The application fee for a marijuana processor license is two hundred fifty dollars. The applicant is also responsible for paying the fees required by the approved vendor for fingerprint evaluation.
- (b) The annual fee for issuance and renewal of a marijuana processor license is one thousand three hundred eighty-one dollars. The board will conduct random criminal history checks at the time of renewal that will require the licensee to submit fingerprints for evaluation from the approved vendor. The licensee is responsible for all fees required for the criminal history checks.
- (c) The application window for marijuana processor licenses is closed. The board may reopen the marijuana processor application window at subsequent times when the board deems necessary.
- (3) Any entity and/or principals within any entity are limited to no more than three marijuana processor licenses.
- (4)(a) A marijuana processor that makes marijuana-infused solid or liquid product meant to be ingested orally (marijuana edibles) must obtain a marijuana-infused edible endorsement from the department of agriculture as required under chapter 15.125 RCW and rules adopted by the department to implement that chapter (chapter 16-131 WAC). A licensee must allow the board or their designee to conduct physical visits and inspect the processing facility, recipes, and records required under WAC 314-55-087 during normal business hours or at any time of apparent operation without advance notice.
- (b) A marijuana processor licensed by the board must ensure marijuana-infused edible processing facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapter 15.125 RCW and rules promulgated to implement chapters 16-131, 16-165 and 16-167 WAC.
- (5)(a) A marijuana processor may blend tested useable marijuana from multiple lots into a single package for sale to a marijuana retail licensee so long as the label requirements for each lot used in the blend are met and the percentage by weight of each lot is also included on the label.
- (b) A processor may not treat or otherwise adulterate useable marijuana with any organic or nonorganic chemical or other compound whatsoever to alter the color, appearance, weight, or smell of the useable marijuana.
 - (6) Recipes, product, packaging, and labeling approval.
- (a) A marijuana processor licensee must obtain label and packaging approval from the board for all marijuana-infused products meant for oral ingestion prior to offering these items for sale to a marijuana retailer. The marijuana processor licensee must submit a picture of the product, labeling, and packaging to the board for approval. More information on the product, packaging, and label review process is available on the board's website.

- (b) All recipes for marijuana-infused products meant for oral ingestion (marijuana edible products) must be approved by the department of agriculture under chapter 16-131 WAC. Licensees must obtain recipe approval from the department of agriculture prior to submitting any marijuana edible products, packages, and labels for review and approval by the board. The recipe for any marijuana-infused solid or liquid products meant to be ingested orally must be kept on file at the marijuana processor's licensed premises and made available for inspection by the board or its designee.
- (c) If the board denies a marijuana-infused product for sale in marijuana retail outlets, the marijuana processor licensee may request an administrative hearing under chapter 34.05 RCW, Administrative Procedure Act.
- (7) With the exception of the marijuana, all ingredients used in making marijuana-infused products for oral ingestion must be a commercially manufactured food as defined in WAC 246-215-01115.
- (8) Marijuana-infused edible products in solid or liquid form must be homogenized to ensure uniform disbursement of cannabinoids.
- (9) A marijuana processor may infuse food or drinks with marijuana, provided that:
- (a) The product or products do not require cooking or baking by the consumer;
- (b) Coatings applied to the product or products are compliant with the requirements of this chapter;
- (c) The product and package design is not similar to commercially available products marketed for consumption by persons under twenty-one years of age, as defined by WAC 314.55.105 (1)(c).
- (10) To reduce the risk to public health, potentially hazardous foods as defined in WAC 246-215-01115 may not be infused with marijuana. Potentially hazardous foods require time-temperature control to keep them safe for human consumption and prevent the growth of pathogenic microorganisms or the production of toxins. Any food that requires refrigeration, freezing, or a hot holding unit to keep it safe for human consumption may not be infused with marijuana.
- (11) Other food items that may not be infused with marijuana to be sold in a retail store include:
 - (a) Any food that has to be acidified to make it shelf stable;
 - (b) Food items made shelf stable by canning or retorting;
- (c) Fruit or vegetable juices (this does not include shelf stable concentrates);
 - (d) Fruit or vegetable butters;
 - (e) Pumpkin pies, custard pies, or any pies that contain egg;
- (f) Dairy products of any kind such as butter, cheese, ice cream, or milk; and
 - (g) Dried or cured meats.
- (h) Vinegars and oils derived from natural sources may be infused with dried marijuana if all plant material is subsequently removed from the final product. Vinegars and oils may not be infused with any other substance, including herbs and garlic.
- (i) Marijuana-infused jams and jellies made from scratch must utilize a standardized recipe in accordance with 21 C.F.R. Part 150, revised as of April 1, 2013.
- (12) Consistent with WAC 314-55-104, a marijuana processor may infuse dairy butter or fats derived from natural sources, and use that extraction to prepare allowable marijuana-infused solid or liquid products meant to be ingested orally, but the dairy butter or fats derived from natural sources may not be sold as stand-alone products.

[2] OTS-2297.2

The board may designate other food items that may not be infused with marijuana.

- (13) Marijuana processor licensees are allowed to have a maximum of six months of their average useable marijuana and six months average of their total production on their licensed premises at any time.
- (14) **Processing service arrangements.** A processing service arrangement is when one processor (processor B) processes useable marijuana or an altered form of useable marijuana (marijuana product) for another licensed processor (processor A) for a fee.
- (a) Processor A is the product owner. However, processor B may handle the product under its license as provided in chapter 69.50 RCW and this chapter. Processor B is not allowed to transfer the product to a retailer and may only possess marijuana or marijuana products received from processor A for the limited purposes of processing it for ultimate transfer back to processor A.
- (b) Processing service arrangements must be made on a cash basis only as provided in WAC 314-55-115 and payment for the service and return of the processed product must be made within thirty calendar days of delivery to processor B. Failure to do so as provided by the preceding sentence is a violation of this section and any marijuana or marijuana product involved in the transaction will be subject to seizure and destruction. Payment with any marijuana products, barter, trade, or compensation in any form other than cash for processing service arrangements is prohibited under processing service arrangements.
- (c) Each processor that enters into a processing service arrangement must include records for each service arrangement in recordkeeping documents which must be maintained consistent with this chapter.
- (15) Marijuana may not be returned by any retail licensee to any processor except as provided in this section.
- (a) Every processor must maintain on the licensed premises for a period of five years complete records of all refunds and exchanges made under this section including an inventory of marijuana and marijuana products returned to the processor by any retail licensee.
- (b) Marijuana may be returned by a retail licensee in the event a retailer goes out of the business of selling marijuana at retail and a cash refund, as defined by WAC 314-55-115, may be made upon the return of the marijuana or marijuana products, so long as WSLCB approval is acquired prior to returns and refunds under this subsection.
- (c) Marijuana products different from that ordered by a retailer and delivered to the retailer may be returned to a processor and either replaced with marijuana products which were ordered or a cash refund, as defined by WAC 314-55-115, may be made. These incorrect orders must be discovered and corrected within eight days of the date the delivery was made to be eligible for returns and refunds under this subsection.
- (d) A marijuana processor may accept returns of products and sample jars from marijuana retailers for destruction, but is not required to provide refunds to the retailer. It is the responsibility of the retailer to ensure the product or sample jar is returned to the processor.
- (16) The board may take disciplinary action against any marijuana processor that fails to comply with the provisions of WAC 246-80-021.