



Virginia Department of Planning and Budget **Economic Impact Analysis**

18 VAC 110-20 Regulations Governing the Practice of Pharmacy

18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians

18 VAC 110-30 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

18 VAC 110-50 Regulations Governing the Licensure of Advanced Practice Registered Nurses

18 VAC 90-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen

Town Hall Action/Stage: 6327/10369

October 10, 2024

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented below represents DPB’s best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) is proposing to amend six regulations to increase fees for its licensed professions in order to comply with Virginia Code § 54.1-113 B (the Callahan Act).²

Background

The Callahan Act requires the Department of Health Professions (DHP) and its boards to revise fees in situations in which “expenses allocated to [the board] for the past biennium...[are]

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

² See <https://law.lis.virginia.gov/vacode/title54.1/chapter1/section54.1-113/>.

more than ten percent greater or less than moneys collected on behalf of the board.”³ DHP reports that over the 2022-2024 biennium, the Board’s total expenditures were \$11,096,178 and total revenues were \$10,016,277. Since the expenses exceed the revenues by 11 percent, these numbers would appear to satisfy the requirements of the Callahan Act, suggesting that a fee increase is necessary. DHP also reports that the Board is not currently in a deficit, with a cash balance of \$1,714,255 at the end of FY 2024. However, the Board is projected to have a deficit of roughly \$1.05 million by the end of FY 2026.⁴

DHP reports that the fees for this Board were last increased in 2020⁵ and that the Board had instituted one-time fee reductions three times prior to the 2020 increase.⁶ DHP reports that since the 2020 fee increase, the Board has experienced several increases that drove up costs. Namely, increases in salaries (enacted by the General Assembly), the number of disciplinary cases and related workload, and the number of regulated entities. Regarding the latter, in 2019, the Board began registering nonresident third-party logistics providers, nonresident warehouse, and limited-use physician selling drugs; and in 2021, the Board began registering pharmacy technician trainees.

To prevent the anticipated deficit, the Board proposes to increase fees for most categories of practitioners and programs by 45-50 percent. DHP reports that although the bulk of Board funding is provided by renewal fees of individual licensees, such as pharmacists, the Board has made a concerted effort to ensure that the majority of the proposed increases are borne by entities and facilities rather than individual practitioners. This unequal application of the required fee increase is also intended to address the cost of facility inspections, which is currently higher than the initial permitting, renewal, or reinspection fees applied to those facilities. Lastly, the Board proposes to add a new sterile compounding fee for pharmacies and nonresident pharmacies where sterile compounding is done. DHP reports that these inspections cost roughly \$2,374 every two years and are essential to protect public safety because the process is inherently risky. The proposed fee increases, which are listed in the following table, are expected to generate

³ It should be noted that the Callahan Act does not specify whether “moneys collected on behalf of the board” refers only to the revenues in the immediately preceding biennium or if it also includes the cash balance from the biennium prior to that.

⁴ See page 3 of the Agency Background Document (ABD) https://townhall.virginia.gov/L/GetFile.cfm?File=30\6327\10369\AgencyStatement_DHP_10369_v3.pdf.

⁵ See <https://townhall.virginia.gov/L/ViewAction.cfm?actionid=4938>.

⁶ See <https://townhall.virginia.gov/L/ViewAction.cfm?actionid=4772>.

approximately \$2.4 million in additional revenue per year.⁷ Lastly, fees associated with pharmacy technician training programs would be eliminated due to statutory changes that removed the Board's authority to approve such programs.

FEE TYPE	CURRENT FEE	PROPOSED FEE	DOLLAR CHANGE	PERCENTAGE CHANGE
<i>Pharmacy, 18 VAC 110-20</i>				
<i>Initial application fees:</i>				
Pharmacy permit	\$500	\$700	\$200	40.00 %
Physician licensed to dispense drugs	\$500	\$700	\$200	40.00 %
Medical equipment supplier permit	\$235	\$350	\$115	48.94 %
Outsourcing facility permit	\$350	\$900	\$550	157.14 %
Nonresident pharmacy registration	\$350	\$700	\$350	100.00 %
Nonresident outsourcing facility registration	\$350	\$900	\$550	157.14 %
Controlled substances registration	\$120	\$180	\$60	50.00 %
Pilot program approval	\$325	\$415	\$90	27.69 %
Repackaging training program approval	\$65	\$85	\$20	30.77 %
Sterile compounding	\$0	\$200	\$200	N/A
<i>Annual renewal fees:</i>				
Pharmacy permit	\$350	\$490	\$140	40.00 %
Physician licensed to dispense drugs	\$350	\$490	\$140	40.00 %
Medical equipment supplier permit	\$235	\$350	\$115	48.94 %
Outsourcing facility permit	\$350	\$1,100	\$750	214.29%
Nonresident pharmacy registration	\$350	\$490	\$140	40.00 %
Nonresident outsourcing facility registration	\$350	\$1,100	\$750	214.29%
Controlled substances registration	\$120	\$180	\$60	50.00 %
Innovative pilot program	\$260	\$375	\$115	44.23 %
Repackaging training program	\$20	\$25	\$5	25.00 %
Sterile compounding	\$0	\$400	\$400	N/A
<i>Reinstatement fees:</i>				
Pharmacy permit	\$315	\$440	\$125	39.68 %

⁷ Pages 8-20 of the ABD contain detailed explanations for each fee change.

Physician licensed to dispense drugs	\$315	\$440	\$125	39.68 %
Medical equipment supplier permit	\$275	\$385	\$110	40.00 %
Outsourcing facility permit	\$315	\$500	\$185	58.73 %
Nonresident pharmacy registration	\$150	\$440	\$290	193.33 %
Nonresident outsourcing facility registration	\$315	\$500	\$185	58.73 %
Controlled substances registration	\$235	\$350	\$115	48.94 %
Repackaging training program	\$65	\$85	\$20	30.77 %
<i>Other fees:</i>				
Change of Pharmacist-in-Charge	\$65	\$125	\$60	92.31 %
Change of ownership	\$65	\$125	\$60	92.31 %
Inspection for remodeling or change of location for any facility	\$300	\$435	\$135	45.00 %
Reinspection	\$300	\$435	\$135	45.00 %
Inspection of pilot location	\$300	\$435	\$135	45.00 %
Change of pharmacist responsible for approved pilot	\$35	\$150	\$115	328.57 %
Duplicate permit or registration	\$15	\$20	\$5	33.33 %
<i>Licensure of Pharmacists and Registration of Pharmacy Technicians, 18 VAC 110-21</i>				
<i>Initial application fees:</i>				
Pharmacist license	\$235	\$300	\$65	27.66 %
Pharmacy intern registration	\$20	\$30	\$10	50.00 %
Pharmacy technician trainee registration	\$20	\$30	\$10	50.00 %
Pharmacy technician registration	\$35	\$40	\$5	14.29 %
Approval of CE program	\$130	\$190	\$60	46.15 %
<i>Annual renewal fees:</i>				
Pharmacist active license	\$120	\$175	\$55	45.83 %
Pharmacist inactive license	\$60	\$95	\$35	58.33 %
Pharmacy technician	\$35	\$45	\$10	28.57 %
<i>Reinstatement fees:</i>				
Pharmacist	\$275	\$300	\$25	9.09 %
Pharmacist after revocation/suspension	\$650	\$750	\$100	15.38 %
Pharmacy technician registration	\$45	\$50	\$5	11.11 %
Pharm tech trainee or pharm tech after revocation/suspension	\$165	\$200	\$35	21.21 %
Pharmacy technician trainee registration	\$0	\$25	\$25	N/A
<i>Other fees:</i>				
Duplicate license or registration	\$15	\$20	\$5	33.33 %

<i>Practitioners of the Healing Arts to Sell Controlled Substances, 18 VAC 110-30</i>				
<i>Initial application fees:</i>				
Individual license	\$235	\$300	\$65	27.66 %
Location permit	\$315	\$700	\$385	122.22 %
<i>Annual renewal fees:</i>				
Individual license	\$120	\$175	\$55	45.83 %
Location permit	\$315	\$490	\$175	55.56 %
<i>Late fees:</i>				
Location permit	\$50	\$120	\$70	140 %
<i>Reinstatement fees:</i>				
Individual license	\$195	\$300	\$105	53.85 %
Location permit	\$315	\$415	\$100	31.75 %
Individual license following revocation or suspension	\$650	\$750	\$100	15.38 %
Facility reinspection	\$300	\$435	\$135	45.00 %
<i>Wholesale Distributors, Manufacturers and Warehouseurs, 18 VAC 110-50</i>				
<i>Initial application fees:</i>				
Nonrestricted manufacturer permit	\$350	\$1,000	\$650	185.71 %
Restricted manufacturer permit	\$235	\$850	\$615	261.70 %
Wholesale distributor license	\$350	\$750	\$400	114.29 %
Warehouser permit	\$350	\$510	\$160	45.71 %
Nonresident wholesale distributor registration	\$350	\$750	\$400	114.29 %
Controlled substances registration	\$120	\$180	\$60	50.00 %
Third-party logistics provider permit	\$350	\$750	\$400	114.29 %
Nonresident manufacturer registration	\$350	\$1,000	\$650	185.71 %
Nonresident warehouser registration	\$350	\$510	\$160	45.71 %
Nonresident third-party logistics provider	\$350	\$750	\$400	114.29 %
<i>Annual renewal fees:</i>				
Nonrestricted manufacturer permit	\$350	\$1,000	\$650	185.71 %
Restricted manufacturer permit	\$235	\$850	\$615	261.70 %
Wholesale distributor license	\$350	\$1,000	\$650	185.71 %
Warehouser permit	\$350	\$750	\$400	114.29 %
Nonresident wholesale distributor registration	\$350	\$510	\$160	45.71 %
Controlled substances registration	\$350	\$510	\$160	45.71 %
Third-party logistics provider permit	\$350	\$750	\$400	114.29 %

Nonresident manufacturer registration	\$120	\$180	\$60	50.00 %
Nonresident warehouser registration	\$350	\$750	\$400	114.29 %
Nonresident third-party logistics provider	\$350	\$750	\$400	114.29 %
<i>Reinstatement fees:</i>				
Nonrestricted manufacturer permit	\$315	\$440	\$125	39.68 %
Restricted manufacturer permit	\$275	\$385	\$110	40.00 %
Wholesale distributor license	\$315	\$440	\$125	39.68 %
Warehouser permit	\$315	\$440	\$125	39.68 %
Nonresident wholesale distributor registration	\$315	\$440	\$125	39.68 %
Controlled substances registration	\$235	\$300	\$65	27.66 %
Third-party logistics provider permit	\$315	\$440	\$125	39.68 %
Nonresident manufacturer registration	\$315	\$440	\$125	39.68 %
Nonresident warehouser registration	\$315	\$440	\$125	39.68 %
Nonresident third-party logistics provider	\$315	\$440	\$125	39.68 %
<i>Other fees:</i>				
Reinspection	\$300	\$435	\$135	45.00 %
Inspection for change of location, structural changes, security system changes	\$300	\$435	\$135	45.00 %
Change of ownership	\$65	\$125	\$60	92.31 %
Change of responsible party	\$65	\$125	\$60	92.31 %

Estimated Benefits and Costs

The proposed fee increases would increase costs for pharmacists, pharmacy interns, pharmacy technicians, pharmacy technician trainees, and physicians selling controlled substances, as well as for owners of pharmacies, medical equipment suppliers, manufacturers, wholesalers, distributors, logistics providers, outsourcing facilities, and continuing education providers. The increased fees would allow the Board to remain financially solvent and continue to provide oversight for pharmacy professionals and related facilities, including issuing licenses, conducting inspections, investigating complaints, and implementing any disciplinary actions. This in turn would maintain public confidence in these professionals and entities and protect

public safety from unscrupulous actors and inadvertent errors in the supply chain for regulated pharmaceutical products.

Businesses and Other Entities Affected

As mentioned previously, the proposed fee increases would increase costs for current and prospective pharmacists, pharmacy interns, pharmacy technicians, pharmacy technician trainees, and physicians selling controlled substances, as well as for owners of pharmacies, medical equipment suppliers, manufacturers, wholesalers, distributors, logistics providers, outsourcing facilities, and continuing education providers. The following table provides the numbers of each category of professionals and entities licensed or permitted by the Board at the close of FY 2024.⁸

<i>Individuals</i>	Count
Pharmacist	16,357
Pharmacy intern	1,125
Pharmacy technician	12,807
Pharmacy technician trainee	8,014
Physician selling controlled substances	559
<i>Entities/Programs</i>	
Pharmacy	1,737
Non-resident pharmacy	962
Medical equipment supplier	212
Non-resident medical equipment supplier	367
Physician selling drugs location	129
Pilot programs	18
Repackaging training programs	1
Continuing education courses	9
Entities with controlled substances registration	1,498
Outsourcing facility	1
Non-resident outsourcing facility	33
Restricted manufacturer	32
Non-restricted manufacturer	34
Non-resident manufacturer	232
Third party logistics provider	5
Non-resident third party logistics provider	241
Warehouser	128
Non-resident warehouser	142
Wholesale distributor	62
Non-resident wholesale distributor	624

⁸ Source: DHP. See <https://www.dhp.virginia.gov/about/stats/2024Q4/04CurrentLicenseCountQ4FY2024.pdf>.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁹ An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.¹⁰ Since the proposed amendments would increase costs, an adverse impact is indicated for the various pharmacy professionals and entities listed above that would face higher fees.

Small Businesses¹¹ Affected:¹²

Types and Estimated Number of Small Businesses Affected

DHP does not collect data on the number of affected small businesses. However, some independent pharmacies that are not part of national retail pharmacy or grocery chains and continuing education providers are likely small businesses. Other business entities that are part of the supply chain may also meet the definition of a small business.

Costs and Other Effects

Small businesses affected by the proposed changes would face higher fees as described above.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

⁹ Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance.

¹⁰ Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

¹¹ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

¹² If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

Localities¹³ Affected¹⁴

The proposed amendments do not appear to disproportionately affect any locality in particular or affect costs for local governments.

Projected Impact on Employment

The proposed amendments would not be expected to affect employment prospects or entry into the profession for pharmacists or pharmacy technicians. Businesses impacted by the increased fees are unlikely to respond by reducing their staffing, so workers in manufacturing, warehousing, or distribution are unlikely to be affected either.

Effects on the Use and Value of Private Property

The proposed fee increases would increase costs for pharmacies, medical equipment suppliers, and other business entities that are part of the supply chain as listed above. Potentially, this may result in a modest decrease in their value.

The proposed amendments do not affect real estate development costs.

¹³ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹⁴ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.