Virginia Regulatory Town Hall

townhall.virginia.gov

# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

| | |
|---|---|
| **Agency name** | Board of Pharmacy, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation** | 18VAC110-30-10 et seq. |
| **Regulation title** | Regulations for Practitioners of the Healing Arts to Sell Controlled Substances |
| **Action title** | Periodic review – conformity with changes to pharmacy regulations |
| **Document preparation date** | |

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.*

## 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.*

Amendments to regulations governing the practice of pharmacy, adopted in response to an extensive periodic review, became effective on August 25, 2004. Since physicians are licensed under these regulations to store, dispense and sell controlled substances, certain requirements should be comparable, while others are unique to regulations for physicians selling drugs to their patients. Some requirements that should be similar for pharmacists and physicians are now dissimilar with the change to the pharmacy regulations, so there is a need to amend Chapter 30 accordingly. Other requirements are now outdated with changes to the law, such as the registration of pharmacy technicians, or with changes in pharmacy practice. The goal of this action is to conform and update requirements for physicians selling drugs in their practice.

## 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 Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

**Chapter 24** establishes the general powers and duties of the Board of Pharmacy including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals. Excepts from § 54.1-2400 are as follows:

*§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:*

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

The authority for the Board to issue licenses to physicians to dispense drugs is found in § 54.1-3304:

***§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.***

*For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.*

## Substance

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how*

*the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.*

---

**Amendments may be adopted in the following sections:**

**18VAC110-30-10. Definitions.**

Amendments will clarify or update any terminology as necessary to interpret this chapter.

**18VAC110-30-15. Fees.**

Fees will be amended for consistency with similar fees for similar activities by a pharmacist or a pharmacy. Renewal and reinstatement requirements will be also be amended for consistency in the schedule and amount of fee. Currently, there is no fee for a required reinspection of a facility, as there is for a pharmacy that fails to pass the initial inspection. Such a fee will be added to cover the approximate cost of conducting the inspection.

**18VAC110-30-20. Application for licensure.**

No amendments are anticipated.

**18VAC110-30-30. Renewal of license.**

Currently, a practitioner may renew his license by payment of the renewal and late fees within 60 days from the date of expiration; the amendment would allow a late renewal within one year of expiration.

Currently, reinstatement of a lapsed license (after 60 days) requires payment of all unpaid renewal fees and a delinquent fee. For consistency with pharmacy, the amendment will allow reinstatement after one year by payment the current renewal fee and a reinstatement fee. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny reinstatement.

**18VAC110-30-35. Inactive status.**

Amendments will be added to both sections 30 and 35 to specify when it is necessary to have a re-inspection of the practitioner's facility if he allowed his selling license to expire for more than a year or is seeking reactivation of an inactive license that he has held for more than one year. If no other licensee at the same location has held an active license to sell drugs, a re-inspection will be necessary to ensure that the requirements for security, storage and preparation of the prescriptions are met. Without an inspection of the facility, there is no assurance that drugs are being stored under proper conditions to protect the drugs integrity, that expired drugs are not being dispensed or that drugs are being packaged and labeled appropriately. These and other standards necessary for patient health and safety are examined during an inspection.

**18VAC110-30-40. Acts to be performed by the licensee.**

Amendments to this section will allow practitioners who utilize the services of registered pharmacy technicians or other licensed health care practitioners who have been specifically trained in the acts performed by a technician to supervise up to four persons assisting in the preparation, packaging and labeling of prescriptions. Currently, the practitioner is limited to one such person, but amendments to this chapter should reflect changes in pharmacy law and regulation that permit other properly trained individuals to assist in prescription preparation. In situations in which the practitioner is using a registered nurse or physician assistant to assist in preparation of prescriptions, the amended regulation would require specific training for those tasks normally performed by a registered pharmacy technician and specify that a training manual and documentation of training be made available for inspectors.

In addition, compounding of a controlled substance can only be performed by the licensee in the current rules; an amendment would likely expand that activity to allow compounding under a registered pharmacy technician under the practitioner's supervision.

**18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.**

No amendments are anticipated at this time.

**18VAC110-30-70. Maintenance of a common stock of controlled substances.**

No amendments are anticipated at this time.

**18VAC110-30-80. Inspection and notice required.**

Consistent with newly amended language in Chapter 20, the Board will require that if an applicant substantially fails to meet the requirements for issuance of a license and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant must pay a reinspection fee prior to a reinspection being conducted.

**18VAC110-30-90. Physical standards.**

No amendments are anticipated at this time.

**18VAC110-30-100. Access to selling area.**

No amendments are anticipated at this time.

**18VAC110-30-110. Minimum equipment.**

The listing of the equipment the licensee must maintain will be amended to delete reference materials no longer required in a pharmacy and to include a general requirement for other

equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety. In addition, the specific requirement for a laminar flow hood will be replaced with a general requirement for equipment necessary for sterile compounding of controlled substances consistent with USP standards and provisions of § 54.1-3410.2 (enacted by the 2003 General Assembly).

**18VAC110-30-120. Safeguards against diversion of controlled substances.**

The Board will consider whether there should be access to the alarm system by someone other than the licensee in emergency situations.

**18VAC110-30-130. Selling area enclosures.**

Amendments are necessary to recognize newer technology in gaining access to a secured area. Rather than specifying the security of the "door keys" only, the regulation will also refer to "other means of entry" or "other means of opening the locking device." Consistent with the pharmacy regulations, the executive director for the board may be able to approve other methods of securing the emergency keys or access codes to the enclosed area in lieu of the licensee's signature across a seal, as is currently required.

**18VAC110-30-140. Prescriptions awaiting delivery.**

Current regulations allow for prescriptions prepared for delivery to the patient to be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. Then the prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee. For security purposes, the pharmacy regulations now require that a log be maintained of all prescriptions delivered to a patient when the licensee is not present. Such a requirement will be considered for prescriptions delivered in a physician's office when he or she is not present.

**18VAC110-30-150. Expired controlled substances; security.**

An amendment is necessary to specify that any controlled substance which has exceeded the expiration date should be maintained in the selling and storage area prior to the disposal of the expired controlled substances. Current regulations require storage in a "designated area" which may not be secured.

**18VAC110-30-160. Disposal of Schedule II through VI controlled substances.**

The requirements for disposal of schedule II through VI drugs will be reviewed for consistency with current requirements for pharmacies and those of the Drug Enforcement Administration.

**18VAC110-30-170. Sign and written prescription requirements.**

Requirements in this section are intended to ensure that the licensee provides a patient with a written prescription whether or not he intends to sell the controlled substance to the patient and

that the patient is informed that he has a right to obtain the controlled substance from a pharmacy rather than from the practitioner. Amendments may: 1) specify that the sign advising patients of their right to choose may be displayed in the patient examining room(s); 2) provide for electronic maintenance of the prescription records; and 3) provide alternative methods for transferring the patient's prescription to a pharmacy.

**18VAC110-30-180. Manner of maintaining inventory records for licensees selling controlled substances.**

No amendments are anticipated at this time.

**18VAC110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.**

No amendments are anticipated at this time.

**18VAC110-30-200. Automated data processing records of sale.**

Amendments are necessary to conform and update rules related to automated data processing records for consistency with new regulations for pharmacies. Rules will allow an electronic image of a prescription to be maintained in an electronic database provided it preserves and provides an exact image of the prescription which is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Also, if the pharmacy system's automated data processing system fields are automatically populated by an electronic transmission, the automated record can constitute the prescription and a hard copy or electronic image is not required.

**18VAC110-30-210. Repackaging of controlled substances; records required; labeling requirements.**

Rules for determining the expiration date on a prescription will be amending for consistency with the pharmacy regulations, which require conformity to USP guidelines for any repackaged or reconstituted units.

**18VAC110-30-220. Labeling of prescription as to content and quantity.**

A reference to the Virginia Formulary needs to be eliminated since it has been repealed in the Code.

**18VAC110-30-230. Packaging standards for controlled substance sold.**

No amendments are anticipated at this time.

**18VAC110-30-240. Special packaging.**

Rather than requiring a signed release from a patient's requesting nonspecial packaging, documentation of such a release must shall be obtained from the patient or the patient's authorized agent and maintained for two years from the date of dispensing.

**18VAC110-30-250. Choice of controlled substance supplier.**

No amendments are anticipated at this time.

**18VAC110-30-255. Purchase of drugs.**

No amendments are anticipated at this time.

**18VAC110-30-260. Returning of controlled substances.**

Amendments for the return of controlled substances are necessary to track changes in the Code, which permit certain returns and transfer. The regulations will be amended for consistency with pharmacy regulations and provisions of § 54.1-3411.1.

**18VAC110-30-270. Grounds for disciplinary action.**

Only minor editorial changes are anticipated.

## 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.*

The only alternative to amending regulations would be to leave current requirements in place. In several cases, the current rules for physicians selling drugs are now more restrictive than for a pharmacist practicing in a pharmacy. For example, the current regulation specifies that only one person who is not a licensee can be in the storage and selling area with the physician for the purpose of assisting in the preparation, packaging and labeling of a controlled substance. Pharmacy rules now allow up to 4 persons to assist the pharmacist, provided those persons are registered technicians. Likewise, rules for reinstatement of a lapsed license were amended for pharmacists to reduce the burden of returning to active practice in Virginia but remain more burdensome for physicians selling drugs. Rules for equipment that must be maintained by a physician are also now more burdensome. Failure to amend regulations for physicians selling drugs would result in more burdensome requirements those practitioners and their patients.

## Family impact

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.*

There is no potential impact of the proposed regulatory action on the institution of the family and family stability.

## Periodic review

*If this NOIRA is not the result of a periodic review of the regulation, please delete this entire section. If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 21, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

---

1. A Notice of Periodic Review was published in the *Virginia Register of Regulations* and sent to persons requesting to be included on a public participation mailing list for the Board of Pharmacy. The Notice stated that the regulation will be reviewed for consistency and applicability with changes in practice and with recently amended regulations governing the practice of pharmacy. Comment was requested between June 28, 2004 and July 28, 2004, during which time no comment was received.

2. The Board has determined that the regulation is necessary for the protection of public health, safety and welfare in that it specifies requirements for the security, integrity and efficacy of prescription drugs and for the physician to make patients aware of their freedom to choose another provider to fill their prescriptions. The regulation has not been challenged for a lack of clarity, but is now inconsistent with rules governing pharmacies and should be amended accordingly.