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Proposed Regulation
Agency Background Document

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, Third-Party Logistics Providers, and Warehousers
Action title	Increase in fees
Date this document prepared	June 25, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board must amend regulations to ensure it obtains sufficient operating funds for future years. Under the current fee structure, the Board will carry a negative balance of $(1,098,203) for FY2026.[1]

[1] This number is different than the $(688,083) projected shortfall reported in the filing of the NOIRA. This reflects additional salary increases included by the General Assembly in the current FY24-FY26 budget, as well as built in assumptions for future cost of living salary increases.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this action was a projection of fees and expenditures for the Board of Pharmacy. The mandate for this action is Virginia Code § 54.1-113(B), which requires the Board to adjust fees to ensure that the "fees are sufficient but not excessive to cover expenses."

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The Board last initiated a fee increase in 2017, which became effective in 2020. The previous fee increase prior to that was initiated in 2001 and became effective in 2002. The Board instituted one-time fee reductions three times prior to the 2017 action.

Because salaries comprise the bulk of costs for any board within the agency, the five compounded state salary increases instituted since FY2020 have accelerated the need for a fee increase for the Board. When the General Assembly enacts salary increases, general fund state agencies receive allocations through the budget process to cover the increase. DHP, as a special fund agency, receives no such

allocation and must ultimately increase fees on licensees to cover the difference. Fee increases impacting the Board include:

- 5% total salary increase in FY2020;
- 5% salary increase on June 10, 2021;
- 5% salary increase on July 10, 2022;
- 5% salary increase on June 10, 2023;
- 2% salary increase on December 10, 2023;
- Salary increase of 3% on June 10, 2024; and
- Future salary increase of 3% on or about June 2025.

Additional operational changes affecting available funds include: an increase in licensee counts (FY2020: 37,640; FY2023: 45,486); regulated categories added to the Board's jurisdiction (in 2019 the Board began registering nonresident third-party logistics providers, nonresident warehousers, limited-use physician selling drugs; in 2021 began registering pharmacy technician trainees); an increase in disciplinary cases received by the Board (2018: 651 cases; 2023: 878); and an increase in the number of FTEs (2018: 12 FTEs; 2023: 14 FTEs). It should be noted that the number of FTEs has not increased consistent with the increase in workload for the Board. If the number of FTEs had increased at a rate consistent with operational workload increases, the Board would have between 20 and 21 FTEs.

Without adequate revenue to support inspections of pharmacy facilities, licensing, and disciplinary functions, work to protect the public by regulating, licensing, and disciplining the pharmacy workforce under the Board will slow. This will deprive the citizens of the Commonwealth with needed and safe pharmacy services. Additionally, should inadequate revenue cause a backlog of disciplinary cases, public health and safety may be at risk by permitting practitioners actively committing drug diversion or unprofessional conduct to continue practicing unencumbered for months while awaiting review and adjudication of disciplinary matters.

The Board's actual cash balance for FY2023 is $2,270,363. The estimated **FY2024** cash balance, reflecting a projected revenue of $4,953,312 and expenditures of $5,555,671, will be **$1,668,004**. The estimated **FY2025** cash balance, reflecting a projected revenue of $4,983,032 and expenditures of $6,238,671, will be **$412,365**. The estimated **FY2026** cash balance, reflecting a projected revenue of $5,012,930 and expenditures of $6,532,498, will be **-$1,098,203**.

The Medical Cannabis Program, which moved to the Virginia Cannabis Control Authority on January 1, 2024, is not factored into this action or included in the fiscal considerations noted here.

To remain solvent, the Board needs to obtain an approximate 45% - 50% increase in revenue. If the proposed fees in this action become final prior to the December 2025 renewal period, the estimated FY2026 cash balance would be $1,355,977. The estimated cash balance would become a deficit around FY2034. This will occur sooner if revenues are much lower or if expenditures are much higher than the projections.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

To address the deficit in Board funding, the Board will increase fees for all categories of practitioners and facilities that the Board regulates. 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 bulk of the increases needed 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 high above initial permitting, renewal, or reinspection fees applied to those facilities.

Finally, where able, the Board has compared Virginia's fees to those of neighboring jurisdictions (including current proposed fees). Generally, Virginia's fees are lower than other jurisdictions, and for several fees the Board has proposed fees more in line with other jurisdictions.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The primary advantage to the public is the continued licensing and disciplining of healthcare professionals and establishments by the Board of Pharmacy. There are no disadvantages to the public because the Board is a special fund agency that is not funded by the general public.
2) The primary advantage to the agency and the Commonwealth is the continued licensing and disciplining of healthcare professionals and establishments by the Board of Pharmacy. There are no primary disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system . . . Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. 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.

Impact on State Agencies

For your agency: projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources.	There are no expected costs, savings, fees, or revenues to the agency from this regulatory change. This change is solely to ensure continued operation of the agency, not to create profit.
For other state agencies: projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	The Board will benefit by continuing to have operating costs to continue its mission to protect the public.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees, or revenues resulting from the regulatory change.	There are no expected costs, savings, fees or revenues to localities from this regulatory change.
Benefits the regulatory change is designed to produce.	There are no expected benefits to localities from this regulatory change.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The individuals, businesses, or other entities that will be affected by this regulatory change are as follows: pharmacies; medical equipment suppliers; outsourcing facilities; nonresident pharmacies; nonresident outsourcing facilities; individuals and businesses holding a controlled

	substance registration; entities filing an innovative pilot program with the Board; repackaging training programs; sterile compounding pharmacies; pharmacists; pharmacy interns; pharmacy technicians; pharmacy technician trainees; practitioners of the healing arts licensed to dispense medication; manufacturers; wholesale distributors; warehousers; nonresident wholesale distributors; third-party logistics providers; nonresident manufacturers; nonresident warehousers; and nonresident third-party logistics providers.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated, and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The agency provides quarterly reports on the number of licensees, registrants, permits, and other regulated entities in Virginia. Those reports are available here. The most recent numbers for individuals and entities regulated by the Board of Pharmacy as of the filing of this document is for FY24 Q3. Please check the link in the first paragraph for updated numbers.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	The change in cost is contained in the chart of changes, below. The changes will not be listed here for space reasons. The only costs will be related to obtaining, renewing, reinstating, or reactivating licenses, registrations, or permits, or costs related to inspections, reinspections, or other changes to requirements of practicing pharmacy in Virginia.
Benefits the regulatory change is designed to produce.	The benefit will be continued licensing, renewal, and discipline of individuals and entities regulated by the Board. Should the Board run out of funds, all of the individuals and entities that the Board regulates will be negatively affected.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board cannot collect fees unless those fees are set forth in regulation. The Board is also required to fund its activities by collecting fees from regulated individuals and entities. There are no alternatives to regulation.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

The Board has considered the impact of fees on different categories of regulated individuals and entities and has made decisions based on 1) impact to the Board in terms of cost and 2) relative cost to hold a license, registration, or permit compared to other jurisdictions. The Board cannot feasibly or fairly base fees on the size of a permit holder, therefore the Board cannot change requirements for "small businesses," nor exempt small businesses from compliance with fees when small businesses can account for significant expenditures of the Board in inspection and discipline costs.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

Not applicable.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

There were no public comments.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at https://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (http://www.townhall.virginia.gov) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between the existing VAC Chapter(s) and the proposed regulation. If the existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-20	Sets forth fees for the practice of pharmacy	Initial pharmacy permit and sterile compounding The cost to initially obtain a pharmacy permit is $500. The Board proposes to raise that fee to $700. This is a 40% increase. The range for a pharmacy permit in neighboring states is $150 - $700. This increase will cover the cost of

		the required facility inspection upon application, which is on average $679 as of June 2024.[2] The cost for an initial pharmacy permit may also include a new fee added to this chapter for sterile compounding facilities. Inspection of sterile compounding facilities costs the Board on average $2,374. The Board therefore proposes to add a fee for sterile compounding of $200. While this fee is new, it is necessary due to the cost of inspections for compounding facilities. The cost created by these facilities should be at least predominantly borne by the facilities rather than other licensees of the Board which do not perform sterile compounding. West Virginia currently imposes such a fee and Tennessee has included such a fee in its current proposed fee increase regulatory action. The current renewal fee for a pharmacy permit is $350; the Board proposes an increase to $490. Neighboring states charge $200 - $500 for renewal of similar permits. This is a 40% increase in fees. Pharmacies are routinely inspected approximately every two years at an average cost of $826 if the pharmacy is not a sterile compounding pharmacy. Renewal fees may include a renewal of the new sterile compounding fee. The Board proposes a $400 fee to renew sterile compounding. The cost to inspect a sterile compounding pharmacy every 18-24 months is on average $2,504. Reinstatement fees for this category are currently $315; the Board proposes an increase to $440, which is a 40% increase. <u>Permitted physician licensed to dispense drugs</u> The fee for a permitted physician licensed to dispense drugs[3] is currently $500. The Board proposes raising this fee to $700.[4] This is a 40% increase and will cover the average cost of inspection. The renewal fee for this category is $350; the Board proposes an increase to $490. This is a 40% increase. Such facilities are inspected approximately every two years.

[2] Of note: this does not reflect the most recent salary increases by the General Assembly in the FY2025-FY2026 budget because enforcement costs are partially driven by salary and wages for inspectors. Additionally, should the General Assembly raise salaries in the future, this cost will no longer be accurate for the same reason.
[3] This is an old license type with no current permits issued in this category.
[4] There are no neighbor state comparisons for this type. In this document, if no range for neighboring states is included, the Board does not have such information.

		Reinstatement fees for this category are currently $315; the Board proposes an increase to $440, which is a 40% increase. Medical equipment supplier Medical equipment supplier permits are currently $235; the Board proposes an increase to $350. Neighboring states charge $318 - $525. This would be a 49% increase for Virginia permits. It would not cover the cost of the required opening inspection to receive a permit, which is on average $679. The cost of renewal for this category is $235; the Board proposes an increase to $350. Neighboring states charge $200 - $535 for renewal of this type. This is a 49% increase. The cost to routinely inspect these facilities for ongoing permitting is on average $826 every three years. Reinstatement fees for this category are currently $275; the Board proposes an increase to $385, which is a 40% increase. Outsourcing facility An outsourcing facility permit is currently $350; the Board proposes an increase to $700 and a sterile compounding fee of $200. This is a 100% increase plus sterile compounding fee. Tennessee is proposing a fee of $740 for these types of permits. The average cost of the required opening inspection for these permits is $2,185 due to sterile compounding; therefore, this increase, while significant, does not cover the cost of an inspection for this permit type. The cost for a renewal in this category is $350; the Board proposes an increase to $740 plus the renewal fee for sterile compounding of $400. Tennessee has proposed an identical fee structure for renewal of $740 plus a $400 sterile compounding fee renewal. This is a 111% increase. The average cost for routine inspections of these facilities is $2,185 every two years. Reinstatement fees for this category are currently $315; the Board proposes an increase to $500, which is a 59% increase. Nonresident pharmacy registration A nonresident pharmacy registration is currently $350; the Board proposes an increase to $700 and a sterile compounding fee, if applicable. This is a 40% increase for nonresident pharmacies that do not perform sterile compounding. Virginia law requires nonresident pharmacies to pay the same amount as in-state pharmacies. *See* Virginia Code § 54.1- 3434.1. When the

		Board receives an application for a nonresident pharmacy registration, staff must review current inspection reports, deficiencies cited, the appropriateness of any corrective action taken, disciplinary action taken in other states or federally, and obtain additional information as needed. Registration applications may warrant informal conference committee review for further consideration, thereby increasing the cost of such applications. The renewal cost for this category is $350; the Board proposes an increase to $490, with a sterile compounding renewal if applicable. This is a 40% increase. The Board must annually perform the same actions listed for initial registration on renewal of the category, making the average cost to the Board in staff time and agency resources similar. Reinstatement fees for this category are currently $150; the Board proposes an increase to $440, which is a 193% increase, to align with the reinstatement fee of an in-state pharmacy permit as required by law. <u>Nonresident outsourcing facility</u> A nonresident outsourcing facility registration is currently $350; the Board proposes an increase to $700 and a sterile compounding fee, if applicable. This is a 100% increase plus sterile compounding fee for nonresident outsourcing facility registrations due to performing sterile compounding. When the Board receives an application for a nonresident outsourcing facility registration, staff must review current inspection reports, deficiencies cited, the appropriateness of any corrective action taken, disciplinary action taken in other states or federally, and obtain additional information as needed. Registration applications may warrant informal conference committee review for further consideration, thereby increasing the cost of such applications. Renewal for this category costs $350; the Board proposes an increase to $700 plus the $400 sterile compounding fee renewal. This will total a 100% increase plus the sterile compounding fee in renewal costs for this category. The Board must annually perform the same actions listed for initial registration on renewal of the category, making the average cost to the Board in staff time and agency resources similar. Reinstatement for this category costs $315. The Board proposes to increase this fee to $500, which is a 59% increase. <u>Controlled substances registrations</u> Controlled substances initial registrations and renewal currently cost $120; the Board proposes an increase to

		$180 for both initial registration and renewal. This is a 50% increase. Controlled substances initial registrations cost the Board $679 on average in inspection costs, and inspections of locations cost $826 every 2-3 years after, depending on type of activity for which the registration was issued; therefore, although this increase is significant, it will not cover the costs of initial registration for the Board or the subsequent routine inspections. Reinstatement fees for this category are currently $235; the Board proposes an increase to $350, which is a 49% increase. <u>Innovative program approval</u> Innovative program approval applications currently cost $325; the Board proposes an increase to $415. This is a 28% increase. Although opening inspections are generally not associated with these applications, the pilot application must be reviewed by Board staff and adjudicated by an informal conference committee, thereby creating operational costs. Continued approval for this category currently costs $260; the Board proposes an increase to $375. This is a 44% increase and reflects the cost to the Board of continued approval. Each request involves deputy-level Board staff, review and communication with two Board members, and drafting of an approval order by the agency's Adjudication Proceedings Division, for which the Board is billed. <u>Repackaging training program</u> Approval of a repackaging training program currently costs $65; the Board proposes an increase to $85. This is a 30% increase. This is a rarely used category for which the Board only received one application in the last fiscal year. Renewal currently costs $40 every two years; the Board proposes an increase to $50 every two years. Reinstatement fees for this category are currently $65; the Board proposes an increase to $85, which is a 30% increase. <u>Change of PIC</u> The current cost for the change of PIC is $65; the Board proposes an increase to $125. This is a 92% increase. This change for a facility requires the agency's Central Receipting to process the fee, Board staff to ensure the PIC is eligible to serve as a PIC, may involve waiver approval from the Board Executive Director or chairman, staff updates to the Board's licensing system, and the agency IT department to print and mail a new permit. The

		printing and mailing of a new permit alone costs approximately $100. Change of ownership for facility The current cost for change of ownership of a facility is $65; the Board proposes an increase to $125, which is an increase of 92%. Inspection for remodeling or change of location for facility The current cost for this category is $300; the Board proposes an increase to $435, which is a 45% increase. Required inspections of these changes cost the Board on average $679. Reinspection of any facility The current cost for this category is $300; the Board proposes an increase to $435, which is a 45% increase. Reinspections cost the Board on average $679. Board-required inspection of pilot location The current cost for this category is $300; the Board proposes an increase to $435, which is a 45% increase. The inspection costs related to this action are on average $679. Change of pharmacist responsible for an approved pilot The current cost for this category is $35; the Board proposes an increase to $150, which is a 329% increase. This action requires staff to process an application and fee, send the action to the Adjudication Proceedings Division for drafting of a new order, mailing the order, and entering the order (for which the Board is billed).
21-20	Sets forth fees for pharmacists, pharmacy technicians, pharmacy interns, and pharmacy technician trainees	Pharmacist The cost to obtain an initial license as a pharmacist is $235; the Board proposes to increase this cost to $300. The cost charged by neighboring states ranges from $130 - $200. This is a 28% proposed increase, a significantly less increase in revenue generally than the Board requires to remain solvent. The average cost for the agency's Enforcement Division to investigate an individual licensee is $2,000. The current cost to renew an active pharmacist license is $120; the Board proposes to increase this fee to $175, which is a 46% increase. Neighboring states charge a range of $60 - $265.

		The current cost to renew an inactive pharmacist license is $60; the Board proposes to increase this to $95, which is a 58% increase. The cost for reinstatement of a pharmacist license is $275; the Board proposes to raise this to $300 which is a 9% increase. The cost for reinstatement of a pharmacist license after a suspension or revocation is currently $650; the Board proposes to raise this to $750, which is a 15% increase. This higher cost for reinstatement after suspension or revocation reflects the required disciplinary processes (such as investigation by the agency's Enforcement Division, Board member hearings, documentation preparation by the agency's Administrative Proceedings Division, and Board counsel participation) for reinstatement following suspension or revocation. <u>Pharmacy intern</u> The current cost to obtain a registration as a pharmacy intern is $20; the Board proposes increasing this cost to $30. This is a 50% increase, but the cost for this registration will generally remain low. <u>Pharmacy technician</u> The current cost to obtain a registration as a pharmacy technician is $35; the Board proposes an increase to $40. This is a 14% increase. The current cost to renew a pharmacy technician registration is $35; the Board proposes to raise this fee to $45, which is a 29% increase. Neighboring states charge a range of $15 - $100 to renew license types for pharmacy technicians. The average cost for the agency's Enforcement Division to investigate an individual licensee for non-compliance is $2,000. Reinstatement of a pharmacy technician registration currently costs $45; the Board proposes to raise this cost to $50, which is an 11% increase. Reinstatement of a pharmacy technician registration following suspension or revocation is currently $165; the Board proposes to raise this fee to $200, a 21% increase. Similar to pharmacist licensees, this reflects the required disciplinary costs to the Board of reinstating a registration after suspension or revocation. <u>Pharmacy technician trainee</u> The current cost to obtain a registration as a pharmacy technician trainee is $20; the Board proposes increasing this cost to $30. This is a 50% increase, but the cost for

		this registration will generally remain low. This particular category of registration often requires Board Executive Director review of criminal convictions and can require an informal conference committee be convened for further consideration. Additionally, disciplinary cases related to this category can result in summary suspensions and formal administrative hearings, raising disciplinary costs. Reinstatement of a pharmacy technician trainee registration following suspension or revocation is currently $165; the Board proposes to raise this fee to $200, a 21% increase. Similar to pharmacist licensees, this reflects the required disciplinary costs to the Board of reinstating a registration after suspension or revocation. Reinstatement of a pharmacy technician trainee registration following expiration for any length of time is currently not represented in the Board's fee structure. The Board proposes to add this fee to permit a pharmacy technician trainee to apply for reinstatement after moving programs or taking time off from training. The Board proposes a cost of $25. <u>Approval of continuing education program</u> The current cost for obtaining this approval is $130; the Board proposes raising this fee to $190, a 45% increase. This is a rarely used category with only one or two programs approved per year, but it requires review by the Board's Executive Director and one Board member. <u>Fees associated with approval of pharmacy technician training programs</u> These fees are eliminated due to statutory changes that removed the Board's authority to approve such programs.
30-15	Sets forth fees for practitioners of the healing arts to sell controlled substances	<u>License</u> The current cost to obtain an initial license as a practitioner of the healing arts selling controlled substances is $235. The Board proposes to raise this fee to $300, which is a 28% increase. This will align with the proposed pharmacist fee since both license categories perform similar drug dispensing activities. The renewal cost for this category of licensure is $120; the Board proposes to increase this fee to $175, which is a 46% increase. This will align with the proposed pharmacist fee since both license categories perform similar drug dispensing activities. The cost for reinstatement of a license in this category is currently $195; the Board proposes an increase to $300, which is a 53% increase. This makes the reinstatement fee consistent with this same fee for licensed pharmacists. The Board is faced with the same expenditures

		processing reinstatements in this category as with licensed pharmacists, so the fees should be the same. The current fee for reinstatement of a license in this category following revocation or suspension is $650; the Board proposes an increase to $750. This is a 15% increase and reflects the disciplinary costs to the Board associated with these reinstatements. <u>Permit</u> The initial cost for the permit of a facility in which a practitioner of the healing arts sells drugs is $315. The Board proposes an increase of $700, which is a 122% increase. This cost will make the cost of the permit consistent with the cost of a pharmacy permit issued under Chapter 20. These facilities require inspections in the same manner as traditional pharmacies, which cost the Board $679 on average. Therefore, although this increase is significant, the current fee is not sufficient to cover the Board's cost relative to these permits, nor is it currently consistent with similar permits. The current cost for renewal of this category is $315; the Board proposes a fee increase to $490, which is a 55% increase. This large increase again will account for costs to the Board for inspections and bring these permitted facilities in line with pharmacy permit fees. The current late fee for renewal of this category is $50; the Board proposes an increase to $120, which is 140% increase. This will, similar to the other fees in this category, bring permit fees in line with pharmacy permit fees. The current fee for reinstatement of a permit in this category is $315; the Board proposes an increase to $415, which is a 31% increase. The current fee for reinstatement of a permit in this category following revocation or suspension is $650; the Board proposes an increase to $750. This is a 15% increase and reflects the disciplinary costs to the Board associated with these reinstatements. The current cost for reinspection of a facility permitted in this category is $300; the Board proposes an increase to $435, which is a 45% increase. The cost to reinspect a facility is on average $679, less than the cost the Board has proposed as an increased fee.
50-20	Sets forth fees for wholesale distributors, manufacturers, third-party logistics providers, and warehousers	The average cost for a required opening, change of location, or remodel inspection of every license, permit, or registration category in Chapter 50, as listed below, is $679. The average cost of a routine inspection performed every two years is $826.

		Generally, the Board believes the licenses, permits, and registrations in this category are better able to bear the increase needed for the Board to continue operating than individual healthcare practitioners. The changes below reflect that decision of the Board. <u>Nonrestricted manufacturer</u> An initial permit in this category currently costs $350; the Board proposes an increase to $1,000. This is a 186% increase. Neighboring states impose fees ranging from $750 - $1,750, meaning Virginia is currently far below standard fees for this category. Notably, zero permits in this category were issued in the last 4Q. Therefore, this fee increase, while large, will not have a significant impact on stakeholders. The current cost for renewal of this category is $350; the Board proposes an increase to $1,000. This is a 186% increase. As noted above, Virginia currently charges far less for this category than neighboring states. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Restricted manufacturer</u> An initial permit in this category currently costs $235; the Board proposes an increase to $850. This is a 262% increase. Similar to the permit category above, zero permits were issued in this category in the last 4Q, meaning this increase will not have a significant impact on stakeholders. Renewal in this category currently costs $235; the Board proposes an increase to $850. This is a 262% increase. The current reinstatement cost for this category is $275; the Board proposes an increase to $385, which is a 40% increase. <u>Nonresident manufacturer</u> The cost for initial registration in this category is currently $350; the Board proposes an increase to $1,000. This is a 186% increase. The cost for renewal in this category is currently $350; the Board proposes an increase to $1,000. This is a 186% increase. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase.

		<u>Wholesale distributor</u> The current cost for an initial license in this category is $350; the Board proposes an increase to $750. This is an increase of 114%. Neighboring states impose fees ranging from $700 - $1,750, meaning Virginia is again out of alignment with cost imposition. The current cost for renewal in this category is $350; the Board proposes increasing this fee to $750; which is a 114% increase. This will bring Virginia in line with other states regulating this category. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Warehouser</u> The cost for initial permit in this category is $350; the Board proposes an increase to $510, which is a 45% increase. One neighboring state, Tennessee, has proposed an increase in this category to $535. The current cost for renewal of this category is $350; the Board proposes an increase to $510, which is an increase of 45%. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Nonresident wholesale distributor</u> The cost for initial registration in this category is $350; the Board proposes an increase to $750, which is a 114% increase. Current cost of renewal for this category is $350; the Board proposes an increase to $750, which is a 114% increase. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Controlled substances</u> The cost for an initial registration and renewal in this category is $120; the Board proposes an increase to $180 for both initial registration and renewal. This increase is the same as the controlled substances registration increase included in Chapter 20. The costs to the Board of issuing and regulating these registrations is the same across categories.

		The current reinstatement cost for this category is $235; the Board proposes an increase to $300, which is a 28% increase. <u>Third-party logistics provider</u> The cost for an initial permit in this category is $350; the Board proposes an increase to $750. This is a 114% increase. There were no permits in this category issued in the last 4Q. The current cost for renewal in this category is $350; the Board proposes an increase to $750, which is a 114% increase. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Nonresident manufacturer</u> The cost for initial registration in this category is $350; the Board proposes an increase to $1,000. This is a 186% increase. The current cost for renewal in this category is $350; the Board proposes an increase to $1,000, which is an increase of 186%. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Nonresident warehouser</u> The cost for initial registration in this category is $350; the Board proposes an increase to $510, which is a 45% increase. The current cost for renewal in this category is $350. The Board proposes an increase to $510, which is a 45% increase. The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Nonresident third-party logistics provider</u> The cost for initial registration in this category is $350; the Board proposes an increase to $750. This is a 114% increase. The cost for renewal in this category is $350; the Board proposes an increase to $750. This is a 114% increase.

		The current reinstatement cost for this category is $315; the Board proposes an increase to $440, which is a 40% increase. <u>Change or inspection fees for this Chapter</u> Reinspection fees for these categories of regulants is currently $300; the Board proposes an increase to $435, a 45% increase. The average cost of required inspection is $679. The current inspection fee for change of location, structural changes, or security system changes is $300. The Board proposes an increase to $435, a 45% increase. The average cost of required inspection is $679. The current cost for change of ownership for these categories is $65; the Board proposes an increase to $125; which is a 92% increase. The current cost for change of responsible party for these categories is $65; the Board proposes an increase to $125; which is a 92% increase.