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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC 110-20-10 et seq. 18VAC110-30-10 et seq. 18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations for Practitioners of the Healing Arts to Sell Controlled Substances Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Increase in fees
Date this document prepared	9/27/17

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.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The issue to be addressed is the need of the Board of Pharmacy 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 will no longer generate

sufficient funds to pay operating expenses for the Board in the next biennium, consideration of a fee increase is essential. In order to have sufficient funding for the operation of the Board by fiscal year 2019-20, it is necessary to begin the process of promulgating amendments to regulations.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency'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 **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.*

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

Fees charged to applicants and licensees of the Board of Pharmacy have not been increased in 15 years, effective 12/4/02. During that time period, there have been two reductions in renewal fees (2005 and 2009). The number of regulated entities has substantially increased in recent years, to the need for additional staff has increased costs to the Board. Additionally, the cost of inspections has increased as have expenditures for investigation and adjudication of disciplinary cases. 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 ($7,200,032) are projected to exceed revenue ($6,405,058) 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 2020 of (- $261,232). Since it typically takes two years to four years to promulgate regulations for a fee increase, Pharmacy must begin the process of amending regulations to avoid the additional fee assessments that other boards had to adopt.

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 that are being considered, the substantive changes to existing sections that are being considered, or both.

At this time, no specific 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. The board will apply the Principles for Fee Development adopted by the agency in 1999 and amended in 2010 to ensure equitable distribution of costs and fees that are proportional to the activities they support.

Alternatives

The Department of Health Professions could consider two possible solutions to the anticipated deficit of the Board; they 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 consumers 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 effect on quality and availability of services.

2. Reduce department/board operations and staff and remain at current fee level.

In order to prevent deficit spending, the department would 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
- Inspections of pharmacy facilities
- Examinations leading to license
- License renewals
- Regulation

Delays in licensing, inspections, and investigation 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.

The Board of Pharmacy has been understaffed; any further reduction would be extremely detrimental to the public. The option of reductions in board operations and staffing would result in substantial delaying in adjudication of disciplinary cases and delays in or curtailment of inspections; the Board finds such an option to be unacceptable.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or

by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.

A regulatory panel will not be used to develop proposed regulations.