

Office of Regulatory Management
Economic Review Form

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter and Guidance Document citation(s)	18VAC110 110-38
Guidance Document title(s)	Requirement for Non-resident Pharmacies to Submit Inspection Report
Action title	Amendment of Guidance Document 110-38 to incorporate resident outsourcing facilities and provide for additional options for facility inspections
Date this document prepared	4/3/2025
Regulatory Stage (including Issuance of Guidance Documents)	Amend

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	The amendments in this guidance document allow more flexibility for inspections of non-resident pharmacies by entities other than the FDA, which is important as the FDA is extremely behind on inspections. The Board has recently approved an organization who specializes in inspections to perform inspections in addition to other organizations, and that change is indicated in this document. Additionally, general cleanup was performed in this document, including eliminating Code language, unnecessary language, and including links to relevant Code sections. This action has no direct or indirect costs or benefits.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources		

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no status quo to consider.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources		

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no alternative approach to consider.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources		

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on local partners.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(4) Assistance		

(5) Information Sources	
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Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on families.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	
(4) Information Sources		

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	There is no impact on small businesses.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Other Costs & Benefits (Non-Monetized)	N/A	

(4) Alternatives	
(5) Information Sources	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
	(M/A):				
	(D/A):				
	(M/R):				
	(D/R):				
Grand Total of Changes in Requirements:					(M/A):
					(D/A):
					(M/R):
					(D/R):

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count
110-38	575	450	-125

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).