Virginia Regulatory Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq. 18VAC110-50-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Addition of certain administrative fees
Date this document prepared	2/28/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The amendments to Chapters 20 and 50 will authorize the Board to charge an administrative fee for providing duplicate licenses (including permits and registrations) and a fee for verification of licensure (including permits and registrations). There is a need to recover the cost of providing these administrative functions to regulants who need additional services requiring staff time, computer costs and/or postage expense.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and levy fees as sufficient to cover all expenses for the board:

§ 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 or the issuance of a multistate licensure privilege 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…

Need

Please detail 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, delineate any potential issues that may need to be addressed as the regulation is developed.

In order for the Board of Pharmacy to meet its statutory responsibilities of licensure, inspection and discipline, it is necessary to establish fees sufficient to cover administrative costs. Currently, persons or entities that require additional services of providing duplicate licenses or verification of licensure to another regulatory body do not pay a fee, so the board is not upholding its statutory responsibility to cover the costs of providing that service. Sufficient funding is essential in order for the board to carry out its function of protecting the safety and integrity of prescription drugs in the Commonwealth.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The substance of the amended regulation is to establish fees sufficient to cover administrative costs relating to verification of licenses, permits and registrations and for the issuance of a duplicate license, permit or registration. The proposed fee will be $10 for a duplicate license and $25 for verification of licensure.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no alternatives to the proposal, other than to continue providing services to some individuals that are supported by the licensure fees of all pharmacists and pharmacies. All other boards at DHP have fees for providing duplicate licenses or verification of licensure. The amounts proposed are less that some boards (Dentistry - $20 for duplicate license; $30 for verification; Funeral - $15 for duplicate; $50 for verification; proposed Nursing - $15 for duplicate license; $35 for verification). Since verification of licensure can be done on the Department website; it is not necessary for persons or institutions to call the board office for that information or request verification in writing. Some states are now restricting licensure verification to electronic verification only to contain costs, so the Board of Pharmacy can only continue to provide that service upon payment of a $25 fee to minimally cover the costs for handling such requests.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) 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 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website, www.townhall.virginia.gov, or by mail, email, or fax to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233. 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 on proposed regulations and notice of the hearing will be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in

the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The proposed regulation has been developed after a review of fees charged by other boards and an estimate of actual costs to the board for provision of additional administrative services.

Family impact

Assess 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.

There is no impact on the family.