

**PRELIMINARY DETERMINATION
NOTICE OF INTENDED REGULATORY ACTION**

**DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF PHARMACY
18 VAC 110-20-10 et seq.
18 VAC 110-30-10 et seq.**

ITEM 1: LEGAL AUTHORITY THE REGULATION

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 which 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.

ITEM 2: POTENTIAL ISSUES TO BE ADDRESSED

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:

<u>FY Ending</u>	<u>Board</u>	<u>Amount</u>	<u>Percent</u>
6/30/02	Pharmacy	-\$155,900	-6.0%

§ 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 deficits in 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 which will address the deficit in funding for the Board to consider in its adoption of proposed regulations.

ITEM 3: REASONING FOR THE CONTEMPLATED REGULATION

Despite the efficiencies and reductions in staff (MEL from 132 to 119) which the Department and the Board have undertaken in the past five years, funding from fees has failed to keep up with expenditures. The annual renewal fees for pharmacists and for physicians selling drugs in their practices are \$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.)

Renewal Fees and Consumer Price Index (CPI) Adjustments 1990 - 1999

During the period 1990 – 1999, **the CPI has increased approximately 39 percent while health professional renewal fees in Virginia have increased on average 17 percent.**

Biennial Renewal Fees for regulants of the Board of Pharmacy

Occupation	Current fee	FY '98	FY '96
Pharmacist	\$50	\$50	\$50
Physicians selling drugs	\$50	\$50	\$50
Pharmacy, non-restricted manufacturer, warehouse, wholesale distributor	\$200	\$200	\$200

Restricted manufacturer, medical equipment supplier	\$150	\$150	\$150
Humane society	\$10	\$10	\$10

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, **39 have a higher renewal fee for pharmacists**, ranging up to \$150/year in ND and \$125 in WA; ten states' renewal fees are lower. Fees in neighboring states for are: - \$110/annual in NC, \$95/biennial in MD, \$70/annual in KY, and \$30 in WV.

Renewal Schedule

All persons and entities regulated by the Board of Pharmacy renew their licenses or permits annually by December 31st. Regulations would need to be in effect before October 1, 2000 in order to prevent a deficit from occurring by the end of the 2000-2002 biennium. If deficits are allowed to accumulate, additional fee increases would be needed in the future to keep up with current expenditures.

Need for Fee Increases

Fee increases are related to increased need for funds for staff pay and related benefit increases included in the Governor's budget and for the general costs of doing business beyond the department's control (Y2K compliance, the health practitioner intervention program, installation of new computer system, etc.) Attached is a chart of expenses, revenues and the percentage of deficit which is projected for the next two biennia.

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. The renewal fee for physicians selling drugs has always been the same as the renewal fee for pharmacists. In effect, those physicians (233 in the state) have a license to operate a small pharmacy out of their offices.

ITEM 4: ALTERNATIVES CONSIDERED

The department considered **three** possible solutions to the deficits in the Board of Pharmacy.

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 (\$12.5 million annually for over 230,000 providers) will not affect the cost or access to health care. However, failure to fully fund the services through fees will have a detrimental affect on quality.

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 general, the Department's overall expenditures have been very moderate over the past six years. Total expenses for FY 93 were \$8.2 million, for FY 98 \$10.6 million an increase of 29.2 percent for the period or just under *4.5 percent each year*, just slightly more than the amount of employee pay raises and benefit increases for the period.

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 pharmacy 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.

Department of Health Professions
Schedule for Promulgation of Regulations on Fees for the
Virginia Board of Pharmacy

Submission of pre-NOIRA to DPB & SHHR	3/8/99
Submission of NOIRA to Register	3/24/99
Publication of NOIRA	4/12/99
End of 30-day Comment Period	5/12/99
Adoption of proposed regulations	6/15/99
Pre-Submission packages to DPB & SHHR	7/15/99
Submission of proposed regulations to Register	9/22/99
Publication of proposed regulations	10/11/99
End of 60-day comment period	12/11/99
Adoption of final regulations	2/15/00
Submission of final regulations to Register	3/1/00
Publication of final regulations in Register	3/20/00
Final effective dates	4/20/00