Office of Regulatory Management

Economic Review Form

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-60
VAC Chapter title(s)	Regulations Governing Pharmaceutical Processors
Action title	Pharmaceutical processor regulation changes pursuant to 2022 legislation
Date this document prepared	September 6, 2022

Cost Benefit Analysis

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if **all** changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

(1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo. One bullet has been provided, add additional bullets as needed.

(2) Quantitative Factors:
   (a) Enter estimated dollar value of total (overall) direct costs described above.
   (b) Enter estimated dollar value of total (overall) direct benefits described above.
   (c) Enter the present value of the direct costs based on the worksheet.
   (d) Enter the present value of the direct benefits based on the worksheet.

(3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.

(4) Net Benefit: Calculate d minus c OR enter it from the worksheet.

(5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.

(6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
(7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

(1) Direct Costs & Benefits	**1. Non-discretionary changes:** • Patient registration with the Board of Pharmacy is no longer required. • Provision of written certifications received by processors to the Board. **2. Hydrocarbon processing changes** • **(A) Allowance for the use of hydrocarbon-based solvents or other flammable solvents in the manufacture of medical cannabis products.** Direct Costs: If a permitted pharmaceutical processor chooses to utilize hydrocarbon-based solvents or other flammable solvents in the manufacture of medical cannabis products, the pharmaceutical processor will incur costs related to obtaining required equipment and use of such equipment in the manufacturing process, if such equipment is not already in place. Direct Benefits: The pharmaceutical processor industry has requested the allowance to manufacture medical cannabis products by utilizing hydrocarbon-based solvents and other flammable solvents. Enactment #2 of HB 933 directed the Board to promulgate regulations to permit such use. This request was based on a desire to provide additional medical cannabis product types at a time and cost savings to the industry. Industry representatives have calculated a potential cost savings of 66% with utilizing hydrocarbon-based solvent manufacturing. Extraction can result in an efficient production of a diversified range of concentrates. Source: Cannabis Business Times • **(B) 18VAC 110-60-281(B)(8) – closed loop extraction system that is commercially manufactured with certification from a licensed engineer.** Direct Costs: If a permitted pharmaceutical processor chooses to utilize hydrocarbon-based solvents or other flammable solvents in the manufacture of medical cannabis products, the pharmaceutical processor will incur costs of $5,000 to $100,000 depending on size

	and capabilities of the apparatus. Source: Cannabis Business Times states online "Apparatus cost: $5,000 to $100,000 depending on size and capabilities." Commercial vendors offer engineer certification. Source: Precision Extraction Solutions states online "The PX1 extractor is pre-approved and ready for professional engineers to field verify in all 50 states, so you can get operational faster. In partnership with PSI (Pressure Safety Inspectors), our extractors come with a PSI technical report certification and a field verification voucher to meet your state and local regulations. Once your system is installed by a Precision Technician, simply call PSI and schedule your field verification." Direct Benefits: Safety and mitigation of risk for public, employees, and building infrastructure. Hydrocarbon solvents such as butane are flammable and can be very dangerous when not used correctly. Source: Precision Extraction Solutions; NIOSH Pocket Guide to Chemical Hazards; Cameo Chemicals • **(C) 18VACV110-60-281(C), (D) & (E) – requirements for industrial hygienist/professional engineer to certify system, recertify for changes, and maintain copies of the reports on-site** Direct Costs: Commercial vendors offer engineer certification. Source: Precision Extraction Solutions states online "The PX1 extractor is pre-approved and ready for professional engineers to field verify in all 50 states, so you can get operational faster. In partnership with PSI (Pressure Safety Inspectors), our extractors come with a PSI technical report certification and a field verification voucher to meet your state and local regulations. Once your system is installed by a Precision Technician, simply call PSI and schedule your field verification." Maintaining resulting reports on-site should be little to no cost. Direct Benefits: Safety and mitigation of risk for public, employees, and building infrastructure. Hydrocarbon solvents such as butane are flammable and can be very dangerous when not used correctly. Source: Precision Extraction Solutions; NIOSH Pocket Guide to Chemical Hazards; Cameo Chemicals. Maintaining resulting reports on-site will eliminate need to obtain reports for board inspection during routine inspections or investigations. **3. Wholesale distribution of bulk cannabis changes** • **(A) Allowance for bulk cannabis oil, botanical cannabis, and usable cannabis that has not been packaged for sale and has not passed the test required in 18VAC110-60-300(G) and (H) and**

	does not bear an appropriate expiration date may be wholesale distributed between pharmaceutical processors. Direct Costs: If a pharmaceutical processor chooses to obtain bulk wholesale distributed cannabis products from another pharmaceutical processor, they will incur costs related to the purchase of those bulk products. Direct Benefits: The pharmaceutical processor industry has requested the ability to wholesale distribute bulk cannabis products as a means of supporting the industry. Enactment # 4 of HB 933 directed the Board to promulgate regulations to permit such activity. • **(B) A pharmaceutical processor wholesale distributing the products listed in (A) above, must create a record of the transaction to include required information listed in 22VAC110-60-251 D and maintain such record for three years.** Direct Costs: The pharmaceutical processor will incur costs related to creating a record of transaction. Direct Benefits: The pharmaceutical processor wholesale distributing bulk products and the pharmaceutical processor receiving the bulk products will be able to maintain a record of the transaction that can be utilized to track any products manufactured as a result of the transaction. This could be critical information if a recall of a product is required. • **(C) The products being wholesale delivered must conform to the labeling requirements listed in 22VAC110-60-295.** Direct Costs: The pharmaceutical processor will incur costs related to packaging and labeling bulk products. Direct Benefits: The pharmaceutical processor wholesale distributing bulk products and the pharmaceutical processor receiving the bulk products will be able to track the products being wholesale distributed and track any products manufactured as a result of the wholesale distribution. This could be critical information if a recall of a product is required. **4. Cannabis products that do not pass the pesticide chemical residue test cannot be remediated.**

	Direct Costs: The pharmaceutical processor must test every cannabis product for pesticide chemical residue so no additional cost is incurred with this change. Direct Benefit: Cannabis products that contain pesticide chemical residue above allowable limits will not enter the medical cannabis market and therefore not cause potential harm to medical cannabis consumers.

(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	1. (a) $0 2(B)(a) $5,000-$100,000 3(A) N/A to be calculated. 3(B) N/A to be calculated. 3(C) Labels may be purchased for as low as $0.02 a piece; packaging for $0.75 a piece. 4. $150 per test.	1. (c) $0 2(B) (c) currently not allowed 3 (A) – (C) currently not allowed 4. $150 per test	
Direct Benefits	1. (b) $50/year for each patient 2. Benefits have been described by the pharmaceutical processors as very beneficial to the companies. Unable to provide dollar amounts for this due to the complexity of the manufacturing process.	1. (d) $50/year for each patient 2. Cannot be done at this time. 3. Cannot be done at this time. 4. $150 per test.	
(3) Benefits-Costs Ratio	1. 0	(4) Net Benefit	1. $50/year for each patient

(5) Indirect Costs & Benefits	1. None
(6) Information Sources	1. Prior to legislative changes made during the 2022 General Assembly Session, patients with written certifications for medical cannabis had to pay $50 per year for access to pharmaceutical processors. Without that requirement, patients are saving $50/year. Processors must provide the Board a copy of the written certifications they receive from patients. However, this is merely providing a PDF scan of these certifications in bulk. There is no cost associated with this.

	3(C): maijanpackaging.com 4. ECC Test Labs
(7) Optional	The majority of the changes made in this action are required by legislation which was put forth on behalf of the pharmaceutical processors. Although the Board attempted to obtain specific cost/benefit information for some of these processes, the Board was not able to translate the information received into a usable format for this form. The processor sources, however, confirmed the overall beneficial nature of these changes to pharmaceutical processor operations in the Commonwealth.

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)
This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.

(1) Direct Costs & Benefits	**1. Non-discretionary changes:** • The Board had no discretion regarding the changes to patient certification and the requirement that processors provide the Board with copies of written certifications received by the processor. **2. Hydrocarbon processing changes** • **(A) Allowance for the use of hydrocarbon-based solvents or other flammable solvents in the manufacture of medical cannabis products.** Direct Costs: Processors may believe they will miss out on an opportunity to produce high THC-concentrated products more efficiently or distinguish their product line from other processors. Those that elected to build their facilities to potentially accommodate this extraction method one day will not see the full return on their investment. If no processor can use hydrocarbon extraction, then the competitive need to incur the cost will be eliminated. • **(B) 18VAC 110-60-281(B)(8) – closed loop extraction system that is commercially manufactured with certification from a licensed engineer.** Direct Costs: If the facility uses hydrocarbon and other flammable solvents without a commercially manufactured closed loop extraction system, certified by a licensed engineer, harm may result

	to the employees, patients, and the building. Specifically, these solvents are extremely flammable, with a low flashpoint, and could result in catastrophic explosions. Direct Benefits: The facility would not incur the costs of obtaining commercial-grade, certified equipment. • **(C) 18VACV110-60-281(C), (D) & (E) – requirements for industrial hygienist/professional engineer to certify system, recertify for changes, and maintain copies of the reports on-site** Direct Costs: If the facility uses flammable solvents without industrial hygienist/professional engineer certification and recertification for changes, harm may result to the employees, patients, and the building if equipment has not been installed correctly. Direct Benefits: The facility would not incur the costs of paying an industrial hygienist or professional engineer for certifying services. **3. Wholesale distribution of bulk cannabis changes** • **(A) Allowance for bulk cannabis oil, botanical cannabis, and usable cannabis that has not been packaged for sale and has not passed the test required in 18VAC110-60-300(G) and (H) and does not bear an appropriate expiration date may be wholesale distributed between pharmaceutical processors.** Direct Costs: No costs would be incurred by the pharmaceutical processor. Direct Benefits: The pharmaceutical processors would not be allowed to engage in the wholesale distribution of bulk cannabis products, so no direct benefits would exist. The pharmaceutical processor industry has requested the ability to wholesale distribute bulk cannabis products as a means of supporting the industry. Enactment # 4 of HB 933 directed the Board to promulgate regulations to permit such activity. • **(B) A pharmaceutical processor wholesale distributing the products listed in (A) above, must create a record of the transaction to include required information listed in 22VAC110-60-251 D and maintain such record for three years.** Direct Costs: The pharmaceutical processor would not incur costs related to creating a record of transaction.

Direct Benefits: There are no direct benefits. However, without maintaining a record of the transactions between pharmaceutical processors, the industry would be unable to track product material origination in the case of the need for a product recall. Medical cannabis patients could be harmed as a result.

- **(C) The products being wholesale delivered must conform to the labeling requirements listed in 22VAC110-60-295.**

Direct Costs: The pharmaceutical processor would not incur costs related to packaging and labeling bulk products.

Direct Benefits: Without appropriate labeling, the industry would not be able to track product material origination and would be unable to identify product contamination sources in the event of a product recall. This could lead to medical cannabis patients being harmed by contaminated products.

4. Cannabis products that do not pass the pesticide chemical residue test cannot be remediated.

Direct Costs: The pharmaceutical processor must test every cannabis product for pesticide chemical residue so no additional cost is incurred with this change.

Direct Benefit: There are no direct benefits. Allowing cannabis products to enter the market that are contaminated with pesticides above allowable limits could cause potential harm to medical cannabis consumers.

(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			

(6) Information Sources	
(7) Optional	Similar to the previous table, the Board obtained some information from pharmaceutical processors about these changes and the monetary impact of the regulatory changes on the regulated community. The Board was not able to obtain information appropriate to this chart, however. The Board notes that the regulated community requested these changes to allow permitted entities to make beneficial business and operational changes.

Table 1c: Costs and Benefits under an Alternative Approach

This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.

(1) Direct Costs & Benefits	**1. Non-discretionary changes:** • The Board had no discretion regarding the changes to patient certification and the requirement that processors provide the Board with copies of written certifications received by the processor. **2. Other changes on this table:** • No alternative approaches were available to changing the regulations.		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			
(6) Information Sources			

(7) Optional	

Impact on Local Partners

(1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
(2) Quantitative Factors:
  (a) Enter estimated dollar value of total (overall) direct costs described above.
  (b) Enter estimated dollar value of total (overall) direct benefits described above.
(3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.
(4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
(5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
(6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	No impacts on local partners for any changes described in this form.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	
(4) Information Sources	

(5) Assistance	
(6) Optional	

Economic Impacts on Families

(1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
(2) Quantitative Factors:
  (a) Enter estimated dollar value of direct costs.
  (b) Enter estimated dollar value of direct benefits.
(3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
(4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
(5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 3: Impact on Families

(1) Direct Costs & Benefits	No impact on families.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	

(4) Information Sources	
(5) Optional	

Impacts on Small Businesses

(1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, "small business" means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
(2) Quantitative Factors:
  (a) Enter estimated dollar value of direct costs.
  (b) Enter estimated dollar value of direct benefits.
(3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.
(4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
(5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
(6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	These changes do not impact small businesses as defined in Virginia Code § 2.2-4007.1
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	

(4) Alternatives	
(5) Information Sources	
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	**Initial Count**	**Additions**	**Subtractions**	**Net Change**
110-60	360*	20	3	+17

* These numbers are not final and should be viewed as interim.