



## Final Regulation Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18VAC110-20 18VAC110-50
<b>Regulation title</b>	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen
<b>Action title</b>	Change in renewal dates for pharmacies and permitted facilities
<b>Date this document prepared</b>	9/2/09

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

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

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.

All licenses, permits and registrations have expired on December 31<sup>st</sup> 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.

**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 September 2, 2009, the Board of Pharmacy took final action to amend 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy and 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen to replace emergency regulations setting dates for renewal.

**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 numbers, 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.

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 amended 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. 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.

All licenses, permits and registrations have expired on December 31<sup>st</sup> 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 31<sup>st</sup>; 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, warehouse, 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 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.*

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 there are no disadvantages to the public or the Commonwealth, please 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.

**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 of the proposed regulation, which is identical to the emergency regulation currently in effect.

**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.*

There were no comments received during the public comment period.

**All changes made in this regulatory action**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail 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 – <u>due December 31</u>
		2. Pharmacist inactive license – <u>due December 31</u>
		3. Pharmacy technician registration – <u>due December 31</u>
		4. Pharmacy permit – <u>due April 30</u>
		5. Physician permit to practice pharmacy – <u>due February 28</u>
		6. Medical equipment supplier permit – <u>due February 28</u>
		7. Humane society permit – <u>due February 28</u>
		8. Nonresident pharmacy – <u>due April 30</u>
		9. Controlled substances registrations – <u>due February 28</u>
Chapter 50 Section 20	Sets fees for renewal of manufacturers, wholesale	Sets a renewal date of February 28 of each year

	distributors, and warehouseurs	
--	-----------------------------------	--

**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.*

---

There were no alternative regulatory methods.

**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.