Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes ☐ Not Needed ☒

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).

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: 4695 / 8484
February 20, 2019

Summary of the Proposed Amendments to Regulation

Pursuant to 2016[1] and 2018[2] legislation, the Board of Pharmacy (Board) proposes to establish a permanent regulation, to replace an emergency regulation, governing the cultivation of cannabis for production and sale of cannabidiol (CBD) oil and Tetrahydrocannabinolic acid (THC-A) oil.

Result of Analysis

The benefits likely exceed the costs for all proposed changes. A different design would likely yield improved economic results for at least one proposed change.

Estimated Economic Impact

Legislation enacted in 2016 required the Board to promulgate regulations addressing CBD and THC-A oil, including registration by the Board of practitioners and patients, and the issuance by the Board of permits for pharmaceutical processors to manufacture and provide these oils for the treatment of intractable epilepsy.[3] The statute authorized only neurologists and

[1] http://lis.virginia.gov/cgi-bin/legp604.exe?161+ful+CHAP0577
[2] http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0246 & http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0567
[3] In the statute, cannabidiol oil is defined as processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that

doctors that specialize in treatment of epilepsy to issue written certificates for obtaining these oils.

CBD and THC-A are the two primary cannabinoids that occur naturally in the *Cannabis sativa* plant, most commonly known as cannabis. Both of these substances interact with the cannabinoid receptors found in the human body and brain, and both are minimally psychoactive which means that they do not have an intoxicating effect.[4] While either CBD and THC-A can provide relief from some of the same medical conditions, for some other medical conditions one may be better suited than the other. CBD and THC-A oils are normally administered orally, sublingually via an oral syringe, or in a capsule, but it is possible to inhale via vaping or a nebulizer.

Pursuant to 2016 legislation, the Board established emergency regulations that became effective August 7, 2017.[5] Later, 2018 legislation required the Board to amend its emergency regulations to allow any doctor of medicine or osteopathy to recommend the oils for any diagnosed condition or disease that the doctor believes would benefit from their use. The 2018 legislation also made numerous other amendments to the original statute and required the Board to promulgate additional regulations for other aspects of CBD and THC-A oil production and sale.[6]

Consequently, the Board proposes to establish a permanent comprehensive regulation governing all aspects of these oils (e.g. application; issuance, denial, revocation, suspension of licenses and certifications, their duration, and fees; cultivation; production; packaging; labeling; testing; distribution; dispensing; storage; disposal; safekeeping; reporting; record keeping; training; prohibited practices; etc.) for processors, doctors, employees involved, and patients or their legal guardians.

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contains at least 50 milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol; and THC-A oil is defined as processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

[4] National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research.* National Academies Press (US); 2017 Jan 12.

[5] http://townhall.virginia.gov/l/ViewStage.cfm?stageid=7740

[6] http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0567

The enabling legislation limits the number of permits the Board may issue to "one for each health service area [HSA] established by the Board of Health." Currently there are five HSAs statewide; each HSA covers nine, 26, 27, 32, and 41 localities, respectively.

Pursuant to the emergency regulations, the Board received 51 applications along with a $10,000 fee per application, and issued five permits. These five entities will (per the regulation) pay an initial permit fee of $60,000 and pay an annual renewal fee of $10,000 for each permit. These and other fees would be used to cover the Board's expenses to evaluate applications, issue permits, certificates, conduct inspections, take actions for violations, etc.[7]

Currently, processors are setting up their operations, and CBD and THC-A oil has not yet been sold; the Board expects sales to start sometime in 2019. Statute limits each registered patient to no more than a 90-day supply of CBD or THC-A oil in a 90-day period, and states that "prior to the initial dispensing" of oil pursuant to each written certification, the patient, parent, or legal guardian must present their certification and a current photo identification "at the location of the pharmaceutical processor." Pursuant to § 54.1-3408.3, each such certification expires after one year.

The five processors will be the only entities authorized to produce and sell CBD and THC-A oil products in their assigned HSA. The news media have reported on the locations of four of the five permitted processors, indicating facilities will be opened in Bristol, Staunton, Richmond, and Manassas; the location in the Hampton Roads-based HSA does not appear to be available.[8] According to board staff, registered patients are not restricted to purchasing oils only in their HSA, and may purchase from any processor in the Commonwealth. As a result, it appears that a patient may purchase from the processor that is closest to them, regardless of which HSA they reside in. However, the patient must physically present their photo identification and the renewed certificate annually at the location of each processor they choose to purchase from.

Estimated Economic Impact on Processors

[7] In addition to these permit and renewal fees, the proposed regulation establishes other fees: $100 for change of a processor name or of any other information provided on the application; $1,000 for any acquisition, expansion, remodel, change of location; $1,000 for re-inspection; and $25 for registration of each CBD or THC-A oil product.
[8] Richmond Times-Dispatch, *Virginia regulators pick five companies to open state's first medical cannabis dispensaries*, September 25, 2018.

Under the proposed regulatory design, an economic benefit would accrue to the processors. Even though they would incur costs associated with fees, setting up initial operations, and compliance with health, safety, and security requirements, they would apply for a permit only if they expect benefits would exceed the costs. In fact, because there is very limited competition and no price controls contemplated in the regulation, the permitted processors have the flexibility to set prices to ensure a certain level of revenues. Therefore, the proposed regulation should provide a net benefit to processors.

Under the proposed regulatory design, the only apparent factor that would work to keep prices under control in a given HSA is the option for patients to buy oils from processors in other HSAs. However, depending on the distance patients must travel to the next-closest processor, the transportation costs (including charges associated with use of an authorized delivery agent) may offset any potential savings available from the lower prices offered by another processor. Any such potential savings may be further reduced given the statutory requirements that the maximum amount that can be dispensed (and purchased) at one time is a 90-day supply, and that a patient must present documentation "at the location of the pharmaceutical processor" once each year.

Within the proposed regulation, other factors that may minimize the potential for market competition that could lead to lower prices include the mechanism whereby the incumbent processors may renew their permits annually, for an indefinite period of time, as long as they comply with the regulation. In addition, under the current statutory framework no more than five processors statewide may be permitted. In combination, these factors impact the opportunity for prices to be lowered through competitive forces by limiting the number of new firms that could enter the market.

Estimated Economic Impact on Patients

The proposed regulation would benefit all patients by allowing them to legally purchase CBD or THC-A oil in the Commonwealth. The Board has issued registration cards to 283 patients so far, even though no CBD or THC-A oil is available for sale, and proposes to establish

certain fees for patients.[9] Although the legal access to CBD or THC-A oil is the main benefit, some patients may also have peace of mind from carrying a registration card which may help them avoid potential legal issues that may otherwise result from possession of these oils. Because only those patients who value the access to these oils more than the cost of the fees would obtain a registration card, we can reliably infer that the benefits of registration would exceed the cost of registration for these patients.

However, the ability of some patients to benefit from legal use of these oils, especially patients with lower incomes, may be somewhat limited if prices are higher than would otherwise exist if the market consisted of more than five processors. In addition, the distance between patient's location and the location of the nearest processor may be a limiting factor for their access to the oils, as the patients would have to absorb travel time and costs to purchase the oils or pay a delivery fee. Because the legislation only allows purchases to occur in five locations, it would not be uncommon for many patients to travel more than few hours to get to the nearest processor. Thus, travel costs or delivery fees would add to the price of oils and may limit patient access.

Estimated Economic Impact on Practitioners

Similar to the patients, doctors who decide to obtain registration to recommend CBD or THC-A oils indicate that the benefits of doing so exceed the costs for them. The main benefits to the registered doctors are the potential to expand their customer base through patients who would benefit from these oils, as well as providing more effective treatment for current patients. The proposed regulation limits the number of such patients a doctor may treat to 600 at any given time, but allows the doctor to petition the Board for a higher limit. The proposed regulation also establishes a $50 fee for initial registration, a $50 fee for annual renewal, and $50 for replacement certificate to recommend the oils. According to DHP, there are 230 registered doctors.

Other Estimated Economic Impacts

[9] The board proposes to establish a $50 fee for initial registration of a patient, a $50 fee for annual renewal, a $25 fee for initial registration of a parent or guardian (in the emergency regulation, this fee was $50), a $25 fee for renewal of parent or guardian registration, and a $25 fee for replacement of lost, stolen, destroyed certificates.

The issuance of certificates and permits to patients, doctors, and processors and enforcement of the proposed rules would require additional staff time for the Department of Health Professions (DHP). DHP has already dedicated two employees on a part-time basis to meet the current workload demands, and anticipates that three more full time positions would be needed once the oils are offered for sale. The funding source for the four positions will be the fees collected.

The five localities where the processors will be operating would see a positive impact from this regulation as the processors hire new employees to grow and process the plant and get the final products ready for sale. However, the five localities may also have to deal with attempts to steal these oils or the cannabis plants from the processors or their delivery agents.

Finally, the proposed regulation is expected to reduce crime. The enabling legislation made what used to be a misdemeanor crime a lawful activity, and made the certificate from the Board an affirmative defense against any misdemeanor charge the patient may face for possession of CBD and THC-A oils. As a result, the number of misdemeanor charges and convictions for possession of these oils should decline. A decline in crime would free up the resources required for enforcement, prosecution, and incarceration of a number of cases and reduce the burden on the criminal justice system.

Alternative Regulatory Designs

As discussed above, the proposed regulation would produce a net benefit to processors, patients, and doctors. However, statutory limitations on the number of processors, plus the impact of transportation and other costs, could limit the ability of some patients to benefit from the lower prices that would likely exist in a more competitive market. If changes to this statutory framework were made, alternative regulatory designs could be pursued that could potentially allow patients to more fully realize the benefits resulting from this regulation. These alternatives include either increasing the number of processors, or limiting the number of annual renewals, in order to allow additional processors to enter the market. If either course was chosen, the Board could then request new proposals with a lowest price guarantee (e.g. per ounce of the oils) for the duration of the permit, or with higher permit fees. These alternatives could increase the net benefits to patients by lowering prices or providing revenues that could be used to support compassionate need programs.

Businesses and Entities Affected

This regulation applies to CBD and THC-A oil processors, patients, and doctors. Currently, there are five processors with conditional approval, 283 registered patients, and 230 registered doctors. The number of registered patients and doctors would likely significantly increase when the processors actually start selling CBD or THC-A oils.[10]

Localities Particularly Affected

The proposed regulation would disproportionately affect the five particular localities where the processors are operating. These affected localities would likely see an increase in economic activity stemming from increased employment and business activity by the processors. However, there may also be instances of theft at the processor facilities or from the processor's delivery agents.

Projected Impact on Employment

The proposed regulation would have a positive impact on employment, particularly in the areas where processors operate.

Effects on the Use and Value of Private Property

The proposed regulation would have a large positive impact on the asset value of processors as a result of the potential perpetual price setting power they are granted.

Real Estate Development Costs

Except for potential impacts, near the location of the five processors the proposed amendments would not directly affect real estate development costs.

Small Businesses:

Definition

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."

[10] According to a presentation made to the Board on July 1, 2016, 1% of the population have epilepsy and 1/3 of this population do not respond to currently approved drug therapy, which translates to 27,000 Virginians. Source: http://townhall.virginia.gov/l/GetFile.cfm?File=meeting\30\24620\Minutes_DHP_24620_v3.pdf

Costs and Other Effects

The proposed amendments would not impose costs on small businesses. Whether any of the processors would qualify as a small business is not known. If they would qualify as small businesses, the other effects on them would be the same as the impact on processors described above.

Alternative Method that Minimizes Adverse Impact

The proposed regulation does not impose adverse impacts on small businesses.

Adverse Impacts:

Businesses:

The proposed regulation does not impose adverse impacts on businesses.

Localities:

The proposed regulation may adversely affect particular localities in terms of the increased risk of theft at the processor facilities or from the processor's delivery agents.

Other Entities:

The proposed regulation does not impose adverse impacts on other entities.

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(C): 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.