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Proposed 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	3/25/16

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 (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

In compliance with the second enactment clause of Chapter 117 of the 2015 Acts of the Assembly, the Board of Pharmacy is promulgating 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.

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

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. A more detailed discussion is provided in the "Detail of changes" section below.

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 a 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated 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**	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 no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. On-going expenditures relating to facility inspections or investigations should be offset by fees collected from applicants and permit holders.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Facilities from which physicians are selling drugs are required to obtain a permit from the Board of Pharmacy beginning June of 2016.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the number of facilities; the Board has 624 physicians who are licensed to sell drugs from their practices. A few may be solo practitioners but most practice in multi-practitioner group practices which would be considered small businesses. Others are employees of urgent care facilities, such as Patient First, and would probably not qualify as small businesses.

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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The individual practitioner will pay a reduced application fee (from $240 to $180) since the facility fee is intended to partially cover the cost of an initial inspection. The cost for a facility permit will be $240 initially, and $240 annually to renew the permit. Facilities in which there is a solo practitioner will not be required to pay the application or renewal fee but will be required to obtain a permit.
Beneficial impact the regulation is designed to produce.	Permits for facilities in which physicians are selling drugs will provide more consistency and greater compliance with requirements for security and efficacy of drug stocks.

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.

There are no viable alternatives to the proposal considered. The agency has adopted fees and requirements to minimally cover the cost of conducting inspections, issuing permits, and investigating and adjudicating any disciplinary cases that arise from complaints against facilities in which physicians are selling drugs.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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 is no alternative regulatory method; the action is mandated by legislation passed in the 2015 General Assembly.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

There was a comment period on the NOIRA to replace emergency regulations from 12/28/15 to 1/27/16. No comment was received.

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 and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

The proposed 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 selling drugs	The section is reorganized to subsections 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.