

Office of Regulatory Management
Economic Review Form

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20; 18VAC110-21
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy; Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Initiation of Treatment by Pharmacists
Date this document prepared	October 12, 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	<ul style="list-style-type: none"> • The majority of these changes were mandated as emergency and then permanent regulations by Ch. 731 of the 2020 Acts of Assembly. • Changes to 18VAC110-21-46 include a requirement to notify a patient’s primary health care provider that treatment has been initiated or a drug or device dispensed to the patient as long as the patient consents to notification. The notification is required by statute and should have no cost associated with it. • Additional changes state that a pharmacist must counsel certain patients regarding preventative care and offer lists of providers if asked. Both of these requirements are already part of other pharmacy requirements and do not have a cost associated with them. • One deviation from the enacting legislation is the change to 18VAC110-20-150, which requires that the physical setting in which a pharmacist initiates treatment, dispenses, or administers drugs protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d <i>et seq.</i> No specific requirements were dictated, and pharmacies are already subject to HIPAA standards, so there should not be a cost associated with this requirement. It was put in place by the Board for patient safety. • Additionally, the Board added record retention requirements to 18VAC110-21-46. These requirements mirror regulations of the Board of Medicine with regard to patient records. <i>See</i> 18VAC85-20-26(D). This may have some record retention costs associated with it, but pharmacies are already required to keep fairly extensive patient records for dispensed medications. 	
(2) Quantitative Factors	Estimated Dollar Amount	Present Value
Direct Costs	(a) \$0	(c) \$0
Direct Benefits	(b) \$0	(d) \$0

(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			
(6) Information Sources			
(7) Optional			

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	<ul style="list-style-type: none"> The Board has no option to leave the regulations as they were prior to the 2020 legislation. 		
(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			

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	• No alternative approach available.		
(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	None
(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	May reduce cost of healthcare for families.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) <u>Possible</u> benefits are approximately \$80/year
(3) Indirect Costs & Benefits	\$0
(4) Information Sources	Assumed \$20 co-pay for healthcare services provided by a pharmacist initiating treatment. Currently there is no co-pay model for providing these services. The pharmacy/pharmacist bills insurance for the provision of drugs and devices, not for the clinical services being provided (which is billed to insurance for doctor’s office visits).
(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	Some possible benefit to small businesses because independently-owned pharmacies could provide these services to patients for cash payments. However this would be decided by the individual pharmacy and there is no way to predict what the cash amount would be as it would not be tied to anything tangible.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) Unable to determine.
(3) Indirect Costs & Benefits	Unable to determine.
(4) Alternatives	No alternative due to statutory requirement.
(5) Information Sources	Legislative and regulatory language. Discussion with Executive Director of the Board of Pharmacy regarding potential cash payments to independent pharmacies for services.
(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
18VAC110-20	81*	1	0	+1
18VAC110-21	48*	1	0	+1

*These numbers are rough counts and should not be considered final.