Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq. 18 VAC 110-30-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy Regulations Governing Physicians Selling Drugs
Action Title:	Fee increase
Date:	9/30/02

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

Amendments to regulation are adopted in order to increase certain fees for the regulants of the Board, including pharmacists and pharmacies, as necessary to provide sufficient funding for the licensing, inspection and disciplinary functions of the Board. The Board has reduced the proposed fees by 10%, so an annual renewal fee for a pharmacist or for a physician selling drugs would be increased from $50 to $90 (rather than $100) and for a pharmacy from $200 to $270 (rather than $300). Other fees would be increased correspondingly.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

In the adoption of final regulations, the Board has made changes to the proposed regulations by reducing the proposed renewal fees by 10%. Other fees that are based on the renewal fee, such as the application fees, late fees, and reinstatement fees are also reduced accordingly.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On September 30, 2002 , the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy, in order to implement a fee increase as required by law as necessary to have sufficient funds to meet expenditures.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

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

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the*

same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.

12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The specific statutory mandate for an increase in fees is found in § 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.

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the amended regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

§ 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. At the close of the 2000-2002 biennium, the Board of Pharmacy had actual revenue of $1,138,846 and expenditures of $1,1393,931. Expenditures will continue to exceed revenue, so by the end of FY 03, a deficit of ($521,858) is projected and by the end of FY 04, a deficit of ($1,1898,126) is projected. Since the fees from licensees will no longer generate sufficient funds to pay operating expenses for the Board, a fee increase is essential.

The purpose of the amendments is to establish fees sufficient to cover the administrative and disciplinary activities of the Board of Pharmacy. Without adequate funding, the licensing of practitioners and pharmacies by the Board and the inspections required for opening or remodeling a pharmacy could be delayed. In addition, sufficient funding is essential to carry out the inspections, investigative and disciplinary activities of the Board in order to protect the public health, safety and welfare.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

Section 20 is being amended to comply with a statutory mandate for the Board to provide sufficient funding to cover expenses related to licensing, inspections, investigations and disciplinary proceedings. Renewal fees for pharmacists and for physicians selling drugs will increase from $50 to $90 per year; renewal fees for pharmacies will increase from $200 to $270 per year. Most of the fees charged to applicants, licensed pharmacists and other pharmacy facilities are being increased accordingly.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

1) The primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions:

Fee increases proposed by the Board of Pharmacy should have no disadvantage to the consuming public. There is no projection of a reduction in the number of applicants for licensure or the number of licensed persons available to provide pharmaceutical services to the public. For example, an increase in the biennial renewal fee will result in an additional $40 per year for a pharmacist license and $70 per year for a pharmacy permit. It is not anticipated that the proposed fee increases will have any effect on prescription drug prices for consumers.

There would be considerable disadvantages to the public if the Board took no action to address its deficit by increasing its fees to cover expenses. The only alternative currently available under the Code of Virginia would be a reduction in services and staff, which would result in delays in licensing applicants who would be unable to work and delays in approval or disapproval of candidates to sit for examinations. Since a pharmacist earns an average of $300 for an 8-hour day of work, even a one-day delay in RPH licensing could result in a loss of income greater than the increase in the application fee. Likewise, the cost of a delay in issuing a pharmacy permit would far exceed the additional application cost of $70. If an opening is delayed, the pharmacy would lose revenue from the sale of prescription and over-the-counter drugs but would still incur costs for leasing, personnel and promotional advertising.

Potentially, the most serious consequence would be a reduction in or reprioritization of inspections intended to detect diversion from or irregularities in the inventories of controlled substances and of investigation of complaints against pharmacists and pharmacy permit holders. In addition, there

may be delays in adjudicating cases of substandard practice, resulting in potential danger to the patients in the Commonwealth.

Practitioners and facilities licensed by the Board of Pharmacy will experience increased renewal fees under the amended regulations. While that is a disadvantage to the licensees, the alternative of reduced services for the Board would be unacceptable to applicants, licensees and the general public. As a special-fund agency, renewal fees pay the vast majority of the expenses of Board operations, which include inspections, investigation of complaints, adjudication of disciplinary cases, review and approval of applicants, verification of licensure and education to other jurisdictions and entities, and communications with licensees about current practice and regulation.

2) The primary advantages and disadvantages to the agency or the Commonwealth:

As is stated above, the consequence of not increasing fees of the Board of Pharmacy would be a reduction in services and staff, resulting in delays in licensing, reductions or delays in the cases investigated and brought through administrative proceedings to a hearing before the Board and fewer inspections of pharmacies by the Department. The Board and the Department of Health Professions are solely funded by the fees charged to applicants and licensees. If higher fees are not adopted, the agency would have to cut its staff, both within the Board of Pharmacy and within other divisions of the Department of Health Professions since the agency is dependent on revenues from the Board for approximately 7.3% of its costs.

3) Other pertinent matters of interest to the regulated community, government officials, and the public:

During the development of the NOIRA and proposed regulations, representatives of various pharmacy groups and the Virginia Pharmacist Association have been present; yet there was no comment from interested parties during the 30-day comment period on the NOIRA. While the regulated community will not welcome a significant increase in fees, the Board believes that it will recognize that there has not been an increase in fees for 13 years, during which time the consumer price index has risen approximately 37.4 percent. For the past several years, expenditures of the Board have exceeded revenue, but surpluses of previous years have delayed the need for a fee increase. By the conclusion of FY 03, the carry-over income will be exhausted and the Board will experience a deficit which will carry over to FY 04 and beyond.

Other government entities and officials could be affected by any potential staff reductions at the Board because the Executive Director and pharmacy inspectors currently participate as members of numerous committees and task forces. Any reduction in staff resulting from insufficient funding would mean a reduction in the Board's ability to provide expertise in these types of operations and exercises.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on July 15, 2002. Public comment was requested for a 60-day period ending September 13, 2002. There was no written or electronic comment.

A Public Hearing before the Board was held on August 19, 2002, at which time there was comment from two persons on the proposed fee increases.

1) Tom Stallings, representing the Virginia Association of Chain Drug Stores, expressed appreciation to the Board for keeping fees stable for a number of years and recognized the need for a fee increase at this time. He stated that the proposed fee for pharmacies would be the highest in the country, and the fee for pharmacists would be the eighth highest. He requested that the Board reexamine the revenue and expenditures to determine whether the proposed increase was necessary. He also requested that the fees for pharmacy technicians be kept low, at $25 or less.

Board response:

The Board concurs with the comment that fees have been stable. In fact, there has been no increase in fees for 13 years, and there was a one-time fee reduction during that period. As to fees in other states, there are five other states with fees equal to or greater than the proposed fee for pharmacies in Virginia (many states add a controlled substance registration fee that must be paid with the renewal). There are thirteen other states with fees higher than the proposed fee for pharmacists in Virginia. The Board has reexamined the revenue and expenditures for this fiscal year and projections for the next biennium and determined that the increased fees will result in sufficient revenue without exceeding a 10% surplus of revenue over expenditures. The Board is required by law to review its account at the close of any biennium and revise fees to insure that fees are sufficient but not excessive to cover expenses.

The Board did revise its figures for FY02 to reflect actual revenue and expenditures and requested the Finance Office of the Department to reexamine the allocated costs for the Board over the next two fiscal years. The resulting analysis indicated that proposed fees could be reduced by 10% without creating a deficit in spending by the end of FY04.

2) Becky Snead, representing the Virginia Pharmacists Association, told the Board that she had discussed the proposed fees with pharmacists in all regions of the state and had received no opposition. Pharmacists recognize the need to cover expenses of the Board. She did urge caution in the future if the need for fee increases should arise again.

Board response:

The Board appreciates the efforts of the VPHA to circulate information about the proposed fee increase and is cognitive of the need to keep control on expenditures to avoid another increase in the near future.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the

proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy

18 VAC 110-20-20. Fees.

Amendments are proposed to establish the fees as follows:

B. Fees for initial pharmacist licensure.

- An application fee will increase from $50 to $180, but may now include up to 15 months of licensure prior to the first renewal, the wall certificate, the license as well as a review of credentials (approximately 200 per year).
- The application fee for a person whose license has been revoked or suspended indefinitely will increase from $300 to $500 to more accurately reflect the actual cost of an investigative report and hearing (approximately 4 per year).

C. Renewal of pharmacist license.

- The annual renewal fee for an active pharmacist license will increase from $50 to $90 (approximately 7800 per year).
- The annual renewal fee for an inactive pharmacist license will increase from $35 to $45 or approximately ½ of the active license (approximately 800 per year).
- The fee for a late renewal within the first 60 days will increase from $25 to $30 or approximately 1/3 of the renewal fees (approximately 75 per year).
- The fee for reinstatement of a license lapsed beyond 60 days includes a delinquent fee, which is increased from $50 to $70 (approximately 20 per year).

D. Fees for other licenses, permits or facility registrations.

- The fee for an application, change of ownership or renewal of a permit for a pharmacy, a non-resident pharmacy, a permitted physician, a non-restricted manufacturer, a wholesale distributor, a non-resident wholesale distributor, or a warehouser will increase from $200 to $270 to cover the cost of inspections conducted when a facility opens for business or changes ownership and approximately every two years thereafter (approximately 100 applications per year).
- The fee for an application, change of ownership or renewal of a permit for a restricted manufacturer or medical equipment supplier will increase from $150 to $180 (approximately 20 applications per year).
- The fee for a humane society will increase from $10 to $20 (approximately 45 per year).
- The fee for applying to change the pharmacist-in-charge registered with the Board will increase from $25 to $50 (approximately 300 per year), and the fee for an inspection necessary for a change of location or remodeling will increase from $100 to $150 (approximately 60 per year).
- Late fees for renewal of a facility permit will be approximately 1/3 of the renewal fee. For example, the late fee for a pharmacy, nonrestricted manufacturer, wholesale distributor, warehouser or permitted physician will be $90 (approximately 25 per year) and for a medical equipment supplier or restricted manufacturer will be $60 (approximately 30 per year).
- The fee for reinstatement of a pharmacy license or permit lapsed beyond 60 days includes a delinquent fee, which is increased from $50 to $150 (approximately 20 per year).

E. Controlled substances registration.

- The application and annual renewal fee for a controlled substances registration will be increased from $20 to $90 to cover the cost of an inspection (approximately 350 per year).
- A late fee of $30 is charged for renewal within 60 days of the expiration date (approximately 20 per year).
- The fee for reinstatement of a controlled substances registration lapsed beyond 60 days includes a delinquent fee, which is increased from $25 to $35 (approximately 5 per year).

F. Other fees.

- The fee for a returned check will increase from $15 to $25, consistent with all other Boards within the Department and will the actual costs for processing and rebilling (approximately 3 per year).
- There are no changes in the fees for a wall certificate, Board approval of an individual CE program, or an inspection of a robotic pharmacy system as these fees are already in line with actual cost.

18 VAC 110-30-10 et seq. Regulations Governing Physicians Selling Drugs

18 VAC 110-30-15. Fees.

B. Fees for initial license for practitioner of the healing arts to sell controlled substances.

- The application fee for a person whose license has been revoked or suspended indefinitely will increase from $300 to $500 to more accurately reflect the actual cost of an investigative report and hearing.

C. Renewal of practitioner license.

- The annual renewal fee for an active license will increase from $50 to $90 (approximately 250 per year).
- The fee for a late renewal within the first 60 days will increase from $25 to $30 or approximately 1/3 of the renewal fees (approximately 5 per year).
- The fee for reinstatement of a license lapsed beyond 60 days includes a delinquent fee, which is increased from $50 to $70 (included in totals for pharmacists - approximately 20 per year).

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability. There will be a modest impact on disposable family income, as pharmacists and pharmacies will experience an increase in the cost of licensure. Compared to other costs of doing business, such as finding and

hiring qualified personnel, third party billing and purchasing prescription drugs, licensure fees are relatively insignificant.