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 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Eliminates requirement for alarm system for alternative delivery sites
Document preparation date	12/2/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 proposed amendments to Sections 275 and 710 are intended to eliminate the requirement for an alarm system for alternative sites for delivery of dispensed prescriptions provided the prescriptions are held in a locked room or device with access limited to the practitioner or responsible party listed on an application for a controlled substance registration or his designee.

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 December 1, 2005, the Virginia Board of Pharmacy voted to amend sections 275 and 710 of 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy, under a fast-track action to eliminate the requirement for alternative delivery sites to have alarm systems provided certain conditions for safety and security are met.

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.

Regulations Governing the Practice of Pharmacy, 18VAC110-20-10 et seq., are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6), 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:*
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> *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 specific statutory authority for the Board of Pharmacy to establish requirements for the security and integrity of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

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 proposed regulatory action is necessary to eliminate a costly requirement for certain entities that would otherwise be required to have their facilities fully alarmed in accordance with regulations for drug security. Since the Board does not require licensed pharmacies to maintain prescriptions awaiting delivery in an alarmed area, the requirement for alternative delivery sites to be alarmed, such as community service boards, seemed unnecessary. These sites are not maintaining a stock of drugs to be dispensed; they are serving as delivery sites for prescriptions that have already been dispensed to a patient. To enforce the current alarm requirement for community service boards, other alternative delivery sites and humane societies could jeopardize their ability to provide certain services and could be detrimental to the health and safety of the public. With the proposed rule, the drugs will be secured in a locked room or cabinet and only accessible to the responsible party at the facility or his designee.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. 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 elimination of the alarm requirement for alternative delivery sites and humane societies will benefit all such entities and avoid expenditures that could jeopardize their services. The Board is satisfied that the requirement to maintain prescriptions awaiting delivery at such sites in a locked area or cabinet with limited access is sufficient to protect the safety and security of the drugs. Therefore, everyone who has worked on a solution to this dilemma has agreed to the proposed regulation, which needs to be promulgated on a fast-track to eliminate a very burdensome rule.

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 proposed amendment will eliminate the requirement for alternative delivery sites and humane societies to have alarm systems provided certain conditions for safety and security are met.

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) The advantage to the public which is served by alternative delivery sites or humane societies is the availability of those services without the additional costs of installing and maintaining an alarm system. There are no disadvantages to the public; the prescriptions are limited in quantity, awaiting pick-up by a client or a patient, typically Schedule VI drugs without any significant risk for diversion or theft.
2) The primary advantage to the Commonwealth is the elimination of a requirement that, if enforced, could significantly add to the cost of Community Service Boards and other alternative delivery sites, such as student health centers in colleges and universities. There are no disadvantages.
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 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.

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.

Since the proposed regulatory action is less stringent for compliance with requirements, there were no alternative methods considered.

Economic impact

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 is a one-time expense of approximately $1,000 for promulgation of the amended rule. 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 costs. There would be no on-going expenditures
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals affected by the regulation would be alternative delivery sites, such as community services boards and university health centers, and humane socities.
Agency's best estimate of the number of such	There are approximately 130 community services

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.	boards in Virginia that serve as alternative delivery sites for their clients receiving certain drugs. The number of other types of alternative delivery sites, including such places as student health centers, is unknown. There are 44 human societies currently licensed with the board.
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.	Though community services boards and humane societies are not considered small businesses, there would be a cost savings for not having to install an alarm system and have it monitored. Costs would vary depending on whether it would be necessary to alarm a building or only a room within a building.

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.

Entities that maintain a stock of controlled substances must be registered with the Board of Pharmacy, including humane societies, community services boards and other locations that serve as alternate delivery site such as student health centers. Such facilities are required to obtain a controlled substances registration and to comply with current requirements for storage and security. The requirement for an alarm system is problematic and expensive to many such sites, especially the CSB's and humane societies, where the stock of drugs would be limited to certain types. Since facilities holding a controlled substance registration must be inspected, the lack of an alarm system has been noted as a deficiency, which led to a request by the CSB's throughout the state for relief from the requirement. Since the Board does not require community pharmacies to maintain dispensed drugs awaiting customer pick-up in an alarmed area, the requirement for an alarm on an alternative delivery site seemed unnecessary and overly burdensome. Therefore, the Board is proceeding with a fast-track regulation and has concurred that the alarm requirement will not be enforced provided inspectors find that drugs are being kept in locked rooms or cabinet when not in use and access is limited to the responsible party named on the registration or his designee.

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 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	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
275	n/a	Requires alternative sites (other than pharmacies) where prescriptions are waiting to be picked up by a patient to meet the requirements for18VAC110-20-710, which includes an alarm system.	Allows alternative delivery sites to hold prescriptions awaiting pickup in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access must be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.
710	n/a	Requirement for facilities not staffed 24 hours a day to store drugs in an area that has a security system with exception for researchers and animal control officers	Would add humane societies and alternative delivery sites to those entities that do not have to have security systems provided drugs are stored in a secured room or area.