Virginia Regulatory Town Hall

Proposed 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:	

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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. An annual renewal fee for a pharmacist or for a physician selling drugs would be increased from $50 to $100 and for a pharmacy from $200 to $300. Other fees would be increased correspondingly.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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 and levy fees.

§ 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 proposed 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 proposed 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. It is projected that by the close of the 2000-2002 biennium, the Board of Pharmacy will incur a deficit and that the Board will continue to have a deficit through the next biennium. 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 proposed 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 providing detail of the regulatory action's changes.

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 $100 per year; renewal fees for pharmacies will increase from $200 to $300 per year. Most of the fees charged to applicants, licensed pharmacists and pharmacy facilities are being increased accordingly.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 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 $50 per year for a pharmacist license and $100 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 $100. 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 proposed 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 12 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 02, the carry-over income will be exhausted and the Board will experience a deficit which will carry over to FY 03 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than $2,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be pharmacies

Estimate of number of entities to be affected:

Currently, the following are licensed or registered by the Board:

Pharmacists	8218
Pharmacy interns	873
Permitted physicians	15
Pharmacies	1524
Business controlled substance registrations	287
Humane societies	47
Medical equipment suppliers	259
Non-resident pharmacies	347
Non-resident wholesale distributors	389
Non-restricted manufacturers	19
Restricted manufacturers	68
Warehousers	25
Wholesale distributors	160
Physicians selling drugs	171

Projected costs to the affected entities:

The cost for compliance will depend on the type of license or registration held and the particular fee being paid. For example, if a pharmacist pays his renewal before the expiration date, he will pay $100; if the renewal fee is late, he will owe an additional $35. For the projected costs to each of the affected entities and a projection of the number of persons or entities that will be affected, see a description of the changes below.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed 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 $200, 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 $100 (approximately 7800 per year).
- The annual renewal fee for an inactive pharmacist license will increase from $35 to $50 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 $35 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 $300 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 $200 (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 $100 (approximately 25 per year) and for a medical equipment supplier or restricted manufacturer will be $65 (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 $100 to cover the cost of an inspection (approximately 350 per year).
- A late fee of $35 is charged for renewal within 60 days of the expiration date (approximately 30 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 $100 (approximately 250 per year).
- The annual renewal fee for an inactive pharmacist license will increase from $35 to $50 or approximately ½ of the active license (included in totals for pharmacists – approximately 800 per year).
- The fee for a late renewal within the first 60 days will increase from $25 to $35 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).

Alternatives

Please describe the specific 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.

In the Code of Virginia, § 54.1-2400 requires the Board 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*" and § 54.1-3307 mandates the Board to maintain "*the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered*." In order to carry out its statutory mandates to protect the supply of prescription drugs and devices and to levy sufficient fees to cover the direct expenses of the Board of Pharmacy and the departmental expenses allocated to the Board, an increase in fees was necessary.

Funding from fees failed to keep up with expenditures in the past biennium ('98 – '00). The annual renewal fee for pharmacists or for physicians selling drugs in their practices is $50 each year, and for licensed pharmacies, it is $200. Those fees **have not been changed since 1989**. (There was a one-time fee reduction in 1994 to eliminate a surplus in revenue.) Since the Board had accumulated a surplus from prior years, it has been able to avoid a fee increase up until now. In 1999, a NOIRA was published notifying the public and licensees that the need for a fee increase was projected. By the end of fiscal year '99, the Board had under-spent its budget by $107,874 and revenue realized was in excess of the estimate. Those combined factors made it unnecessary to go forward with increased fees at that time

For FY '02 (from 7/1/01 through 1/31/02), the revenue collected is $1,049,377, and the Board's projected budget is $1,767,864. While there may be a small amount of additional revenue to be collected from applications and miscellaneous fees, all renewal fees, which represent the bulk of the Board's revenue, have been collected. Even with the balance carried forward from previous biennial budgets of $440,611, it is likely that the Board will incur a deficit of approximately $277,876 by June 30, 2002.

Renewal fees in other states

Comparative data on pharmacy fees in other states would indicate that renewal fees in Virginia are among the lowest in the nation. Among the 50 states, **36 have a higher renewal fee for pharmacists**, ranging up to $150/year in ND and $125 in WA; ten states' renewal fees are lower; and three states are identical to Virginia. Fees for renewal of a pharmacist license in neighboring states for are: - $110/annual in NC, $150/biennial in MD, $80/annual in KY, and $50/annual in WV. Fees for renewal of a wholesale distributor license in neighboring states are: $350/annual in NC, $500/annual in MD, $100/annual in KY, and $400/annual in WV. Fees for renewal of a pharmacy license in neighboring states are: $125/annual in NC, $250/annual in MD, $100/annual in KY, and $75/annual in WV. However, in Virginia the pharmacy renewal fee **includes the cost** of a controlled substance registration and the cost of the biennial inspection, which is estimated to be $400.

Renewal Schedule

All persons and entities regulated by the Board of Pharmacy renew their licenses or permits annually by December 31st. **Regulations need to be in effect before the end of 2002** to address the anticipated deficit from the 2000-2002 biennium and prevent an even greater deficit from occurring by the end of the 2002-2004 biennium. If deficits are allowed to accumulate, additional fee increases will definitely be needed to keep up with expenditures.

Options for fee increases

The Board considered three proposals for increasing fees. The bulk of the income is derived from renewal fees, and the renewal fee is used as the basis for calculating the appropriate amount of other fees including those for applications, late renewal and reinstatement. The first option was to increase the renewal fee for a pharmacist from $50 to $100 and a pharmacy from $200 to $300; fees for other facilities would only be increased by $50 or would not be increased at all. With option #1, the resulting **deficit** at the end of FY 04 would be approximately $500,000. Option #2 proposed an increase in pharmacist renewal fees from $50 to $75 and increases of $50 in facility fees. The resulting **deficit** at the end of FY 04 would be approximately $1,100,000. The Board found both options unacceptable.

Option #3 was adopted with the proposed fees detailed in the section of changes above. That option will result in an estimated deficit of $277,876 by the end of FY 02. With the fee increase, the revenue of the Board for FY03 is projected to be $1,845,925. However, with the expected move of the Department in FY03 to new offices, the budget of the Board will increase to approximately $1, 915,830 for that year, resulting in a continuation of the deficit. By FY04, the

revenue is anticipated to exceed expenditures ($1,868,675 in revenue versus $1,817,401 in expenditures). Since the Board will carry forward a deficit from the previous two fiscal years, it will continue to have a deficit of approximately $296,507 by the end of FY04. While the Board was concerned about the continuation of deficit spending, it was reluctant to increase fees above the proposal in Option #3. Since the Board has historically under-spent its budget in the direct costs portion and conservatively estimated its revenue, it is anticipated that the deficit may be less than projected by the end of FY04.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the Board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the Board. Public comment was received until November 21, 2001. During the 30-day comment period, no comments were received from members of the public.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The proposed regulations were considered in an open meeting with a number of persons representing various pharmacy groups present. There were no questions or comments about the need for clarification. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations are currently under review and will be reviewed again during the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.