



**Virginia  
Regulatory  
Town Hall**

**Notice of Intended Regulatory Action  
Agency Background Document**

<b>Agency Name:</b>	Board of Pharmacy, Department of Health Professions
<b>VAC Chapter Number:</b>	18 VAC 110-20-10 et seq. 18 VAC 110-30-10 et seq.
<b>Regulation Title:</b>	Regulations Governing the Practice of Pharmacy Regulations for Physicians Selling Drugs
<b>Action Title:</b>	Increase in fees
<b>Date:</b>	5/1/2001

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

**Purpose**

*Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.*

The issue to be addressed is the need of the Board of Pharmacy to increase their fees to cover expenses for essential functions of licensing, investigation of complaints against pharmacists, adjudication of disciplinary cases, and the pharmacy inspections required for the safety of the drug supply in the Commonwealth.

In its analysis of the funding under the current fee structure for programs under the Board of Pharmacy, the following deficit has been projected:

<b><u>FY Ending</u></b>	<b><u>Board</u></b>	<b><u>Amount</u></b>	<b><u>Percent</u></b>
6/30/02	Pharmacy	-\$772,881	-20.89%

§ 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, consideration of a fee increase is essential.

No preliminary regulatory language has been developed; the agency will develop alternative fee structures that will address the deficit in funding for the Board to consider in its adoption of proposed regulations.

### Basis

*Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.*

**18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy and 18 VAC 110-30-10 et seq. Regulations Governing Physicians Selling Drugs** 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 **contemplated regulation is mandated by § 54.1-113**; however the Board must exercise some discretion in the amount and type of fees that will be increased in order to comply with the statute.

*§ 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.*

**Substance**

*Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.*

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

In June 2000, the expenditure and revenue summary showed that the Board had overspent the annual budget for enforcement by \$130,674 due to a revised inspection policy. Although the Board under-spent in other budget categories, the result was an annual balance of (\$30,564). For FY '01 and FY '02, the projected revenue is \$2,078,380, and the Board's projected budget is \$3,699,925. Even with the balance carried forward from previous biennial budgets, it is likely that it will incur a deficit in excess of 20% by 2002.

Attached is a chart of expenditures and revenues of the Board for the past fiscal year and a chart showing the projected revenue balance for June 30, 2002.

**Renewal Fees and Consumer Price Index (CPI) Adjustments 1990 - 2000**

During the period 1990 to January, 2001, the CPI has increased approximately *37.4 percent* while renewal fees for pharmacists and pharmacies in Virginia **have not been increased** during that same period of time.

**Biennial Renewal Fees for regulants of the Board of Pharmacy**

<b>Occupation</b>	<b>Current fee</b>	<b>FY '98</b>	<b>FY '96</b>
Pharmacist	<b>\$50</b>	<b>\$50</b>	<b>\$50</b>
Physicians selling drugs	<b>\$50</b>	<b>\$50</b>	<b>\$50</b>
Pharmacy, non-restricted manufacturer, warehouse, wholesale distributor	<b>\$200</b>	<b>\$200</b>	<b>\$200</b>
Restricted manufacturer, medical equipment supplier	<b>\$150</b>	<b>\$150</b>	<b>\$150</b>

Humane society	\$10	\$10	\$10
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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, \$95/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, \$250/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, \$150/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.

**Need for Fee Increases**

Fee increases are related to increased need for funds for staff pay and related benefit increases over the past few years and for the general costs of doing business, such as operation of the DHP data system and the health practitioner intervention program. Other costs are specifically related to the Board of Pharmacy. For example, in the '98-'00 biennium the Board overspent its budget for enforcement (which includes inspections of facilities) by \$101,673. Inspections have been established on a regular two-year schedule for all facilities and are now conducted routinely. Since there was a backlog of facilities that needed to be inspected, there was a 30% increase in the number of inspections from 1999 to 2000. Likewise, there was a 43% increase in the number of inspections required for remodeling or changes to the facility. The annual renewal fee for a facility is set at \$200; it costs approximately \$400 to conduct a routine inspection every two years. Therefore, the facility renewal fee may cover the inspection cost but covers none of the administrative cost of licensing, investigations, or disciplinary proceedings.

Fee increases for some categories of licensees regulated by the Board of Pharmacy are necessary in order for the Board and the Department to continue performing essential functions of licensing new pharmacists and pharmacies and of protecting the public from continued practice by incompetent or unethical practitioners and diversion of drugs. Ensuring the safety, integrity and efficacy of the drug supply in the Commonwealth is, in part, the responsibility of the Board – having sufficient funding to carry out its statutory mandate is essential to the public’s health, safety and welfare.

**Renewal Schedule**

All persons and entities regulated by the Board of Pharmacy renew their licenses or permits annually by December 31<sup>st</sup>. Regulations would need to be in effect in 2002 in order 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 would be needed in the future to keep up with current expenditures.

## Alternatives

*Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.*

In 1999-2000, the department considered **three** possible solutions to the deficits incurred by several boards. Those same options are available to the Board of Pharmacy and are as follows:

### **1. Increase fees through the promulgation of regulations.**

As required by law, the Board is obligated to establish and collect fees that are necessary to fund operations of the Board and the Department. An alternative is to seek the revenue from licensees and applicants to fully fund appropriated expenditures. Costs of services will be paid by patients who use the services of providers, but licensure fees represent a miniscule percentage of the over-all costs of health care. The cost of operation of regulatory boards does not significantly affect the cost or access to health care. However, failure to fully fund the licensing and disciplinary services through fees will have a detrimental affect on quality and availability of care.

### **2. General Fund Support.**

If the alternative is not to increase professional fees to meet increased cost of operations, then the only other source of funding the cash deficit is the General Fund. To permit General Fund support, the *Code of Virginia* would need to be amended to allow such funding as the *Code* restricts board revenue to fees. There are, however, potential and serious consequences with General Fund support.

1. Increasing General Fund support as more boards acquire deficits in the future.
2. Negative public reaction.
3. The use of general revenues (taxes) to support health regulatory boards which does not target costs to providers and consumers of services.

### **3. Reduce department/board operations and staff and remain at current fee level.**

In order to prevent deficit spending, the department would basically need to lay off staff to reduce expenses associated with operations. The net result being a delay in the performance of or the elimination of the following responsibilities:

- **Investigations and discipline**
- **Examinations leading to license**
- **License renewals**
- **Regulation**
- **Inspections and approvals of new facility permits**

Delays in licensing and investigation could place the general population at health risk as pharmacists who should not be practicing would continue to practice, pharmacies with poor security or risky filling and dispensing habits would remain undisciplined and the opening of new pharmacies would be delayed or curtailed. It is believed that these consequences would not be acceptable to the administration, the General Assembly, or to the general public.

### Family Impact Statement

*Please provide a preliminary analysis of the potential impact of the proposed 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.*

The proposed regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, or strengthen or erode the marital commitment. There will be a modest decrease in disposable family income depending on the category of licensure, the type of fees that may be increased and amount of that increase.