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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	10/6/15

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 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

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

This is an emergency regulation because the second enactment of Chapter 117 of the 2015 Acts of the Assembly requires that the Board of Pharmacy promulgate regulations to be effective in 280 days or less from enactment, which was March 16, 2015. Therefore, the Board has authority to promulgate an emergency regulation under § 2.2-4011 of the *Code of Virginia.*

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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.

The authority to promulgate emergency regulations is found in the Administrative Process Act in:

§ 2.2-4011. Emergency regulations; publication; exceptions.

…B. Agencies may also adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment and the regulation is not exempt under the provisions of subdivision A 4 of § 2.2-4006. In such cases, the agency shall state in writing the nature of the emergency and of the necessity for such action and may adopt the regulations. Pursuant to § 2.2-4012, such regulations shall become effective upon approval by the Governor and filing with the Registrar of Regulations.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Board of Pharmacy currently 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 550 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.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the healthy, safety, or welfare of Virginians.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no viable alternatives to meet the essential purpose of the action. Section 54.1-3304.1 specifies that it is unlawful for a practitioner of the healing arts to dispense controlled substances unless licensed by the Board of Pharmacy and that facilities from which such practitioner dispenses must obtain a permit. The second enactment requires the Board to promulgate regulations within 280 days of enactment.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.

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.