Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-60 Regulations Governing Pharmaceutical Processors
Department of Health Professions
Town Hall Action/Stage: 5452/9166
February 19, 2021

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to prohibit pharmaceutical processors from producing or dispensing any cannabis oil that contains vitamin E acetate if that oil is intended to be vaporized or inhaled.[1] This ban on cannabis oil products containing vitamin E acetate was first implemented via an emergency action in response to a spike in lung injury among users of e-cigarettes and vaping products.[2] The proposed amendment would make this ban permanent.

Background

The Board seeks to ban the use of vitamin E acetate (also known as tocopheryl acetate) in cannabis oil products that are intended for vaping. Specifically, the proposed amendment would add the following sentence to section 280 on the cultivation and production of cannabis oil: "No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate."[3]

The Board first sought to address the outbreak of e-cigarette or vaping product use-associated lung injury (EVALI) in November 2019. As of November 13, 2019, the Centers for Disease Control (CDC) reported 2,172 cases of lung disease associated with e-cigarette or vaping

[1] A pharmaceutical processor is a facility that has obtained a permit from the Board to cultivate cannabis plants for the production of cannabis oil, and dispense the oil to patients registered by the Board for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the physician to benefit from such use.
[2] See https://townhall.virginia.gov/L/ViewStage.cfm?stageid=8856, which became effective August 6, 2020.
[3] The emergency regulation referred to "THC-A oil or cannabidiol oil." However, due to legislation passed in the 2020 General Assembly, these terms have been eliminated and "cannabis oil" is used instead. See https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP1278.

product use in 49 states (including Virginia) and 42 deaths in 24 states.[4] Currently, the CDC's main findings regarding EVALI are as follows:

- National and state data from patient reports and product sample testing show tetrahydrocannabinol (THC)-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak.
- Vitamin E acetate is strongly linked to the EVALI outbreak. Vitamin E acetate has been found in product samples tested by the Food and Drug Administration and state laboratories and in patient lung fluid samples tested by CDC from geographically diverse states. Vitamin E acetate has not been found in the lung fluid of people who do not have EVALI.
- Evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases.[5]

The Board initially considered a ban on vaping products containing cannabis oil altogether, but decided to more narrowly ban the use of vitamin E acetate in such products once the CDC had identified this chemical to be responsible for EVALI.[6]

Estimated Benefits and Costs

Prohibiting pharmaceutical processors from producing or dispensing THC-containing e-cigarettes or vaping products that contain vitamin E acetate would protect registered patients who are eligible to obtain these products, thereby benefiting them. By selectively banning vitamin-E acetate, the proposed amendment mitigates any costs or losses that pharmaceutical processors may have incurred had the Board sought to implement a general ban on THC-containing e-cigarettes or vaping products.

[4] See page 2 of the Agency Background Document (ABD): https://townhall.virginia.gov/L/GetFile.cfm?File=30\5452\9166\AgencyStatement_DHP_9166_v1.pdf.
[5] See https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.
[6] As per the Department of Health Professions (DHP); see note 3 for a link to the ABD.

Businesses and Other Entities Affected

There are currently four pharmaceutical processors who have been issued permits. Assuming they complied with the ban when the emergency action was first promulgated, the proposed amendment to make the ban permanent would not lead to any additional costs to them.[7] Further, should the Board allow new entrants in the future, they would be unlikely to face additional costs or be discouraged from entry as a result of the proposed amendment.

Small Businesses[8] Affected

It is unknown if any of the pharmaceutical processors are small businesses, and the Board did not indicate if any processors were small businesses. However, the proposed amendment is unlikely to disproportionately impact any small business processors since it would likely not produce an adverse impact on any of the pharmaceutical processors.

Localities[9] Affected[10]

The proposed amendment does not introduce new costs for local governments and is unlikely to affect any locality in particular.

Projected Impact on Employment

The proposed amendment is unlikely to affect employment by pharmaceutical processors.

Effects on the Use and Value of Private Property

The proposed amendment is unlikely to affect the use and value of private property. Real estate development costs are not affected.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment

[7] DHP reported that the Board did not receive any comments or complaints from the pharmaceutical processors following the emergency action.

[8] Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

[9] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[10] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.