Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy; Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Elimination of conflicting or unnecessary regulation for nuclear pharmacies
Date this document prepared	6/4/08

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

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

The Board has amended its regulations pertaining to the general requirements for pharmacies providing radiopharmaceutical services and repealed the section of regulations that establishes the qualifications for a nuclear pharmacist. Amendments will refer to standards and requirements of the U. S. Nuclear Regulatory Commission (NRC) and the Virginia Department of Health (VDH) related to the staffing and operation of a nuclear pharmacy.

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.

The Board of Pharmacy adopted the amendments to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy on June 4, 2008.

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 General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of 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 Long-Term Care Administrators, 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…*

In addition, the Board has general authority to regulate and license pharmacies in the Drug Control Act (Chapter 34 of Title 54.1)

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.

Proposed amendments modifying the requirements for nuclear pharmacies eliminate conflicting or overlapping regulations for entities and persons that are already tightly regulated by the federal government and the Virginia Department of Health, the state agency that has oversight responsibility for radiological health programs. Some of the Board's regulations were not consistent with current requirements and qualifications for nuclear pharmacists; others were no longer necessary. By streamlining the regulation and addressing only those aspects of pharmacy practice that are not regulated by other agencies, the Board's requirements focus on the transmission of orders, labeling of containers and packaging as necessary for public health and safety.

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?

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i)

file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The Board has determined that a fast-track process is appropriate because there is no controversy with this action. It will eliminate conflicting or overlapping regulations for pharmacies and pharmacists who are already subject to state and federal requirements for other agencies. The amendments have been developed with the Director of the Radioactive Materials Program at VDH and are consistent with the request from that department for amendments.

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.)

The Board's amendments eliminate conflicting language in subsection A and unnecessary provisions of subsections B and G. Subsection C is amended to reference compliance with NRC and VDH requirements for staffing and operation of a nuclear facility. Subsection D is amended to use correct terminology – prescriber rather than practitioner. Section 230, which sets out the qualifications of a nuclear pharmacist, is repealed as unnecessary since those agencies have more stringent qualifications.

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.

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1) There are no particular advantages or disadvantages to the public since regulations have been clarified and made consistent with requirements of other agencies that are already in place.

2) There are no advantages or disadvantages to the agency or the Commonwealth. There are less than 10 nuclear pharmacies in Virginia, so oversight has not been problematic.

3) There is no other pertinent matter of interest related to this action.

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.

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	a) 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 for necessary functions of regulation; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists and conducting a public hearing. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will be no on-going expenditures related to this action.
Projected cost of the regulation on localities	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the regulation	The businesses affected by this regulation would be pharmacies that provide radiopharmaceutical services.
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 estimated that there are less than 10 such pharmacies, most located within large health institutions or systems.
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 of the regulation.

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 request for amendments to the Board's requirements for nuclear pharmacies initially came as a petition for rulemaking from Dr. Carl Armstrong, Division of Radiological Health at the Department of Health. After conversation with Mike Welling, Director of Radioactive Materials Program at VDH, it was determined that staff could work together to discern which regulations should be amended or repealed. As a result, all the recommended changes set forth in the VDH petition were adopted or concerns resolved with concurrence for the proposed amendments.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family or 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
220	Sets out the general requirements for pharmacies providing radiopharmaceutical services	Subsection A is deleted. The provision for access to a nuclear pharmacy by a "qualified pharmacist" is in conflict with rules of NRC and VDH. The requirement to have a qualified nuclear pharmacist for a permit to operate is unnecessary because VDH checks the qualifications prior to issuing a permit to handle radioactive materials. Subsection B is deleted. It is unlikely that any pharmacy providing radiopharmaceutical services is also providing ordinary pharmacy services. If they are, other pharmacy regulations are sufficient. Subsection C (becomes A) is amended to eliminate any requirement for space and equipment and reference NRC and VDH requirements for staffing and operation. Physical standards, security and other requirements are already specified in other rules that nuclear pharmacies must follow. Subsection D (becomes B) is amended to change "practitioner" to "prescriber" to accurately reflect who can write an order.

		Subsection G is eliminated as it is unnecessary and confusing.
230	Sets out the qualifications for a nuclear pharmacist	The section is repealed as it is duplicative of NRC federal rules and is now inconsistent with those rules.