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# Proposed Regulation
# Agency Background Document

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| **Agency name** | Board of Pharmacy, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation(s)** | 18VAC 110-20-10 et seq.<br>18VAC110-30-10 et seq.<br>18VAC110-50-10 et seq. |
| **Regulation title(s)** | Regulations Governing the Practice of Pharmacy<br>Regulations for Practitioners of the Healing Arts to Sell Controlled Substances<br>Regulations Governing Wholesale Distributors, Manufacturers and Warehousers |
| **Action title** | Increase in fees |
| **Date this document prepared** | 3/30/18 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

The Board of Pharmacy proposes 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.

§ 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.

## 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

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

Fees charged to applicants and licensees of the Board of Pharmacy have not been increased in over 15 years, effective 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 in the 2018-20 biennium. While the Board has maintained a positive cash balance due to carry-over revenue, expenditures in FY18 of $3,745,630 are projected to exceed revenue of $3,131,895 by June 30, 2018. The imbalance with continue to grow in the next biennium and beyond. Therefore, the Board will have a projected shortfall in its budget by 2021 of ($648,614) which is projected to grow to ($2,657,527) by June 30, 2022. 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 proposed regulatory action, 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, please indicate.*

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 proposed 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 proposed regulations are necessary to provide revenue for essential board functions and do not represent any restraint on competition.

## Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.*

There are no applicable federal requirements.

## Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities particularly affected.

## Public participation

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. 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 this stage 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.

## Economic impact

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

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| **Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and** | a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically |

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| **b) a delineation of one-time versus on-going expenditures** | the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures. |
| **Projected cost of the new regulations or changes to existing regulations on localities.** | There is no cost to localities. |
| **Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.** | All persons and entities regulated by the Board. |
| **Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.** Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | Business CSR **1,196**<br>CE Courses **9**<br>Limited Use Pharmacy Technician **19**<br>Medical Equipment Supplier **258**<br>Non-resident Medical Equipment Supplier **335**<br>Non-resident Outsourcing Facility **26**<br>Non-resident Pharmacy **732**<br>Non-resident Wholesale Distributor **749**<br>Non-restricted Manufacturer **29**<br>Permitted Physician **1**<br>Pharmacist **14,714**<br>Pharmacy **1,857**<br>Pharmacy Intern **1,848**<br>Pharmacy Technician **14,552**<br>Pharmacy Technician Training Program **140**<br>Physician Selling Controlled Substances **727**<br>Physician Selling Drugs Location **175**<br>Pilot Programs **10**<br>Repackaging Training Program **2**<br>Restricted Manufacturer **66**<br>Warehouser **47**<br>Wholesale Distributor **116** |
| **All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:**<br>**a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and**<br>**b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.** | All persons and entities regulated by the Board will incur additional cost as specified in the detail of changes. |
| **Beneficial impact the regulation is designed to produce.** | The benefit is the proposed regulation is assurance of sufficient revenue to cover expenditures for the next several biennia to avoid disruption of essential functions of licensing, inspections, and investigations. With the proposed fee increase, the Board is projected to have sufficient revenue to offset expenditures by June 30, 2021. |

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.*

The proposed regulatory action is essential to ensure that the Board has sufficient revenue to carry out its statutory responsibility for protection of the safety and integrity of controlled substances in the Commonwealth. There are no alternative methods to achieve the essential purpose of the action. Without a fee increase, the shortfall is projected to the ($648,614) by June 30, 2021 and grow to (2,574,527) by June 30 2022.

Failure to increase fees would lead to delays in licensing, inspections, and investigation, which could place the public at risk as victims of unscrupulous practitioners and could increase costs as new licensees would not be available. It is believed that these consequences would not be acceptable to the administration, the General Assembly, or to the general public.

This action is unrelated to the issuance of permits for pharmaceutical processors that will produce CBD and THC-A oils for dispensing to registered patients: the expenditures and revenue for processors and registration of patients and physicians will be maintained in a separate cost center under the Board.

## Regulatory flexibility analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.*

There is no alternative regulatory method; fees are established by regulation, which must be amended for any reduction or increase.

## Public comment

*Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.*

There was a comment period on the NOIRA from 1/8/18 to 2/7/18; there was no comment.

## Family impact

*Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

There is no impact on the family and family stability.

## Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.*

| Current section number | Current requirement | Proposed change, intent, and likely impact of proposed requirements |
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| Chapter 20, section 20 | Sets out fees for initial applications, renewals, late renewals, reinstatements, and miscellaneous board activities | The proposes changes are as follows:<br>Subsection C. Initial application fees.<br>1. Pharmacist license $180$235<br>2. Pharmacy intern registration $15$20<br>3. Pharmacy technician registration $25$35<br>4. Pharmacy permit $270$500<br>5. Permitted physician licensed to dispense drugs $270$500<br>6. Medical equipment supplier permit $180$235<br>~~7. Humane society permit~~ ~~$20~~<br>8.7. Outsourcing facility permit $270$350<br>9.8. Nonresident pharmacy registration $270$350<br>10.9. Nonresident outsourcing facility registration $270$350<br>11.10. Controlled substances registrations $90$120<br>12.11. Innovative program approval. $250$325<br>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.<br>~~13.~~ Approval of a pharmacy technician training program $150$200<br>~~14.~~ Approval of a continuing education program $100$130 |

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| | | ~~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 |

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| | | 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 |

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| | | 13. Approval of a repackaging training program $10$15<br><br>*Late fees are set at approximately 1/3 of the renewal fee, so each of those also increased by 30%.*<br><br>Subsection F. Reinstatement fees..<br>1. Pharmacist license $210$275<br>2. Pharmacist license after revocation or suspension $500$650<br>3. Pharmacy technician registration $35$45<br>4. Pharmacy technician registration after revocation or suspension $125$165<br>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:<br>a. Pharmacy permit $240$315<br>b. Physician permit to practice pharmacy $240$315<br>c. Medical equipment supplier permit $210$275<br>~~d. Humane society permit~~ ~~$30~~<br>e.d. Outsourcing facility permit $240$315<br>f.e. Nonresident pharmacy registration $115$150<br>g.f. Nonresident outsourcing facility registration $240$315<br>h.g. Controlled substances registration $180$235<br>i.h. Approval of a pharmacy technician training program $75$100<br>j.i. Approval of a repackaging training program $50$65 |

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| | | *All reinstatement fees were increased by 30%.*<br><br>Subsection G. Application for change or inspection fees for facilities or other entities.<br>1. Change of pharmacist-in-charge $50$65<br>2. Change of ownership for any facility $50$65<br>3. Inspection for remodeling or change of location for any facility $150$300<br>4. Reinspection of any facility $150$300<br>5. Board-required inspection for a robotic pharmacy system $150$300<br>6. Board-required inspection of an innovative program location $150$300<br>7. Change of pharmacist responsible for an approved innovative program $25$35<br><br>*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%.*<br><br>H. Miscellaneous fees.<br>1. Duplicate wall certificate $25$50<br>2. Returned check $35<br>3. Duplicate license or registration $10$15<br>4. Verification of licensure or registration $25$35<br><br>*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.)*<br>*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 |

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| | | renewal fee shall not exceed ~~$200~~$260 per approval period.<br><br>*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, section 20 | Sets out all fees associated with permits, registrations, or licenses for manufacturers, wholesale distributors, warehousers, or third-party logistics providers | All fees in section 20 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. |