townhall.virginia.gov

Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-30-10 et seq.
Regulation title(s)	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Action title	Permits for physician selling drugs locations
Date this document prepared	3/21/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

In compliance with the second enactment clause of Chapter 117 of the 2015 Acts of the Assembly, the Board of Pharmacy has promulgated regulations to implement the requirement of law that practitioners of the healing arts must dispense controlled substances in permitted facilities. Regulations set fees for approval of applications, renewal of permits, and reinstatement of lapsed permits. Requirements for inspections, physical standards for the facility, and notification to the Board now fall to the facility permit rather than the individual licensee. The only change in physical requirements is specificity about the availability of hot and cold water, which must be within 20 feet of the selling and storage area and not located within an examination room or restroom. This final stage replaces emergency regulations currently in effect and expiring on June 6, 2017.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

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 March 21, 2017, the Board of Pharmacy amended 18 VAC 110-30-10 et seq. Regulations for Practitioners of the Healing Arts to Sell Controlled Substances.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

18 VAC 110-30-10 et seq. Regulations for Practitioners of the Healing Arts to Sell Controlled Substances 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 authority to issue permits and regulate facilities in which practitioners of the healing arts dispense controlled substances is found in:

§ 54.1-3304.1. Authority to license and regulate practitioners.
A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is

licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe 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 Board of Pharmacy licenses individual physicians to sell controlled substances to their own patients and already has regulations for security, record-keeping, storage and other requirements relating to the facility from which physicians licensed to sell drugs dispense. Oversight of physicians selling drugs was relatively simple when there were approximately 100, but the total is now over 600 and continues to increase. The increase is due to an increasingly larger supply of drugs on the market repackaged specifically for physicians to sell, an increase in the number of urgent care centers that dispense drugs when treating patients, and an increase in drugs available to treat popular dermatological issues.

The practice of physicians selling drugs is analogous to pharmacies dispensing drugs. In regulating the practice of pharmacy, the Board licenses both pharmacists and pharmacies. This level of oversight for both the individuals and the facility works well and this proposal seeks to mirror this level of oversight for physicians selling drugs. Additionally, during inspections of facilities where multiple licensed physicians sell drugs, it is reasonable to hold the facility responsible for any possible violations and not an individual physician. This proposed process is also analogous to the inspection process currently used for pharmacies.

Failure to promulgate regulations would perpetuate the Board of Pharmacy's difficulty in overseeing a growing number of physicians who are now licensed to dispense drugs and limit the Board's ability for whom it may take disciplinary action when violations are noted during routine inspections. With a facility permit, which is similar to a pharmacy permit, the Board can hold the permit holder responsible and accountable for the stock of drugs. Clearer regulation and accountability will foster public protection in assuring the safety and integrity of prescription drugs.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

Regulations set fees for approval of applications, renewal of permits, and reinstatement of lapsed permits. Requirements for inspections, physical standards for the facility, and notification to the Board now fall to the facility permit rather than the individual licensee. For an individual license, the fee is reduced from $240 to $180, since the facility permit fee will now help cover

the cost of inspections. For a facility permit, the application fee is $240, which is similar to a pharmacy application and is intended to help cover the cost of an initial inspection.

The only change in physical requirements is specificity about the availability of hot and cold water, which must be within 20 feet of the selling and storage area and not located within an examination room or restroom.

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 to the public is more accountability and consistency in the maintenance and security of controlled substances in physician practices that are selling drugs to their patients. There are no disadvantages;
2) The primary advantage to the agency is a single entity to hold accountable when there are complaints or inspection violations rather than trying to assign responsibility to a physician within a multi-practitioner group; and
3) Promulgation of regulations for the issuance of permits to facilities is a statutory mandate: "*Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances.*"

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.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There were no changes made since the proposed stage.

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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

The proposed stage was published on 10/17/16 with comment requested until 12/16/17; no comment was received. A public hearing was conducted on 12/12/16; no one appeared to comment.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

The final regulations are identical to the emergency regulations that became effective 12/7/15.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
15	n/a	Sets the fees for physicians	The section is reorganized to subsections

		selling drugs	for types of fees, similar to the fee section in Chapter 20 for pharmacies and pharmacists. Subsection B sets the initial application fees: For a practitioner license, the fee is reduced from $240 to $180, since the facility permit fee will now help cover the cost of inspections. For a facility permit, the application fee is $240, which is similar to a pharmacy application and is intended to help cover the cost of an initial inspection. Subsection C sets the annual renewal fees: The fee of $90 is unchanged for practitioners. A renewal fee of $240 is set for facility permits, which is similar to a pharmacy renewal and is intended to help cover the cost of periodic inspections. Subsection D sets the late fees, which is unchanged for practitioners and set at $40 for facilities. Subsection E sets the reinstatement fees for licenses or permits lapsed for more than one year. The fee for practitioners is reduced from $210 to $150 to reflect the reduced application fee. The reinstatement fee for a facility is $240 to help cover the cost of a reinstatement inspection. The fee for reinstatement of a license that has been revoked or suspended remains unchanged. Subsection F states the provision in law that facility fees are waived for locations at which only one practitioner is licensed to dispense.
20		Sets the requirements a practitioner of the healing arts to apply for and obtain a license to sell controlled substances.	Subsection A is amended to specify that practitioners must engage in selling of prescription drugs in a permitted facility, within six months from the effective date of the regulation. Subsection C currently sets out the specific requirements for issuance of a limited use permit that waives certain

			provisions of regulation. Since the facility will not apply for a limited use permit, those provisions have been moved to Section 21.
n/a	21	Sets the requirements for a location at which practitioners of the healing arts sell controlled substances to obtain a permit; sets out the provisions for requesting and issuance of a limited use permit	Subsection A specifies that any location at which practitioners engage in selling of prescription drugs must obtain a permit within six months from the effective date of the regulation. Subsection B sets out the provisions for a limited use permit, which are identical to current provisions in subsection C of 18VAC110-30-20 with the exception of B 3. Currently, in accordance with Guidance Document 110-29, the executive director may grant a waiver of the security system when a facility is storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use. That provision from Board guidance is included in regulation in this proposal.
30	n/a	Sets out the requirements for renewal of licenses and permits.	All of the requirements for renewal and reinstatement of a permitted facility are the same as those for a practitioner license.
50	n/a	Sets out the requirements for a licensee who ceases to sell controlled substances.	Subsection A is amended to require surrender of the facility permit if the practitioner is surrendering his license to dispense, unless there is another licensed practitioner at the same location who is continuing to dispense. Subsection D is amended to include facility permit in the provision that allows a licensee who has surrendered his license to request reactivation without an additional fee within the same renewal year.
70	n/a	Sets requirements for the maintenance of a common stock of drugs	Currently, there are requirements for a facility in which two or more practitioners share a common stock of drugs, including designation of one licensee as the primary person in charge. The same requirements are promulgated for the permitted facility in this section.
80	n/a	Sets out the requirements for inspection and notice to the Board	The section is amended to specify the current requirements for permitted facilities that now fall to the individual licensee.
90	n/a	Sets the physical standards for the storage and selling area in a facility	Currently, the rule states that a sink with hot and cold running water must be available within the “immediate vicinity” of

			the selling and storage area. That term has been difficult for licensee and inspectors alike. The standard advised has been within 20 feet and not located within an examination room or restroom. With promulgation of this rule, that standard is incorporated.