Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18 VAC 110-30-10 et seq.
Regulation title	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Action title	Periodic review of regulations
Document preparation date	9/13/05

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.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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 recently-amended regulations governing the practice of pharmacy, the Board proposes to amend Chapter 30 by eliminating unnecessary requirements for equipment and security, allowing electronic transmission and storage of records, amending a burdensome reinstatement requirement and clarifying rules for repackaging and storage. In addition, regulations are updated for consistency with Code changes requiring registration and training of pharmacy technicians and counseling of patients.

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 September 13, 2005, the Board of Pharmacy adopted final 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

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 numbers, 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.

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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.

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.

Statute text

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.

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 it 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.

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.

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.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The substantive provisions and changes are as follows:

Fees and renewal/reinstatement requirements:

Fees are amended for consistency with similar fees for similar activities by a pharmacist or a pharmacy. Renewal and reinstatement requirements are also amended for consistency in the

timing and amount of fee. A fee is added to cover the approximate cost of conducting a re-inspection, if required.

Acts to be performed by the licensee.

Amendments to this section will allow practitioners to 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 a person who can assist in the preparation, packaging and labeling of prescriptions. In situations in which the practitioner is using a registered nurse or physician assistant to assist in preparation of prescriptions, the amended regulation requires specific training for those tasks normally performed by a registered pharmacy technician and would 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 expand that activity to allow compounding under a registered pharmacy technician under the practitioner's supervision.

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. 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.

Minimum equipment.

The listing of the equipment the licensee must maintain is 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).

Selling area enclosures.

Amendments 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 should 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.

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: 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.

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.

Repackaging of controlled substances; records required; labeling requirements.

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

Special packaging.

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

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 are amended for consistency with pharmacy regulations and provisions of § 54.1-3411.1.

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 consistency in regulation between a permitted pharmacy and a physician's practice in which drugs are being stored, compounded, prepared and dispensed. Without the same precautions related to labeling, preparation of a prescription, storage, record-keeping and supervision, patients receiving prescription medication through a physician's practice would not have the same assurances of the drug integrity and efficacy. Amended rules will also ensure that patients understand their right to have a prescription filled elsewhere and that a prospective drug review and counseling will occur before a drug is dispensed. There are no disadvantages to the public.

2) There are no disadvantages to the agency. There may be an advantage in having a regulation that is consistent with rules for the practice of pharmacy, and the Board will be able to recover some of its costs for inspections by institution of a reinspection fee.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes to the text of the proposed regulation since it was published at 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.

Proposed regulations were published on June 13, 2005 with a comment period that closed on August 12, 2005. A public hearing on the proposed regulation was held on June 22, 2005. There was no public comment.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
10	n/a	Defines practitioners to include a doctor of osteopathy	Changes the term to osteopathic medicine for consistency with Medicine regulations
15	n/a	Application fee for initial licensure is $200 Late renewal fee owed within 60 days; reinstatement required thereafter Reinstatement requires delinquent fee of $70 plus all unpaid renewal fees	Application fee of $240 for consistency with pharmacy fee and to cover costs for an initial inspection Renewal can occur by payment of a late fee for one year following expiration before reinstatement required. Adopted for consistency with Fee Principles and other professions in the Department and Board. Reinstatement fee is set at $210 after a license has been lapsed for more than one year. Removes "penalty" for someone wanting to move back to Va. and reestablish a practice.
20	n/a	Makes a limited-use permit contingent only on using prepackaged containers.	Eliminates the requirement to allow practices to dispense drugs that have been packaged and labeled by the physician selling the drug.
30	n/a	B. Renewal permitted for 60	B. Renewal permitted for one year by payment of

		days following expiration by payment of late fee and renewal fee. C. Reinstatement required after 60 days with payment of all back renewal fees and a delinquent fee.	renewal and late fee. C. Reinstatement permitted after one year with payment of reinstatement fee plus re-inspection fee if required. Clarifies that reinstatement can be granted if no grounds to deny exist. D. Specifies when a re-inspection of the physician offices may be required. If another practitioner has been actively practicing in the same location, inspection may not be necessary, but the practitioner cannot stock drugs to sell until approved by the board or its agent. E. Clarifies that selling controlled substances without a current, active license is unlawful and may be grounds for disciplinary action.
35	n/a	Provides for an inactive license and reactivation.	Repeals the section. There is no advantage to a practitioner in maintaining an inactive license. New language in section 50 allows someone who has surrendered his active license to request re-activation within one year at no additional fee. Beyond one year, an inspection and application would be required anyway.
40	n/a	A(1) Establishes that compounding must be personally performed by the licensee. A(2) Allows one person to assist the practitioner in the storage and selling area	A(1) Allows compounding to be performed by a registered pharmacy technician under the licensee's supervision. A(2) Allows a licensee to supervise one person to assist provided he is a registered technician or a nurse or physician assistant with specific training in tasks delineated for technicians. The change is consistent with current law that requires a person to be trained and registered as a pharmacy technician in order to assist the pharmacist in preparation of a prescription for dispensing. This regulation would expand that practice to include a nurse or PA who has been trained in preparation, packaging, labeling, etc. A(3) Establishes the areas in which a nurse or PA would have to be trained in order to function as a pharmacy technician in a physician's practice. The tasks are consistent with those specified in § 54.1-3321 for technicians. Since nurses and PA's have a higher level of basic medical knowledge than registered technicians, the Board has not required that they graduate from a board-approved training program or pass a competency examination. A(4) A practitioner who employs persons to assist must also develop and maintain a site-specific training program and manual for work in that particular practice. This requirement is consistent with the requirement for a pharmacy that employs technicians in its practice to ensure that they understand the policies and procedures, data systems and use of equipment used in the practice.

		B. Sets out the requirements for a practitioner prior to dispensing the drug	A(5) Requires maintenance of documentation on the site-specific training for 2 years from date of termination of employment. Again, this requirement is consistent with the requirement for pharmacies. B. Adds a requirement to conduct a prospective drug review and offer to counsel. Both acts are required for dispensing by a pharmacist and are necessary to ensure that patients are not receiving a drug that may be contraindicated or in conflict with another medication and that the patient understands proper dosing and handling of the drug.
50	n/a	n/a	New subsection D – Allows a licensee who has surrendered his license to reactivate within one renewal cycle without an additional fee provided the location has been inspected and approved.
80	n/a	n/a	New subsection E – Requires payment of a reinspection fee if an applicant substantially fails an inspection or is not ready for the inspection and fails to notify the board with 24 hours of the scheduled time. New subsection F – Requires a licensee to notify the Board of any substantive changes to the approved selling and storage area and requires a reinspection fee. Both E and F are currently required of pharmacies and are necessary to ensure that the Board is properly notified of changes that could affect the safety and security of controlled substances.
110	n/a	Sets out the minimum equipment necessary for a practitioner to sell controlled substances	Consistent with pharmacy regulations, a requirement for hard copy of paper documents that are accessible electronically is eliminated. The specific piece of equipment for sterile compounding is replaced with a requirement for equipment consistent with USP-NF standards and the Code. Prescription balances are required only when dispensing activities require weighing of components. A general requirement is added to specify the practitioner should have any equipment, supplies or references necessary for public safety.
130	n/a	Sets out rules for securing the selling area	Allows a means of entry into a locked area other than with door keys and approval of other methods of securing the emergency keys or access codes. Proposed for consistency with pharmacy's rules.
150	n/a	Provides that expired stock must be separated from the other drugs	Clarifies that expired drugs cannot be dispensed or old and must be maintained in the selling and storage area. Maintenance on any controlled substances outside the designated areas might invite abuse or diversion.
170	n/a	Sets out the requirement to provide a patient with a written prescription and the	A. Requires notification of right to obtain the prescription elsewhere to be posted in the patient examination rooms – with an assumption that is

		opportunity to have that prescription filled outside the physician's office.	where the patient has time to notice and read such a sign. New subsection C provides if a patient chooses to have the prescription filled at a pharmacy, the licensee must give them a written prescription or transmit the prescription orally or electronically. New subsection D gives the licensee the option of giving the patient a written prescription or having him sign a waiver that is kept with the dispensing record, so it is available for inspection.
180	n/a	Establishes rules for taking inventory and maintaining inventory records	Adds a requirement for the inventory record to be signed and dated and indicated whether taken prior to opening of business or after the close. The rule is consistent with the pharmacy requirements.
190	n/a	Establishes rules for maintaining drug records	Adds a requirement for maintaining a record for 2 years from last refill and for filing chronologically from date of dispensing. Allows maintenance of records in an electronic form in lieu of hard copy prescriptions.
200	n/a	Establishes rules for automated data processing records of sale	Eliminates requirement to place a hard copy prescription on file and maintain for two years. Adds a requirement that a printout be available for inspection within 48 hours. Both are consistent with current pharmacy rules.
210	n/a	Establishes rules for repackaging on controlled substances	Rather than specifying expiration dates in rules, the amendment would state that establishment of an appropriate expiration date must be consistent with USP-NF standards and the date must appear on the repackaged or reconstituted drug.
220	n/a	Establishes rules for labeling of prescription	Eliminates the Code reference for the Virginia Voluntary Formulary, which has been deleted from the Code.
240	n/a	Establishes the rules for use of non-special packaging	Eliminates the requirement for a signed release and allows the patient's authorized agent to give such permission. Consistent with pharmacy rules.
260	n/a	States that drugs can be accepted for resale if they have not been stored in conditions that may lead to contamination	Restates the rule to specify that the drugs must be stored in a manner that meets official compendium requirements. Provides more guidance to the licensee and is consistent with pharmacy rules
270	n/a	Uses term doctor of osteopathy	Amends term to doctor of osteopathic medicine

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

In its analysis of the final regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability.