Virginia Regulatory Town Hall

townhall.virginia.gov

Fast Track 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
Action title	Non-resident renewal schedule & prohibition on suspended pharmacist in prescription department
Date this document prepared	6/10/14

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

An amendment to section 20 will change the schedule of renewal of permit for nonresident pharmacies from April 30th of each year to annually at the date of initial registration. An amendment to section 190 will prohibit a pharmacist from allowing access to the prescription department by a person whose license or registration has been revoked or suspended.

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.

PIC = Pharmacist-in-charge

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 taking the action, and (3) the title of the regulation.

On June 4, 2014, the Board of Pharmacy amended sections 20 and 190 of 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

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 establish renewal schedules:

> *§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:*
>
> *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…*

The specific authority to control prescription drugs in the Commonwealth is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

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 the regulation 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.

The purpose of the regulatory action in section 20 is to facilitate the work of Board in renewing the permits of nonresident pharmacies. A prerequisite for renewing a nonresident pharmacy is submission of a copy of a current inspection report from the state in which the pharmacy is located or from a duly authorized agency. Therefore, the renewal process for nonresident pharmacies is a labor-intensive, hands-on task. By tying the renewal to the date of initial

registration rather than a set date on the calendar, the task can be spread throughout the year and handled more expeditiously by staff of the Board. If there are any issues with the inspection report, staff will have more time to work with the nonresident pharmacies to resolve and meet the statutory requirements. Therefore, the change will facilitate renewals and avoid possible delays which could impact pharmacies that dispense prescriptions to patients in Virginia.

The purpose of the regulatory action in section 190 is to protect the security of the drugs in the prescription department. If a pharmacist, pharmacy technician, or pharmacy intern has had his license or registration suspended or revoked, he represents a risk to the dispensing work of the prescription department. There is opportunity for diversion or adulteration that could threaten the health and safety of a community. Therefore, the amendment would prohibit the PIC or pharmacist on duty from permitting such a person to have access to the prescription department or controlled substances.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The amendments are very straightforward and proposed to address specific problems recently encountered by the Board. The Board does not expect the rulemaking to be controversial so it adopted the proposed changes by a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

An amendment to section 20 on fees will change the renewal date for nonresident pharmacy from "no later than April 30" to no later than "the date of initial registration."

An amendment to section 190 on prescription departments will add a rule that a PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.

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) The primary advantage to the public is facilitation of renewal of nonresident pharmacy permits to avoid disruptions in dispensing of prescriptions for patients in Virginia. There is an advantage to the public if persons whose license or registration has been suspended or revoked are prohibited from access to controlled substances and the prescription department to avoid a risk of diversion or adulteration of drugs. There are no disadvantages.
2) The advantage to the agency is the ability to space out renewal of nonresident pharmacy permits which are time-consuming and labor-intensive. There are no disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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 requirements in this proposal more restrictive than 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.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, 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.

There are no regulatory methods that will accomplish the objectives of applicable law. Renewal schedules are set in regulation and can only be changed by an amendment to section 20. The Board could adopt guidance advising against giving access to persons whose license or

registration has been suspended or revoked, but such guidance would not be enforceable and therefore would not achieve the public protection intended.

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 requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The entities likely to be affected would be nonresident pharmacies. There may be a few independent pharmacy owners who would be affected by a prohibition against a pharmacist who has had his license suspended or revoked being in the prescription department.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	There are 505 nonresident pharmacies with a current permit to do business in Virginia. There is no information on how many would be considered small businesses. There is no estimate of the number of independent owners who may be affected; one in the past few months would fall into this category.
Benefits expected as a result of this regulatory proposal.	The primary benefit is a more orderly renewal process for nonresident pharmacies.
Projected cost to the state to implement and enforce this regulatory proposal.	There are no costs to the state.
Projected cost to localities to implement and enforce this regulatory proposal.	There are no costs to localities.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	Nonresident pharmacies would have a modest benefit in the implementation of a different renewal schedule because the new expiration date would be set to give every pharmacy the benefit of at least one year before expiration. For example, if a nonresident pharmacy permit currently is due to be renewed on April 30, 2015, but its date of initial registration was February 9th – the next renewal for that pharmacy would be February 9, 2016. The pharmacy would have an additional 9 months on its permit.

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.

No alternatives were considered. Both regulatory actions address problems the Board has recently encountered. The statutory requirement for a current inspection of nonresident

pharmacies was the result of legislation passed by the 2013 General Assembly, so the first renewal cycle the Board experienced was April of 2014. The requirement raised numerous questions from out-of-state pharmacies seeking to comply and renew – especially those that do sterile and non-sterile compounding and are required to show compliance with USP-NF standards. The process was highly labor-intensive and required a lot of time and effort that diverted staff from other responsibilities. By spreading out the renewal date and tying it to the date of initial registration, staff can more efficiently deal with renewals throughout the year.

In April of 2014, the Board revoked the license of a pharmacist who was found to be in violation of numerous laws and regulations. Subsequently, the Board recently reports that he was continuing to be allowed in the prescription department, which represents a potential danger to public health and safety. The amendment to section 190 is intended to make it clear that such a person is prohibited access.

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. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
20	Sets out the fees for renewal of licenses, permits and registrations	Changes the renewal deadline for nonresident pharmacies from April 30th of each year to an annual renewal on the date of initial registration. *The likely impact is more orderly and expeditious renewal of such permits.*
500	Sets out the requirements for the security of the prescription department	Adds a requirement that*: A PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.* Such a person potentially represents a risk to the drugs and to the safety of the dispensing process and therefore a risk to the public. The intent is to provide a clear prohibition for PIC's and pharmacists to follow.