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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC 110-20-10 et seq. 18VAC110-30-10 et seq. 18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations for Practitioners of the Healing Arts to Sell Controlled Substances Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Increase in fees
Date this document prepared	9/25/19

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please 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 of Pharmacy has adopted amendments to increase their fees to cover expenses for essential functions of review of applications, licensing, inspections, investigation of complaints against licensees, and adjudication and monitoring of disciplinary cases required for public health and safety in the Commonwealth.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On September 25, 2019, the Board of Pharmacy amended 18VAC110-20, Regulations Governing the Practice of Pharmacy; 18VAC110-30, Regulations for Practitioners of the Healing Arts to Sell Controlled Substances; and 18VAC110-50, Regulations Governing Wholesale Distributors, Manufacturers and Warehousers.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

§ 54.1-113 of the *Code of Virginia* requires that at the end of each biennium, an analysis of revenues and expenditures of each regulatory board shall be performed. It is necessary that each board have sufficient revenue to cover its expenditures. Since the fees from licensees no longer generate sufficient funds to offset operating expenses for the Board, a fee increase is essential. In order to have sufficient funding for the operation of the Board by fiscal year 2019-20, the Board has proposed a 30% increase in all fees with the exception of those functions that require an inspection, including an initial pharmacy permit and changes in location or remodeling. Those fees are set at an amount to offset the actual charge to the Board by the Enforcement division of the Department.

Legal Basis

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

Regulations of the Board of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary and the authority to **levy and collect fees** that are **sufficient to cover all expenses** for the administration of a regulatory program.

§ 54.1-2400. General powers and duties of health regulatory boards.--*The general powers and duties of health regulatory boards shall be:*

5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 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 proposed regulation is mandated by § 54.1-113:.

> ***§ 54.1-113. Regulatory boards to adjust fees.--****Following the close of any biennium, when the account for any regulatory board within the Department of Professional and Occupational Regulation or the Department of Health Professions maintained under § 54.1-308 or § 54.1-2505 shows expenses allocated to it for the past biennium to be more than ten percent greater or less than moneys collected on behalf of the board, it shall revise the fees levied by it for certification or licensure and renewal thereof so that the fees are sufficient but not excessive to cover expenses.*

Purpose

Please 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's intended to solve.

Fees charged to applicants and licensees of the Board of Pharmacy have not been increased in almost 17 years; regulations became effective on 12/4/02. During that time period, there have been three reductions in renewal fees (2005, 2006 and 2009). The number of regulated entities has substantially increased in recent years (12,861 in 2002 to 37,608 in 2018), so the need for additional staff (six in 2002 to 12 in 2018) has increased costs to the Board. Additionally, the cost of inspections has increased as have expenditures for investigation and adjudication of disciplinary cases. Enforcement inspection and investigative hours have increased from 7,179.30 in FY02 to 13,220.30 in FY17. The number of cases adjudicated have increased from 269 in 2002 to 651 in 2017. Additionally, the Board's share of allocated expenditures has grown as costs to the Department have increased. For example, in FY02, IT costs were approximately $300,000; in FY17, IT costs were $1.84 million.

Expenditures are now projected to exceed revenues by 2021. While the Board has maintained a positive cash balance due to carry-over revenue, expenditures in FY19 of $3,871,405 exceeded revenue of $3,480,862. The imbalance will continue to grow in the next biennium and beyond. Therefore, the Board will have a projected shortfall in its budget by 2021 of ($585,181) which is

projected to grow to ($4,664,817) by June 30, 2024. The Board of Pharmacy must amend regulations as soon as possible to avoid the additional fee assessments that other boards had to adopt or being forced to curtail vital functions of inspection and investigation.

Without adequate revenue to support inspections of pharmacy facilities, licensing and discipline functions, applicants for licensure or pharmacy permits cannot be approved in a timely manner thus depriving the citizens of the Commonwealth with the pharmacy services needed. Additionally, if there is a substantial backlog of disciplinary cases, public health and safety may be at risk by allowing practitioners guilty of drug diversion or unprofessional conduct to continue in practice for several months awaiting a review and adjudication of an investigative report.

Substance

Please 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.

The Board has proposed a 30% increase in all fees with the exception of those functions that require an inspection, including an initial pharmacy permit and changes in location or remodeling. Those fees are set at an amount to offset the actual charge to the Board by the Enforcement division of the Department.

Issues

Please 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 avoidance of a reduction in investigations or inspections. There are no disadvantages to the public;
2) The advantage to the agency is adequate revenue to offset expenditures so a growing shortfall can be avoided, which would necessitate a one-time assessment for all regulated entities or an additional fee increase; and
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system.*" Additionally, the Code of Virginia requires:
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered…
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

The amended regulations include an across-the-board fee increase of 30% with the exception of fees directly related to actual costs to the Board for conducting inspections. Therefore, the regulations are necessary to provide revenue for essential board functions and do not represent any restraint on competition.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected - none

Localities Particularly Affected - none

Other Entities Particularly Affected - none

Public Comment

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

There was a 60-day comment period from 5/27/19 to 7/26/19; a public hearing was conducted on 6/5/19. There was no comment.

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

There have been no changes made since the proposed stage.

Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Current section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
Chapter 20, section 20	Sets out fees for initial applications, renewals, late renewals, reinstatements, and miscellaneous board activities	The proposes changes are as follows: Subsection C. Initial application fees. 1. Pharmacist license $180$235 2. Pharmacy intern registration $15$20 3. Pharmacy technician registration $25$35 4. Pharmacy permit $270$500 5. Permitted physician licensed to dispense drugs $270$500 6. Medical equipment supplier permit $180$235 ~~7. Humane society permit~~ ~~$20~~ 8.7. Outsourcing facility permit $270$350 9.8. Nonresident pharmacy registration $270$350 10.9. Nonresident outsourcing facility registration $270$350 11.10. Controlled substances registrations $90$120 12.11. Innovative program approval. $250$325 If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee. ~~13.~~ Approval of a pharmacy technician training program $150$200 ~~14.~~ Approval of a continuing education program $100$130 ~~15.~~ Approval of a repackaging training program $50$65 *With the exception of initial applications for a pharmacy permit or a permitted physician (a physician's office that is permitted to dispense drugs to the public, not just to his patients), all fees are increased by 30%.* *Initial applications for pharmacy permits require an opening inspection; the average time for such an inspection is 4.1 hours of an inspector's time for a cost of $602 charged to the Board of Pharmacy. At an initial fee of $500, the pharmacy or the permitted physician application fee*

		does not fully cover the average opening inspection cost, but the Board did not choose to make the fee higher than $500 which is consistent with some neighboring jurisdictions (NC is $500; TN is $310 to $600). *The Board no longer requires a separate permit for a humane society or animal shelter. Shelters have always been required to obtain a controlled substance registration, so the additional permit was deemed unnecessary.* Subsection D. Annual renewal fees. 1. Pharmacist active license – due no later than December 31 $90$120 2. Pharmacist inactive license – due no later than December 31 $45$60 3. Pharmacy technician registration – due no later than December 31 $25$35 4. Pharmacy permit – due no later than April 30 $270$350 5. Physician permit to practice pharmacy – due no later than February 28 $270$350 6. Medical equipment supplier permit – due no later than February 28 $180$235 ~~7. Humane society permit – due no later than February 28~~ ~~$20~~ 8.7. Outsourcing facility permit – due no later than April 30 $270$350 9.8. Nonresident pharmacy registration – due no later than the date of initial registration $270$350 10.9. Nonresident outsourcing facility registration – due no later than the date of initial registration $270$350 11.10. Controlled substances registrations – due no later than February 28 $90$120 12.13. Innovative program continued approval based on board order not to

		exceed $200$260 per approval period. 13.14. Approval of a pharmacy technician training program — $75$100 every two years 14.15. Approval of a repackaging training program — $30$40 every two years *All renewal fees are increased by 30%, so all categories of regulated entities share the increased costs to the Board. Renewal fees were reduced 3 times in the past 16 years since the last fee increase.* Subsection E. Late fees. 1. Pharmacist license — $30$40 2. Pharmacist inactive license — $15$20 3. Pharmacy technician registration — $10$15 4. Pharmacy permit — $90$120 5. Physician permit to practice pharmacy — $90$120 6. Medical equipment supplier permit — $60$80 ~~7. Humane society permit~~ — ~~$5~~ 8. Outsourcing facility permit — $90$120 9. Nonresident pharmacy registration — $90$120 10. Nonresident outsourcing facility registration — $90$120 11. Controlled substances registrations — $30$40 12. Approval of a pharmacy technician training program — $15$20 13. Approval of a repackaging training program — $10$15 *Late fees are set at approximately 1/3 of the renewal fee, so each of those also increased by 30%.* Subsection F. Reinstatement fees.. 1. Pharmacist license — $210$275 2. Pharmacist license after revocation or suspension — $500$650 3. Pharmacy technician registration — $35$45

		4. Pharmacy technician registration after revocation or suspension	$125$165
		5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
		a. Pharmacy permit	$240$315
		b. Physician permit to practice pharmacy	$240$315
		c. Medical equipment supplier permit	$210$275
		~~d. Humane society permit~~	~~$30~~
		e.d. Outsourcing facility permit	$240$315
		f.e. Nonresident pharmacy registration	$115$150
		g.f. Nonresident outsourcing facility registration	$240$315
		h.g. Controlled substances registration	$180$235
		i.h. Approval of a pharmacy technician training program	$75$100
		j.i. Approval of a repackaging training program	$50$65
		All reinstatement fees were increased by 30%.	
		Subsection G. Application for change or inspection fees for facilities or other entities.	
		1. Change of pharmacist-in-charge	$50$65
		2. Change of ownership for any facility	$50$65
		3. Inspection for remodeling or change of location for any facility	$150$300
		4. Reinspection of any facility	$150$300

		5. Board-required inspection for a robotic pharmacy system $150<u>$300</u> 6. Board-required inspection of an innovative program location $150<u>$300</u> 7. Change of pharmacist responsible for an approved innovative program $25<u>$35</u> *A change of location or a remodeling of a pharmacy requires an inspection; the average cost for such an inspection (4.25 hours) is $625. Therefore, those fees, the reinspection fee, and any Board-required inspection are increased by 50%.* H. Miscellaneous fees. 1. Duplicate wall certificate $25<u>$50</u> 2. Returned check $35 3. Duplicate license or registration $10<u>$15</u> 4. Verification of licensure or registration $25<u>$35</u> *The duplicate wall certificate fee is increased to $50 which is closer to the fee charged by other boards and to the actual cost of producing a duplicate (staff time, mailing, etc.)* *The returned check fee was not changed because that fee is consistent across boards, so a different fee would be confusing in Finance.*
Chapter 20, section 121	Sets out requirements for approval of an innovative pharmacy program	The informal conference committee shall determine the appropriate fee for continued approval of the program based on the requirements for review and monitoring. Such renewal fee shall not exceed ~~$200~~<u>$260</u> per approval period. *Approval of an innovative pharmacy program (pilot) requires convening an informal conference and may require an inspection. The fee for continued approval is listed in section 20, but also referenced in section 121.*
Chapter 30, section 15	Sets out all fees associated with physicians selling drugs to their patients, including a permit for the location and a license for the practitioner.	All fees in section 15 are increased by 30%, consistent with fees for the practice of pharmacy. The fee for a reinspection is changed from $150 to $300 to more closely reflect the charges from Enforcement to the Board of Pharmacy.
Chapter 50,	Sets out all fees associated with permits, registrations, or	All fees in section 20 are increased by 30%, consistent with fees for the practice of pharmacy. The fee for a

section 20	licenses for manufacturers, wholesale distributors, warehousers, or third-party logistics providers	reinspection is changed from $150 to $300 to more closely reflect the charges from Enforcement to the Board of Pharmacy.