Significant Legislative Rule Analysis

WAC 246-80-021
a Rule Concerning Prohibition – vitamin E acetate

July 27, 2020

SECTON 1:

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The State Board of Health (Board) is proposing to adopt a new section of rule, WAC 246-80-021, to ban the sale of vapor products containing vitamin E acetate This 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 means including by telephone or other method of voice transmission, the mail or any other delivery service or the internet or other online service.

In July 2019, the U.S. Centers for Disease Control and Prevention (CDC), U.S. 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 2,807 confirmed cases reported across 50 states, the District of Columbia, Puerto Rico and the US Virgin Islands, including 68 deaths confirmed in 29 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 48 samples of fluid collected from the lungs of patients with vaping-associated lung disease from 10 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 82% of the samples, and nicotine was identified in 62% of the samples. A further study found 94% 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.

SECTION 2:

Is a Significant Analysis required for this rule?

The Board has determined, under RCW 34.05.328(5)(c)(iii)(A), that a significant analysis is required. The proposed rule will adopt substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction.

SECTION 3:

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

This rule seeks to implement RCW 43.20.050(2)(f), which allows the Board to adopt rules for prevention and control of infectious and noninfectious diseases, including food and vector borne illness. Vitamin E acetate has been clearly identified as a contributor to EVALI, a noninfectious disease, and its prohibition is in line with the goals of preventing noninfectious disease under RCW 43.20.050(2)(f).

SECTION 4:

Explain how the Board determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

An alternative to rulemaking would be to not address the issue of vitamin E acetate in vapor products. The consequences of this approach would be that individuals who use vape products would be susceptible to developing e-cigarette or vaping product associated lung injury (EVALI), which can result in serious harm or death.

An additional alternative to rulemaking would be to instead rely on disclosure of ingredients and allow consumers to determine whether to utilize products containing vitamin E acetate or not. This alternative would require consumers of vapor products to assess for themselves whether vitamin E acetate is an ingredient that is safe for consumption. Additionally, this alternative would not guarantee the availability of products for consumers to choose that do not contain vitamin E acetate.

The Board determined that the alternatives to this rulemaking would not meet the goal of preventing and controlling EVALI. By continuing to allow products on the market that contain vitamin E acetate, there remains a risk that individuals will purchase and use these products and potentially develop EVALI.

SECTION 5:

Explain how the Board determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rule bans the sale of vapor products containing vitamin E acetate This 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 means including by telephone or other method of voice transmission, the mail or any other delivery service or the internet or other online service.

Based on the information that has been provided to the Board by industry, there is no entity in Washington who has disclosed prior use of vitamin E acetate in vapor products. This does not include online retailers of vapor products. Washington State saw 27 cases of EVALI since April 2019

Benefits: The removal of vitamin E acetate from vapor products is likely to reduce instances of EVALI and therefore reduce the need for acute and long-term medical intervention. In their review of e-cigarette and vapor induced lung injury, the United States Centers for Disease Control and Prevention (CDC) assessed, the medical treatment of individuals with EVALI. Of 342 patients with information available, nearly half (47%) were required to be transferred to an intensive care unit at some point during their treatment with 22% requiring mechanical ventilation or endotracheal intubation[1]. While many individuals will recover from EVALI, there is limited data as to how those individuals will fare long-term. A study conducted in January 2020 found 2.7% of individuals hospitalized for EVALI were re-admitted within a median 4 days and that seven individuals died within a median 3 days of discharge[2]. This has been reported to be more prevalent among those with co-morbidities and also among those discontinuing corticosteroid treatment[3].

Cost: Industry in Washington has indicated that vitamin E acetate was not previously used in vapor products in Washington State. Therefore, the Board has determined that there is no cost to this rulemaking to these entities. For online or other retailers where information regarding the use of vitamin E acetate is not as clear, the Board made efforts to determine the cost of replacing vitamin E acetate with another thickening agent. An online search found an alternative, hemp based thickening agent, which is available at a cost of $520 for 32 ounces. According to the manufacturer's instructions, no more than 10% of the product should be the thickening agent[4]. Most e-cigarette or vapor products have capacity no more than 5mL of liquid, therefore, if 10% were a thickening agent, at $520 for 32 ounces, the cost would be $0.27 per 5 mL vapor product.

Cost of thickening agent per product =

$$\frac{\text{Total cost of total thickening agent}}{\text{Total thickening agent / (Total volume of product * percent thickening agent per product)}}$$

Cost-Benefit: As described above the cost of a replacement thickening agent can be as low as $0.27 per 5 mL product. Given that 95% of those diagnosed with EVALI were hospitalized an estimate for the cost of treatment will be based on this assumption. The average hospitalization in Washington State for interstitial lung disease with major complications had an average charge

[1] https://www.cdc.gov/mmwr/volumes/68/wr/mm6841e3.htm
[2] https://www.cdc.gov/mmwr/volumes/68/wr/mm685152e1.htm
[3] https://www.yalemedicine.org/conditions/evali/#:~:text=EVALI%20is%20the%20name%20given,product%20use%2Dassociated%20lung%20injury.
[4] https://www.peaksupplyco.com/cannabis-oil-thickener

of $58,430[5]. The average cost of prednisone, cited as the corticosteroid used in EVALI treatment, was $9.94[6],[7].

Based on this this quantitative and qualitative evidence, the Board has determined that the probable benefits of this rule outweigh the costs.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

The Board considered not undertaking rulemaking in relation to vitamin E acetate. This option would not have addressed vitamin E acetate as a contributing cause of EVALI. The prohibition of vitamin E acetate, as proposed in this rule, is the least burdensome alternative to address the issues. The industry has previously informed the Board that the regulated market for e-cigarette and other vapor products does not utilize vitamin E acetate and therefore no burden exists to remove this additive. Additionally, the requirement to discontinue use of a specific additive for vapor products requires change at the point of manufacturing, who then must disclose these ingredients to the US Food and Drug Administration. Retailers are therefore easily able to identify products that do contain vitamin E acetate and comply with this rule by not selling those products.

SECTION 7:

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The Board has determined that the rule does not require those to whom it applies to take an action or action that violate requirements of another federal or state law.

SECTION 8:

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The Board has determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

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[5] http://www.wahospitalpricing.org/Report_INP.aspx

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6913849/

[7] https://www.goodrx.com/prednisone#:~:text=About%20Prednisone&text=It%20is%20covered%20by%20most,average%20retail%20price%20of%20%249.94.

SECTION 9:

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The proposed rule does not conflict with any federal regulation or statute applicable to this subject matter.

SECTION 10:

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.