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 18VAC110-50
Regulation title	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Change in renewal dates for pharmacies and permitted facilities
Date this document prepared	12/11/08

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

Chapter 330 (HB1129) of the 2008 Acts of the Assembly eliminated the specified date of December 31 for renewal of various permits and registrations under the Board of Pharmacy and added that a date must be determined by the Board in regulation. The second enactment on Chapter 330 required that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, emergency regulations are in effect but must be replaced by September 22, 2009.

All licenses, permits and registrations have expired on December 31st of each year, which has created an exceptional workload for staff during one period of time. The Board sought legislation to allow expiration dates for permitted or registered facilities to be set on dates different from those of licensed pharmacists or registered technicians to distribute the renewals.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

The legal authority to promulgate the proposed regulation is found in Chapter 330 of the 2008 Acts of the Assembly (HB1129): *§§ 54.1-3434, 54.1-3434.2, 54.1-3435, 54.1-3435.01, 54.1-3435.2, 54.1-3435.4, and 54.1-3439 of the Code of Virginia, relating to the expiration of various pharmacy licenses.* The authority to promulgate regulations to set the renewal date for permitted and registered facilities is mandatory.

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.

All licenses, permits and registrations have expired on December 31st of each year, which has created an exceptional workload for staff during one period of time. The Board sought legislation to allow expiration dates for permitted or registered facilities to be set on dates different from those of licensed pharmacists or registered technicians. All facility permits or registrations that currently expire on December 31st; permits will continue to be in effect until the next renewal date as set by the Board in regulation. Resident and non-resident pharmacy permits will next expire on April 30, 2009, so they will get an extra four months on their permits. Manufacturers, wholesale distributors, warehousers, physicians permitted to practice pharmacy, medical equipment suppliers, humane societies, and controlled substance registrations will expire on February 28, 2009, so they will get an extra two months. The goal is to distribute the workload for Board and Department staff and to make it less burdensome for pharmacies, some of which pay the renewal for the pharmacy permit and all licensed or registered staff.

A single expiration date means that the Board of Pharmacy staff annually renews all of its 20,000+ licenses at the same time. This creates a very unequal workload during this time of the year. Because of recent significant increases in numbers of licensees, the addition of registered pharmacy technicians, and increases in non-resident facility licenses, the Board's ability to renew licenses in a timely manner is being challenged. Even though a number of persons use on-line licensure renewal, many facilities choose not to do so, and non-residents facilities are not able to do this because of requirement to show proof of resident licensure and a pharmacist-in-charge who holds a Virginia license.

The action is necessary to protect the health and safety of the citizens because a staggered renewal system will assist staff in assuring that all requirements of renewal have been met.

Substance

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

Renewal dates for pharmacies and other types of licenses and permits, other than pharmacists and technicians, have been changed to February 28 or April 30.

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 so indicate.

1) There are no particular advantages or disadvantages to the public.
2) There is an advantage to the agency in greater distribution of the workload associated with renewals.
3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are 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 more restrictive than applicable 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 by the proposed regulation.

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 is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the 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 by mail, email or fax to Elaine J. Yeatts, Senior Policy Analyst, Virginia Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; Email: elaine.yeatts@dhp.virginia.gov. 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). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, 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 the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. There would be a one-time expense of approximately $1,000 for promulgation of the amended rule, including meetings of the Regulation Committee at which this regulation has been developed. 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 regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The businesses affected would be: 1663 pharmacies permitted in Virginia 541 non-resident pharmacies 96 Manufacturers 746 Wholesale distributors 42 Warehousers 14 Physician permits 421 Medical equipment suppliers 673 Controlled substance registrations
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 of the permitted pharmacies are small businesses, but the number would be a small minority. Most pharmacies are now owned by large, national corporate chains.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There are no projected costs; all affected entities will have a cost-savings. Pharmacies, both resident and non-resident, have been given an additional 4 months (Dec. 31 to April 30) of licensure and been issued new permits with the new expiration date. Other facilities, controlled substances registrations and physician permits have been given an additional 2 months (Dec. 31 to February 28), so there is a cost-savings for all these entities

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.

The alternative would be to leave the current date in statute, but this will require either additional expenditures for temporary staff during this time period, or may result in licenses not being renewed before they expire. This also may result in staff turnover, because the Board has not, in the past several years, been in the position of allowing staff to use leave during this time period which coincides with the holiday season.

Public comment

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

There was no comment on the Notice of Intended Regulatory Action during the comment period from 10/13/08 to 11/12/08.

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 of the proposed regulatory action on the institution of the family and family stability.

Detail of changes

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

Current section number	Current requirement	Proposed change and rationale
Chapter 20 Section 20	Sets fees for renewal of licenses, permits and registrations	1. Pharmacist active license – due December 31
		2. Pharmacist inactive license – due December 31
		3. Pharmacy technician registration – due December 31
		4. Pharmacy permit – due April 30
		5. Physician permit to practice pharmacy – due February 28
		6. Medical equipment supplier permit – due February 28
		7. Humane society permit – due February 28
		8. Nonresident pharmacy – due April 30
		9. Controlled substances registrations – due February 28
Chapter 50 Section 20	Sets fees for renewal of manufacturers, wholesale distributors, and warehousers	Sets a renewal date of February 28 of each year