

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 18VAC110-30 18VAC110-50
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians Regulations for Practitioners of the Healing Arts to Sell Controlled Substances Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen
Action title	Increase in fees
Date this document prepared	7/16/2024
Regulatory Stage (including Issuance of Guidance Documents)	Proposed

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)

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p>As extensively described during the NOIRA stage of review, the Board of Pharmacy is raising fees as the current projections by our finance department indicate that current revenue will not be enough to cover costs and the board cash balance will fall into the negative. As a recap of the previous stage’s information, below are included FY2023, 2026 and 2027 estimated revenue and expenses, largest expenditures for the board, and major factors in expenditure increases. Additional information on these fee increases was supplied during the NOIRA stage.</p> <p>Annual revenue for the Board: FY2023: \$4,972,756 FY2026 Estimate: \$5,346,940 FY2027 Estimate: \$5,489,832</p> <p>Annual expenditures for the Board: FY2023: \$5,198,421 FY2026 Estimate: \$6,469,085 FY2027 Estimate: \$6,727,849</p> <p>Projected cash balance without fee increase: FY2023: \$2,270,363 FY2026 Estimate: (\$688,083) FY2027 Estimate: (\$1,926,100)</p> <p><u>Largest expenditures for the Board of Pharmacy</u></p> <table border="1"> <thead> <tr> <th></th> <th>FY18 Actual</th> <th>FY19 Actual</th> <th>FY20 Actual</th> <th>FY21 Actual</th> <th>FY22 Actual</th> <th>FY23 Actual</th> <th>FY24 Budget</th> </tr> </thead> <tbody> <tr> <td>Direct salaries and benefits: Board of Pharmacy</td> <td>958,311</td> <td>994,313</td> <td>1,207,975</td> <td>1,237,879</td> <td>1,320,886</td> <td>1,442,447</td> <td>1,698,380</td> </tr> <tr> <td>Enforcement expenditures including ENF salaries and benefits</td> <td>1,227,167</td> <td>1,308,835</td> <td>1,336,561</td> <td>1,108,346</td> <td>1,632,666</td> <td>1,800,378</td> <td>1,967,727</td> </tr> <tr> <td>IT, including IT salaries and benefits</td> <td>415,017</td> <td>528,094</td> <td>414,214</td> <td>337,851</td> <td>439,940</td> <td>534,539</td> <td>567,345</td> </tr> <tr> <td>All else</td> <td>1,114,363</td> <td>1,040,162</td> <td>1,011,845</td> <td>1,035,005</td> <td>1,245,210</td> <td>1,421,057</td> <td>1,668,001</td> </tr> </tbody> </table>								FY18 Actual	FY19 Actual	FY20 Actual	FY21 Actual	FY22 Actual	FY23 Actual	FY24 Budget	Direct salaries and benefits: Board of Pharmacy	958,311	994,313	1,207,975	1,237,879	1,320,886	1,442,447	1,698,380	Enforcement expenditures including ENF salaries and benefits	1,227,167	1,308,835	1,336,561	1,108,346	1,632,666	1,800,378	1,967,727	IT, including IT salaries and benefits	415,017	528,094	414,214	337,851	439,940	534,539	567,345	All else	1,114,363	1,040,162	1,011,845	1,035,005	1,245,210	1,421,057	1,668,001
	FY18 Actual	FY19 Actual	FY20 Actual	FY21 Actual	FY22 Actual	FY23 Actual	FY24 Budget																																								
Direct salaries and benefits: Board of Pharmacy	958,311	994,313	1,207,975	1,237,879	1,320,886	1,442,447	1,698,380																																								
Enforcement expenditures including ENF salaries and benefits	1,227,167	1,308,835	1,336,561	1,108,346	1,632,666	1,800,378	1,967,727																																								
IT, including IT salaries and benefits	415,017	528,094	414,214	337,851	439,940	534,539	567,345																																								
All else	1,114,363	1,040,162	1,011,845	1,035,005	1,245,210	1,421,057	1,668,001																																								

Total expenditure for Board	3,714,858	3,871,405	3,970,595	3,715,082	4,638,702	5,198,421	5,901,453
<u>Major factors in expenditure increases</u>							
Approximate %	Description						
30-35%	<ul style="list-style-type: none"> • Salary increases • Compounded increases from 2020 – 2025 (projected): 5% in 2020; 5% in 2021; 5% in 2022; 5% in mid-2023 and another 2% compounded later in the year; 3% in 2024 and/or 2025, <i>projected</i> 						
17%	<ul style="list-style-type: none"> • Hiring; increase in programs, disciplinary cases, licensee counts (e.g., zero pharmacy technician trainee registrants in 2021; 8,053 in 2024) required additional staff • Note: new hires also received salary increases, so original cost for FTEs increased 						
Unknown	<ul style="list-style-type: none"> • IT costs. Boards and agency have gone paperless for disciplinary cases • Huge shift in technology to cloud • Cases are confidential, contain medical information, can be very large, and often have particular information such as x-rays • Cannot PDF, must have specialized system • Costs cannot be differentiated from standard IT costs • IT costs have also increased due to salaries – any state employees received the same salary increases and therefore the IT department simply costs more to employ the same number of people 						
28%	<ul style="list-style-type: none"> • Increase in disciplinary cases at Board level • Requires numerous other costs that are not related to Pharmacy FTEs <ul style="list-style-type: none"> ○ OAG cost for both Board counsel and prosecutor (note: OAG salaries increased as well, both by GA action and within the OAG, and charges to agencies have increased accordingly) ○ Per diem for Board members ○ Rental of hearing space ○ Court reporters 						

	<ul style="list-style-type: none"> ○ Food for participants (hearings are extremely long) 																
23%	<ul style="list-style-type: none"> • Increase in total number of licensees from Q4 FY18 – Q4 FY23 • 36,967 – 45,486 																
<p>The Board considered information regarding inspection costs and licensing fees relative to neighboring states, included below:</p>																	
<table border="1"> <thead> <tr> <th>Type of Inspection</th> <th>Hours to Perform (includes travel)</th> <th>Cost Allocated to Board from Enforcement</th> <th>Fee Paid by Permit Holder</th> </tr> </thead> <tbody> <tr> <td>New, COL, Remodel</td> <td>3.19</td> <td>\$679</td> <td>New: \$500 COL/Remodel: \$300</td> </tr> <tr> <td>Routine, no compounding (performed approximately every 2 years)</td> <td>3.88</td> <td>\$826</td> <td>Annual Renewal: \$350</td> </tr> <tr> <td>Routine, sterile compounding (performed approximately every 2 years)</td> <td>11.76</td> <td>\$2,504</td> <td>Annual Renewal: \$350</td> </tr> </tbody> </table>		Type of Inspection	Hours to Perform (includes travel)	Cost Allocated to Board from Enforcement	Fee Paid by Permit Holder	New, COL, Remodel	3.19	\$679	New: \$500 COL/Remodel: \$300	Routine, no compounding (performed approximately every 2 years)	3.88	\$826	Annual Renewal: \$350	Routine, sterile compounding (performed approximately every 2 years)	11.76	\$2,504	Annual Renewal: \$350
Type of Inspection	Hours to Perform (includes travel)	Cost Allocated to Board from Enforcement	Fee Paid by Permit Holder														
New, COL, Remodel	3.19	\$679	New: \$500 COL/Remodel: \$300														
Routine, no compounding (performed approximately every 2 years)	3.88	\$826	Annual Renewal: \$350														
Routine, sterile compounding (performed approximately every 2 years)	11.76	\$2,504	Annual Renewal: \$350														

License Type	2017 VA Initial/Renewal Fee	Current VA Initial/Renewal Fee	2017 DE Initial/Renewal Fee	Current NC Initial/Renewal Fee	Currently Proposed TN Initial/Renewal Fee	Current WV Initial/Renewal Fee	Current MD Initial/Renewal Fee
Pharmacy	270/270	500/350	318/318	500/200	490/490 (up from 340). Sterile modifier renewal fee 400	150 initial + 10 CS/200 renewal +20 CS; Sterile compounding fee 150 initial/200 renewal; Nuclear pharmacy 150 initial/200 renewal; Mail order 500/1,000	700/500
Medical Equipment Supplier	180/180	235/235	318/318	500/200	525-535/		
Controlled Substances Registration	90/90	120/120			researcher renewal 200 (up from 110)	25-50/50-100	
Third-Party Logistics Providers	270/270	350/350		700/700		750/1500	
Non-restricted Manufacturer	270/270	350/350	709/709	1000/1000	740 (up from 565)/740. Sterile modifier fee 400	500/1000	1,750/1,750
Restricted Manufacturer	180/180	235/235					
Outsourcing Facility					Sterile Modifier Fee 400		
Warehouser	270/270	350/350			535/		
Wholesale Distributor	270/270	350/350	709/709	700/700	740 (up from 575)/740. Sterile modifier fee 400	750/1500	1,750/1,750
Pharmacists	180/90 active/45 inactive	235/120 active/60 inactive	163/163	200/135/ without examination 600	250 by exam (up from 225)/ 265	130 by exam; 255 score transfer, reciprocity, foreign grad/ 120 (biennial). Immunization initial 20/ 20 renewal. Pharmacist consultant 20/20	150/261
Pharmacy Technicians	25/25	35/35		30/30	65/100	25/30 (biennial)	45/45

Percentage Increase in Fees

As voted on by the Board, increases in fees vary depending on the entity. Generally speaking, fees on the individual licensees (pharmacists, pharmacy technicians, etc.) are being increased at a lower rate than pharmacy establishments (which average 50% increase) and wholesale distributors (which average close to 100%). This is to address inspections as one of the driving cost considerations. Complete fee changes are impractical to include in this brief form but will be communicated as part of this action in the Agency Background Document and in the proposed language on TownHall.

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Fees are set to be raised an average of 50% although facilities and distributors will be raised more and individual licenses will be raised less	(b) Allowing the board to cover its costs and stay out of the red, which will keep the board from having to obtain an emergency treasury loan and causing more financial hardship on the practitioners the board regulates
(3) Net Monetized Benefit	Positive; Keeping the board afloat financially will allow our licensing and discipline processes to continue operating and will result in the advancement of a safe and competent healthcare workforce being present in Virginia	
(4) Other Costs & Benefits (Non-Monetized)	Increased healthcare safety in the Commonwealth. Preventing a delay in licensing that will occur if the board runs out of money, which would go against a stated goal of the Governor.	
(5) Information Sources	Previously provided information, internal discussions with Finance on fee increase action	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	The Board of Pharmacy would be unable to cover its costs and would need to take out an emergency treasury loan, which will only require greater fee increases to pay that loan back with interest as required and cover board costs. This has the potential to affect all of DHP as well as Pharmacy is one of the larger boards and a financial strain there could ripple into the rest of the department.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Incalculable, but significant	(b) None
(3) Net Monetized Benefit	Extreme negative	
(4) Other Costs & Benefits (Non-Monetized)	Agency may function at a reduced capacity until an emergency treasury loan that would be taken out, depending on timing.	
(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 fees 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)	Families who include a practitioner regulated by the Board of Pharmacy would be required to pay a higher fee, however this fee increase is not likely to meaningfully impact their livelihood.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Varies depending on license type, but compared to expected salary of practice type should be minor	(b) Keeping the board afloat
(3) Other Costs & Benefits (Non-Monetized)	Net positive	
(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)	Because some pharmacies are independent or are small businesses, they will be impacted by the increased fees. The severity of impact will depend on the financial situation of each pharmacy however it's not expected to contribute to serious financial issues to the individual pharmacies. A far greater harm to these businesses would be the Board ceasing operations due to a lack of funds.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) Between 50%-100% increase in pharmacy establishment fees	(b) Continued board operation and regulation to ensure patient safety and establishment quality
(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
18VAC110-20	(M/A):				
18VAC110-21	(D/A):				
18VAC110-30	(M/R):				
18VAC110-50	(D/R):	1346	0	0	0
Grand Total of Changes in Requirements:					(M/A):
					(D/A):
					(M/R):
					(D/R): 1346

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
All above	Increase in fees	Current fees	Average increase of 50% needed to keep Board afloat	Average cost per regulated entity of 50% increase to current fee

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

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