



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: 5602 / 9072
November 18, 2020

Summary of the Proposed Amendments to Regulation

Chapter 928 (HB1670) of the 2020 Acts of the Assembly¹ authorized pharmaceutical processors to acquire oil from industrial hemp extract to be used in formulating cannabis oil for dispensing to patients, and requires the same third-party testing requirements for industrial hemp extracts as those for cannabis plant extract. The Board of Pharmacy (Board) proposes to incorporate this legislative change in the regulations. In addition, the Board proposes discretionary changes to further ensure patient safety. These include specifying the content of records relating to such acquisition and the time period for maintenance of the record, and requiring policies and procedures for proper storage and handling of the oil, including a process to follow in case of a recall of a product.

Background

Cannabis oil can be extracted from both marijuana and hemp. Both of these are types of the *Cannabis sativa* family, which are annual flowering plants. Both varieties can contain cannabidiol (CBD), but marijuana contains higher amounts of Tetrahydrocannabinol (THC). THC is one of many cannabinoids identified in cannabis and is the principal psychoactive constituent (the chemical that produces an intoxicated feeling). The federal 2018 Farm Bill considers *Cannabis sativa* plants with less than 0.3 percent THC to be hemp or industrial hemp. In Virginia, industrial hemp growers, dealers, and processors are regulated separately from pharmaceutical processors. The Virginia Department of Agriculture and Consumer Services

¹ <https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP0928>

(VDACS) administers a registration program for industrial hemp under the Virginia Industrial Hemp Law² while the Board regulates the pharmaceutical processors.

The 2020 General Assembly authorized pharmaceutical processors to acquire oil from industrial hemp extract to be used in formulating cannabis oil for dispensing to patients as of July 1, 2020. The Board proposes to incorporate this legislative change in the regulations.

Estimated Benefits and Costs

Industrial hemp extract, which may have no more than 0.3 percent THC, can be produced from industrial hemp and can be used by pharmaceutical processors in formulations of cannabis oil with higher THC content for dispensing to patients. In economic terminology, that means there is some degree of possible substitution between hemp and marijuana flower extracts. Pursuant to the 2020 legislation, the proposed regulation would allow pharmaceutical processors to purchase hemp extract from industrial hemp dealers or processors.³ Pharmaceutical processors would likely take advantage of this option if it is economically advantageous. In other words, pharmaceutical processors would be inclined to purchase hemp extract from industrial hemp dealers or processors if doing so is cheaper than the cost of obtaining the marijuana extract by growing it themselves. Generally speaking, that appears to be the case.

This option made possible by the new legislation would allow pharmaceutical processors to reduce their cost of production and create a new market for industrial hemp. The trade would take place only if it is economically advantageous to both parties. Currently there are four licensed pharmaceutical processors in Virginia. Only one of them is actively selling cannabis oil products. The other three are in the startup phase. There are approximately 1,200 registered growers and 337 processors of industrial hemp. However, only 17 of the registered industrial hemp processors have been approved to produce food grade hemp extract, which is the most likely version of the hemp extract that pharmaceutical processors may be interested in purchasing.

The proposed regulation is beneficial because it would allow pharmaceutical processors to acquire suitable hemp extract at lower cost, which may help to bring cannabis oil to market at

² <https://law.lis.virginia.gov/vacode/title3.2/chapter41.1/>

³ Although hemp seed oil is extracted from hemp seeds for other uses, it is the extract from the flowers of the hemp plant that is suitable for cannabis oil products.

lower prices than otherwise would be possible. Such sales would also benefit participating industrial hemp processors.

The size of benefits from this proposed change would depend on the magnitude of the quantity and the market value of hemp extract that may be purchased by the pharmaceutical processors. However, there is no data available to estimate the quantity or the market value of hemp extract that may be purchased by the pharmaceutical processors. Currently, there are approximately 7,000 registered users of cannabis oil, but the market appears to be in its infancy and growing fast.

In addition, the Board proposes to specify the content of records relating to such acquisition and the time period for maintenance of the record; and require policies and procedures for proper storage and handling of the oil, including a process to follow in case of a recall of a product. These particular changes are not expected to create any significant economic effects as the processors are already required to maintain records. However, the proposed clarification may improve compliance and help with recalls to avoid some adverse health consequences should a health risk arise with a particular product.

Businesses and Other Entities Affected

The proposed regulation would directly affect four licensed pharmaceutical processors (only one of whom is currently selling cannabis oil products while the other three are in the process of setting up their operations) and approximately 17 food grade industrial hemp processors. To the extent the legislative change creates a new market for the use of industrial hemp and allows pharmaceutical processors to acquire CBD extract at lower cost and reduce cannabis oil product prices, approximately 1,200 hemp growers and over 7,000 cannabis oil consumers may be indirectly affected.⁴ None of these entities appear to be disproportionately affected.

Small Businesses⁵ Affected:

DHP believes one of the four pharmaceutical processors likely qualifies as a small business. However, the proposed amendments do not appear to adversely affect small businesses.

⁴ Data source: DHP and VDACS

⁵ 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.”

Localities⁶ Affected⁷

The proposed amendments do not affect or introduce costs for local governments.

Projected Impact on Employment

The proposed amendments would allow pharmaceutical processors to purchase CBD extract from industrial hemp processors rather than produce it themselves. This may add to demand for labor in the hemp industry while having an offsetting effect on demand by the pharmaceutical processors. The net impact on total employment is unlikely to be significant.

Effects on the Use and Value of Private Property

To the extent pharmaceutical processors purchase CBD extract from the hemp industry, there may be an increase in the demand for and the use of farm land for hemp production and an increase in the value of such land as well as an increase in the asset values of hemp processors. An increase in the asset values of pharmaceutical processors may also be expected due to enabling them to acquire CBD extract at lower cost than otherwise would be possible.

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 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

⁶ “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.

⁷ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.

proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.