

Office of Regulatory Management  
Economic Review Form

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) Chapter/Guidance Document citation(s)</b>	18VAC110 110-9
<b>Guidance Document title(s)</b>	Pharmacy Inspection Deficiency Monetary Penalty Guide
<b>Action title</b>	Additional changes to Guidance Document 110-9 to capture changes to USP
<b>Date this document prepared</b>	12/26/2023
<b>Regulatory Stage (including Issuance of Guidance Documents)</b>	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)	This change was initiated to correct a technical discrepancy between GD 110-9 and the US Pharmacology guidance for compounding. This action simply aligns Virginia’s guidance with federal guidance and contains 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 as Virginia guidance would be at odds with Federal guidance, which would be problematic.	
(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. The only way to amend a guidance document is through board action.	
(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		

**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	
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**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*

<b>VAC Section(s) Involved</b>	<b>Initial Count</b>	<b>Additions</b>	<b>Subtractions</b>	<b>Net Change</b>

*Cost Reductions or Increases (if applicable)*

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

*Other Decreases or Increases in Regulatory Stringency (if applicable)*

<b>VAC Section(s) Involved</b>	<b>Description of Regulatory Change</b>	<b>Overview of How It Reduces or Increases Regulatory Burden</b>

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

<b>Title of Guidance Document</b>	<b>Original Length</b>	<b>New Length</b>	<b>Net Change in Length</b>
110-9	17 pages	17 pages	No change