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	18VAC110-30
Regulation title	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Action title	Regulatory reform
Date this document prepared	December 27, 2012

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

The Board of Pharmacy has conducted a periodic review of its regulations governing practitioners of the healing arts who are licensed to sell controlled substances to their patients. For consistency with amended regulations governing the practice of pharmacy and in response to the Governor's regulatory reform project, the Board proposes to modify the square footage requirement and eliminate unnecessary requirements the selling and storage area enclosure.

Statement of final agency action

On December 12, 2012, the Board of Pharmacy adopted amended regulations for 18 VAC 110-30-10 et seq., Regulations for Practitioners of the Healing Arts to Sell Drugs to implement changes recommended in a periodic review of regulations.

Legal basis

18 VAC 110-30-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

The specific statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including the dispensing of controlled substances is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.
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 which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:
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.
The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

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 amended regulation is a reduction in the size and enclosure requirements which are not necessary to protect the health of patients and safety of prescription medications.

While security of patient records and stock of drugs is essential, reasonable allowances are made for access when the licensee is on duty or for emergency access by another licensed physician.

Rationale for using fast track process

The Board has opted to use the fast-track process for two reasons: 1) the action is consistent with the Governor's project to reform regulations that are unnecessarily burdensome; and 2) it does not anticipate any objection to the changes.

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.

The substantive changes are: 1) reduction in the square footage for the selling and storage area from 60 to 40 square feet; 2) allowance for maintenance of prescription records outside the area if access is limited to authorized persons; 3) elimination of specific size and height requirements for enclosure; and 4) security access to the area by other persons authorized to assist the practitioner while he is on duty.

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 of the regulatory action is less burdensome and costly regulation for the physical enclosure of the selling and storage area. There are no disadvantages.
2) By reducing the square foot requirement for the selling and storage area, there will be fewer requests for a limited use permit or a waiver from the 60-foot requirement. There are no disadvantages to the Commonwealth.
3) The action is the result of a periodic review conducted pursuant to the Governor's Regulatory Reform Project.

Requirements more restrictive than federal

There are no applicable federal requirements.

Localities particularly affected

The proposed regulation does not affect any locality.

Regulatory flexibility analysis

Since the intent is to promulgate a less burdensome and costly regulation, there are no alternative methods for accomplishing the objective of reducing the regulatory burden.

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 would be little or no additional expense for promulgation of the amended rule. Consideration of the proposed rule has been during 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 *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The businesses that would be affected would be physicians licensed to sell drugs to their patients.
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.	There are currently 591 physicians licensed to sell prescription drugs to their patients. Most are employees of practices such as Patient First, but it is unknown how many are small businesses since each physician holds a license rather than the facility.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the	The changes to regulations will result in cost-savings or cost-avoidance by less restrictive requirements for square footage, allowance to maintain records outside the selling and storage area and less burdensome requirements for the enclosure to the area.

proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	The amended regulation should make it possible physicians who have a need to sell prescriptions to their patients to do so within less square footage in their practice locations and with less burdensome requirements for the enclosure.

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.

Following the close of comment on the periodic review, staff of the Board reviewed the regulation in light of current practices and requirements for pharmacies. Staff recommendations were presented to the Regulation Committee on December 11th and to the full Board on December 12th. There was no public comment on the regulation at either of the meetings.

Periodic review/small business impact review result

The Notice of Periodic Review was published in the Register of Regulations, posted on Townhall and sent to the public participation mailing list for the Board of Pharmacy with the opportunity for comment from November 5th to December 5th. There were no comments.

The regulation meets the criteria in Executive Order 14 as it is necessary for public health and the safety of prescription medications; it is clearly written and easily understandable. There have been no complaints, no concerns about complexity and no conflict with state or federal law or regulation. It was last reviewed and amended in 2006 and has been amended three times since then. Changes to Chapter 30 reflect waivers that have been granted to the physical requirements and incorporate less stringent requirements in pharmacy regulations.

Family impact

There is no impact on the family.

Detail of changes

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

20	Sets out the requirements for an application for licensure to sell controlled substances	The eligibility for a license to sell is currently limited to a practitioner with an active license to practice *medicine.* In section 10 (Definitions) "Practitioner" is defined as a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. Therefore, section 20 is amended for consistency.
90	Sets out the physical standards for the controlled substances selling and storage area.	The requirement for an enclosed area of not less than 60 square feet that is designated as the controlled substances selling and storage area is *modified to require only 40 square feet*. Currently, records must be maintained in that area, but the proposed regulation would allow records related to the sale of controlled substances to be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. *Drugs sold by physician practices are typically limited in type and number and are usually pre-packaged for sale. Currently, the Board will generally grant a request for a waiver to the 60 square foot requirement, so it believes the regulation can be made less burdensome without compromising the safety and integrity of prescriptions sold from the physician office. Currently, Board regulations require records to be maintained in the selling and storage area, but that is not always the best location for record-keeping. Provided the confidentiality and security of those records can be assured by limiting access, the regulation will allow records to be kept in another location.*
100	Establishes requirements for access to the selling area	A reference to the selling and storage area in section 100 currently requires that portion of the office to be at least 60 square feet. The proposed regulation would change the requirement to 40 square feet.
130	Sets out the requirements for enclosure of the selling and storage area	In subsection A, the specific requirements for the height and doorways of the enclosure are eliminated. ~~2. The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances;~~ ~~3. Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions; and~~ ~~4. Doors to the area must have locking devices which will prevent entry in the absence of the licensee.~~ The proposed requirements are focused on the security of the area: 2. The enclosure shall be locked and alarmed at all times when the licensee is not on duty.

		3. The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area. *Specificity about the door to the prescription area in a pharmacy was eliminated several years ago, so the Board determined that it was reasonable to also make the physician selling regulations less burdensome. Requirements for locking and alarming are consistent with regulations for pharmacies (18VAC110-20-190) and with the current requirements in subsection B.* In subsection B, changes are proposed t allow exceptions: B. The door keys or other means of entry and alarm access code to the selling and storage area shall be ~~subject to the following requirements~~ restricted to the licensee with the following exceptions: 1. ~~Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure~~ Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty; and *The amendment allows other persons authorized to assist to have entry into the locked area when the physician is on duty. The exception is similar to the pharmacy regulations in section 190.* 2. ~~The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs; and~~ *Requirement for locking now in subsection A of this section.* ~~3.~~ The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee for emergency access. *The allowance for an emergency key or access code clarifies it is used for emergency access by another licensee.*