



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: 5398/8948
July 13, 2020

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to make permanent the changes effected by an emergency action that became effective December 30th, 2019, and implement two other changes that would conform the regulation to the Code of Virginia.¹ The emergency regulation defines the role of registered agents who are authorized to obtain cannabidiol (CBD) or THC-A oil for registered patients. It also adds a section allowing pharmaceutical processors to engage in the wholesale distribution of CBD and THC-A oils amongst themselves. The Board also proposes to allow pharmaceutical processors to employ individuals with less than two years of experience for certain specific tasks, and to allow processors to begin the cultivation of cannabis once their permit is issued without having to wait for two weeks as per current requirement.

Background

Chapter 690 of the 2019 Acts of Assembly (Act) allows “registered agents” to pick up prescribed quantities of THC-A oil on behalf of registered patients or their legal guardians.² The Act also allows pharmaceutical processors to engage in wholesale distribution of processed CBD or THC-A oils with each other. Further, the Act allows pharmaceutical processors to employ workers with less than two years’ experience to perform cultivation- or extraction-related duties under the supervision of an individual with either a relevant degree in the field or a certification by the Board or at least two years’ experience. Lastly, the Act directed the Board to promulgate

¹ See <https://townhall.virginia.gov/l/ViewStage.cfm?stageid=8778>

² See <https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+CHAP0690+hil>

emergency regulations to implement these changes within 280 days. Thus, the Board now seeks to make these changes to the regulation permanent. In addition, pharmaceutical processors that receive a permit are currently forbidden to cultivate cannabis until two weeks prior to their opening date. This requirement appears to have been made at the Board's discretion, and the Board now seeks to lift this requirement. This would allow pharmaceutical processors to begin cultivation once the permit is issued regardless of their opening date.

Estimated Benefits and Costs

Registered patients or their guardians would have greater flexibility in picking up prescriptions for THC-A oil by using a registered agent. This would be especially beneficial to adult patients or guardians for minor patients who may have limited mobility or access to transportation to obtain the THC-A oil in person. Registered agents are only allowed to represent up to two registered patients to prevent substance misuse and must pay a \$25 fee to be registered and to renew their registration each year. So far only one agent has been registered.

The addition of wholesale distribution between pharmaceutical processors would likely benefit them by being able to stock a wider variety of products than they individually manufacture. If pharmaceutical processors agree to specialize in specific THC-A-based products, they could potentially each lower their production costs. The combination of possible higher revenue and lower costs would increase the pharmaceutical processors' expected profit. Since there are only three processors who have received permits so far and none are yet operational, it would not likely be difficult for them to coordinate their production choices and distribution to each other.³

In addition, pharmaceutical processors would benefit from not having to wait until two weeks prior to opening in order to begin cultivation as it would also allow them to start processing the cannabis sooner and build up inventory that can be distributed to the other providers. They also benefit from having greater flexibility in hiring workers with less than two years of experience in horticulture or pharmaceutical extraction, as long as they ensure that these workers are supervised by individuals with either a relevant degree in the field or a certification by the Board or at least two years' experience. Patients may benefit to the extent that wholesale

³ From the Agency Background Document.

distribution provides them access to specific concentrations or products that would not otherwise have been available to them.

Businesses and Other Entities Affected

The proposed amendments would affect the three pharmaceutical processors that have received permits as well as pharmaceutical processors seeking a permit. The proposed amendments also affect registered agents as well as patients or guardians that seek to use a registered agent.

Small Businesses⁴ Affected

All three pharmaceutical processors that have received permits and would benefit from the proposal are small businesses.

Localities⁵ Affected⁶

The proposal does not disproportionately affect any specific localities, nor introduce new costs for local governments.

Projected Impact on Employment

Pharmaceutical processors would have access to a larger labor pool if they are able to hire individuals with less than two years' experience, which would lower the cost of filling vacancies as well as the cost of expanding the scale of their operations. Thus, employment in the cannabis industry could grow to the extent that pharmaceutical processors respond through one or both of these channels.

Effects on the Use and Value of Private Property

As described above, the proposal to allow wholesale distribution may increase the profitability and value of the pharmaceutical processors. The proposal to expand the pool of potential workers by allowing the hiring of individuals with less than two years' experience if they receive specified supervision, may lower labor costs further increasing profitability and firm

⁴ 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."

⁵ "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.

⁶ § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

value. The proposal to allow processors to begin the cultivation of cannabis once their permit is issued without having to wait for two weeks as per current requirement may also increase revenue and value. Real estate development costs are unlikely to be substantively 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 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.