Virginia Regulatory Town Hall

townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Addition of two administrative fees
Date this document prepared	6/9/11

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.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The amendments to Chapters 20 and 50 will authorize the Board to charge an administrative fee of $10 for providing duplicate licenses (including permits and registrations) and a fee of $25 for verification of licensure (including permits and registrations), which is the least amount charged by every other health regulatory board at the Department of Health Professions.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

None

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., the 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…

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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 briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The amendments to Chapters 20 and 50 will authorize the Board to charge an administrative fee of $10 for providing duplicate licenses (including permits and registrations) and a fee of $25 for verification of licensure (including permits and registrations).

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) There are no primary advantages to the public; individuals who need duplicate licenses or registrations will have to pay $10 for the service provided. Since licensure verification can be accomplished on-line, it should not be necessary for a hard-copy verification, but if requested, there would be a $25 charge.
2) The advantage of two fees for the agency is realization of a small amount of revenue for special services provided upon request.
3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, 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 date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements create the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically fees it charges to practitioners or entities for necessary functions of regulation. There would be a one-time expense of less than $500 for promulgation of the amended rule. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The individuals affected by the regulation would be persons who: 1) have lost their license or registration or who need a duplicate original license or registration; and 2) seek verification of a current

	license, permit or registration.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	It is unknown how many persons would be affected by a duplicate license or verification fee since the Board does not currently charge a fee or track the number of requests. Staff estimates that they provide 10 to 20 duplicate licenses per week and respond to 20 to 30 requests for verification. Of the requests for verification, some would come from large health care entities; the others from individuals or small businesses. Verification of a current license, registration or permit may be accomplished on the Department of Health Professions website without an entity incurring a fee.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The projected costs would depend on the services requested - $10 for a duplicate; $25 for verification.
Beneficial impact the regulation is designed to produce.	A revenue source for the Board of Pharmacy that *every other board at the Department now has in their budget*. Currently, these special services are provided upon request and are paid for by all licensees with their renewal fees.

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no viable alternatives to the proposal.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5)

the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

Since there is a specific statutory mandate for the promulgation of regulations in establishment of fees, there are no alternative methods consistent with health, safety and welfare that will accomplish the objectives of applicable law.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

The Notice of Intended Regulatory Action was published and provided to the public participation mailing list on April 11, 2011 with comment requested until May 11, 2011. No comment was received.

Family impact

Please assess the 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

Current section number	Current requirement	Proposed change, rationale, and consequences
Chapter 20, Section 20	Establishes fees for permitting, licensure and registration	In subsection H, Miscellaneous fees, two fees are added for provision of a duplicate license or registration and for verification of licensure or registration. *Both of these serves are currently provided by the board at no charge, but the demand has increased with the registration of pharmacy technicians so the board is using more staff and fiscal resources to fill*

		the demand. Unlike other boards, Pharmacy has not had such fees because there were relatively few requests for duplicates or verifications.
Chapter 50, Section 20	Establishes fees for permitting of facilities	In subsection I, a fee is added for verification of a license or permit. *Verification is currently provided by the board a no charge, but there are costs incurred for responding to requests, completion of a verification form and mailing hard copy. Verification can be accomplished on-line without contacting the board; establishment of a fee for verification will not hinder an entity or individual from confirming currency of a license or permit. There are very few requests for duplicate licenses or permits by facilities, so no such fee was added in that chapter.*