



Virginia

Regulatory
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Final Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
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 Warehousemen
Action title	Addition of two administrative fees
Date this document prepared	September 9, 2014

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

On September 9, 2014, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy and 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen.

Legal basis

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

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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" 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 there are 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the text since publication of the proposed stage.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Comment on the proposed regulation was requested from 5/19/14 to 7/18/14; no comment was received. A public hearing was conducted on 6/4/14; there was no comment at the hearing.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Current requirement	Proposed change, rationale, and consequences
Chapter 20, Section 20	Establishes fees for permitting, licensure and registration	<p>In subsection H, Miscellaneous fees, two fees are added for provision of a duplicate license or registration and for verification of licensure or registration.</p> <p><i>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.</i></p>
Chapter 50, Section 20	Establishes fees for permitting of facilities	<p>In subsection I, a fee is added for verification of a license or permit.</p> <p><i>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.</i></p>