Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Periodic Review
Document preparation date	5/31/07

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.

Regulations of the Board of Pharmacy are complex and broad in scope and applicability to a variety of practice settings. Periodically, it is necessary to review and revise to clarify existing requirements, add new language to address problems that have arisen, delete outmoded regulation, or revise requirements to allow for newer technologies. In its promulgation of amended regulations as described in the substance section of this document, the Board will consider the need to incorporate interpretative language now found in several guidance documents and will also include some provisions that have been tested in pilot programs that are currently approved.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
…
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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

The specific authority to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

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.

The agency is recommending that the regulation be amended in order to address the numerous questions and recommendations that arose from the periodic review conducted by board members and advisors from all aspects of pharmacy practice. In some cases, there is a need for clarification of a rule; in others there is a need to amend the regulation to allow the practice of pharmacy to be more responsive to patient needs and changing times.

The Board has identified issues with regulations that restrict practice or inhibit modernization and utilization of newer technology, provided the change is within the parameters of law and federal rules and provided it is good policy that protects the health, safety and welfare of the public.

The following sections of the regulations have been identified as having issues that may need to be addressed in the promulgation of amended regulations:

18VAC110-20-10. Definitions.

Several current definitions may need to be amended for clarification or for consistency. For example, the definition of a long term care facility may need to include other facilities. The Board will look at the model rules of the National Association of Boards of Pharmacy (NABP) for institutional pharmacies. The definition of CE and CEU may be redefined consistent with

new definitions of the Accreditation Council for Pharmacy Education (ACPE). In addition, there may be several terms that should be defined, such as "chart order," which would need to be flexible enough to include electronic chart orders and the term "initial," which is used in a number of places throughout the regulation.

18VAC110-20-30. Requirements for practical experience.
Current requirements of the Board may be inconsistent with new ACPE standards for preceptors and experiential training, so the Board will consider amendments to section 30 to conform to national standards for pharmaceutical preceptors and practical experience in order to facilitate reciprocity.
Subsection C requires practical experience can be gained only after completion of the first professional year, but it is unclear when first professional year ends as some schools now operate year-round rather than in semesters. The Board may consider other criteria for practical experience, such as completion of certain core curricula. The ACPE may start allowing practical experience within the first year, so the Board will review the new standard once developed.

18VAC110-20-40. Procedure for gaining practical experience.

The current regulation does not allow for practical experience gained outside the United States. Some flexibility may be considered to accommodate experience in military hospitals outside the U. S. in which pharmacists licensed in the U. S. serve as preceptors. Recently, the Board had a request from a pharmacist licensed in the U.S. and stationed in a U.S. Army hospital in Seoul, South Korea who requested the ability to serve as a preceptor for U.S. pharmacy interns and foreign graduate pharmacy interns, but the regulation did not allow for practical experience to be gained outside of the U.S. In addition, it would have been problematic for Virginia to certify the hours gained in a pharmacy located outside of the state.
Currently, pharmacy intern permits are issued for the period of pharmacy schooling. The Board will consider an extension of that time frame for good cause and with a specified expiration date and a limitation of the years of an internship.
The number of interns that may be supervised may be problematic when the internship programs at different pharmacy schools overlap. The Board will consider a modification to the restriction on supervision of one pharmacy intern during the same time period to alleviate a barrier to obtaining a preceptor. Any modification of the rule would likely retain the principle that the primary assignment of an intern to a preceptor must be one-to-one.

18VAC110-20-50. Curriculum and approved schools of pharmacy.
Number 1 in subsection A is now outdated and will be deleted.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.
The current regulation does not require an applicant to wait a certain time period to take the jurisprudence exam if he has failed it multiple times. There is concern with the security of test items for computerized testing, so the Board will consider a limitation of the number of tries within a specified time period. Provisions of guidance document 110-39, relating to Americans with Disabilities accommodations for taking the NAPLEX and law examination may be incorporated into section 60.

18VAC110-20-70. Requirements for foreign-trained applicants.
The regulations need to be amended to clarify that an applicant must pass the Foreign Pharmacy Graduate Equivalency Examination before becoming an intern. If an applicant cannot pass the FPGEE, the years spent in an internship may be wasted and the public may not be well protected. There should also be some expiration date on intern licenses to prevent "permanent" internships with a mechanism for an extension when good cause is shown.

18VAC110-20-80. Renewal and reinstatement of license.
The Board will consider a provision to notify the Board electronically when there is a change of address and also the addition of a time frame for notification, rather than "immediately" - such as within 14 days of such change.
There continues to be discussion of an annual versus biennial renewal cycle; such a change in regulation would necessitate an amendment to the Code. Currently to reinstate a pharmacist license, the regulation requires 15 hours of CE for each year the pharmacist license was not active, not to exceed a total of 60 hours of CE. The Board will consider amending the 60 hour cap on reinstating a pharmacist license.

18VAC110-20-90. Requirements for continuing education.
In subsection A, the date listed is unnecessary and may be deleted. Subsection D may need to be amended to require maintenance of CE documentation for three years, if the Board chooses to audit for the previous two renewal cycles.
The requirements for continuing education will be examined and may be amended for consistency with changes by the ACPE, which is adopting a topic designator system. The Board will consider a yearly topic designation for a portion of the continuing education hours with sufficient notification to licensees prior to the start of the renewal year.

18VAC110-20-100. Approval of continuing education programs.
Amendments will be considered to require a Board-approved program to have an expiration date; ACPE has an expiration of three years for a written program and one year for a live program. There may also need to be a process for renewal of program approval. In addition, the requirement for maintenance of records should be increased beyond three years for auditing purposes; ACPE requires approved programs to maintain documentation for five years.

18VAC110-20-101. Application for registration as a pharmacy technician.
An amendment should clarify that an individual enrolled in a Board-approved pharmacy technician training program may work for a maximum of 9 months prior to Board registration (would include language from 18VAC110-20-111 (C).

18VAC110-20-102. Criteria for approval for training programs.
Board-approved programs currently have no expiration date. As with board-approved continuing education programs, there should be an expiration date and a process or mechanism for renewing or reviewing programs for law updates, etc. There also needs to be a process and requirement for submitting changes to programs.

There was interest expressed in revising the requirement that only a pharmacist with a current, unrestricted licensee could serve as an instructor. The Board also discussed requiring a criminal background check, but such a requirement may necessitate a Code change.

18VAC110-20-103. Examination.
Provisions of guidance document 110-39, relating to Americans with Disabilities accommodations for taking the pharmacy technician examination may be incorporated into section 103.

18VAC110-20-104. Address of record.
The current provision allows thirty days for notification of a change of address; the Board will consider a more restrictive requirement (14 days) but not as restrictive as the current requirement for pharmacists, which is to notify "immediately." There should be consistency in the rules. The Board will consider allowing for electronic communication.

18VAC110-20-105. Renewal and reinstatement of registration.
Any changes made to renewal and reinstatement of licenses for pharmacists may be made similarily in this section for pharmacy technicians.

18VAC110-20-106. Requirements for continued competency.
Subsection B should appropriately reference 18VAC110-20-100, which sets out requirements for Board approval of continuing education providers. The requirement to maintain documentation of CE needs to be changed from 2 years to 3 years to ensure CE certificates are available for Board audits.

18VAC110-20-110. Pharmacy permits generally.
The Board will consider adding language from guidance document 110-40 regarding about how far in advance of the opening date may a new pharmacy permit be issued. An amendment is necessary to ensure that a permit can not be issued to operate a pharmacy from a private residence or dwelling. The Board will also consider specifying in regulation its long-standing policy that more than one permit may not be issued to operate other types of permits out of the same Rx department space; e.g. a pharmacy could not also get a second pharmacy permit, or a manufacturer's permit to operate both businesses out of the same physical space. There may be an exception for special or limited-use pharmacy permits.

The Board will also consider:

- Requiring the pharmacist-in-charge (PIC) to mark the permit VOID and the effective date of termination as PIC when returning the permit to the Board as currently required.
- Not mandating that an outgoing PIC be required to take inventory, but allowing it if the outgoing PIC wants to do an inventory for his own protection, unless there is good cause shown as to why the pharmacy will not allow it. The Code requires an incoming PIC to take an inventory
- Adding language from Guidance Document 110-33 related to pharmacy interns working as pharmacy technicians in this section and/or in 18VAC110-20-111.

18VAC110-20-111. Pharmacy technicians.

- The Board will add a requirement for a pharmacy to maintain the start date and completion date for each pharmacy technician in training; there is a nine month limitation on performing pharmacy technician related duties when in training, but inspectors are not readily able to check whether the individual is in compliance.
- The Board may add a requirement for pharmacy technicians to post their registrations, similar to the requirement for pharmacists.
- There may need to be clarification regarding the total amount of time a pharmacy technician can remain in training to prevent them from going from program to program without becoming registered. There should also be clarification as to whether a person already certified by PTCB can be unregistered and working as a trainee while enrolled in an approved training program.
- The Board will consider removing subsection C if it decides to include this information in 18VAC110-20-101.

18VAC110-20-120. Special or limited-use pharmacy permits.
Guidance document 110-22 provides guidelines for granting waivers relating to restricted access to a free clinic pharmacy under a special-use permit; the Board will consider placing the criteria in regulation. It will also consider the possibility of allowing a community pharmacy serving a free clinic to get a second permit for that purpose. Currently, a pharmacy is allowed to have only one permit or license at any one location.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.
An amendment is needed to require a closing pharmacy to transfer prescription files somewhere where a patient can access.

18VAC110-20-180. Security system.
The regulation may require an alarm to be “hard-wired” or use the new wireless technology which utilizes a monitored battery. Additionally, there is a need to clarify that all alarms must be monitored.
The Board will consider eliminating the exemption for some pharmacies from having an alarm system in #7, or it may change the requirement for an alarm to be installed within 72 hours if the pharmacy is closed for any period of time to requiring the installment of an alarm prior to closing.

18VAC110-20-190. Prescription department enclosures; access to prescription department.
Subsection A may be amended to allow for drop down gates, therefore a door with lock would be unnecessary. However, the Board may want to require a lock for times when the pharmacist is on-duty, but may not want to pull down gates.
Subsection B should be clarified to provide that the “other secured place” must be within the pharmacy.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

- The Board may incorporate rules to allow for automated will call devices, which is now approved in a pilot.

- There needs to be clarification of the storage of will-call drugs; there is confusion as to whether they have to be in Rx department, which is alarmed after hours, or whether staff can reach over a counter and access them.
- The Board may also need to clarify whether medical devices can be displayed outside the Rx department or maintained similar to drug paraphernalia.

18VAC110-20-210. Disposal of drugs by pharmacies.
There are several issues relating to the disposal of drugs by pharmacies. There are very few, if any, appropriately licensed incenerators for drug disposal in Virginia, therefore it is difficult to use this methodology. Additionally, the laws of many state and federal agencies, e.g. DEA, Board of Pharmacy, EPA, etc., regarding the proper method for drug disposal appear to conflict with one another The Board will examine the DEA rules, the NABP model rules and regulations from other states for suggested amendments.

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

- The Board may require a perpetual inventory for Schedule II drugs and possibly hydrocodone products, to include a monthly count-back to reconcile count at least every 30 days.
- The Board may need to clarify #3 on storage of records to allow for storing records within the building where drugs are located.
- The Board may delete #4 as it is confusing and may be unnecessary.
- It may add a requirement to maintain Schedule VI invoices and may add language in guidance document 110-35 to include allowance for retail pharmacies to use chart orders.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.
There should be clarification of how subsection C applies in institutions, primarily language about initialing the labels on IV's and maybe first doses, with no permanent record.
The Board will consider modification to the ratios of pharmacist to technician trainee and pharmacy technicians. If the ratio is eliminated, there would need to be other safety parameters established.
In subsection E, the Board may add a requirement to retain knowingly forged prescriptions (possibly after verifying with prescriber).

18VAC110-20-275. Delivery of dispensed prescriptions.
A rule is necessary to require that the contract and policy and procedure manual for alternate delivery sites be maintained at both pharmacy and the alternate site.
The regulation may be modified to add allowance for a pharmacy technician to serve as responsible party at an alternate delivery site to follow pilot program.
The provisions for alternate delivery sites, as approved by Board, will be examined to ensure patient safety and compliance are not being compromised for convenience. The language "if required by law" will be removed in subsections B and C

18VAC110-20-280. Transmission of a prescription order by facsimile machine.

The rule should be clarified to mean that a hospice can be home hospice, and the term "nursing home" should be changed to long term care facility.
This section should be clarified to provide that a nurse may fax a verbal order as a prescriber's agent even though the order is not being faxed from prescriber's practice location.
The reference to § 54.1-3408.01 "C"; should be "B".
The Board may amend to allow the faxing of Schedule III-VI written prescriptions to a pharmacy from a facility such as a long-term care facility and establish time requirements to follow-up with hard copy.

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.
The reference to § 54.1-3408.03 "D"; should be "C".

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.
Subsection D may be amended to allow for early refill due to good cause or absence (vacation). That subsection may also be amended to clarify that the intent is refering to the timing of refills and not about the ability to change Rx based on the strength of drug in stock.

18VAC110-20-330. Labeling of prescription as to content and quantity.
The Board may amend this section or possibly create a new section, 335, to provide for labeling/counseling/medication guides in alternative languages (possibly include disclaimer to verify with someone else; may need to require both English & another language). In developing a regulation, the Board will check requirements in other states.

18VAC110-20-340. Packaging standards for dispensed prescriptions.
The Board will consider inclusion of provisions of Guidance Document 110-12 and Guidance Document 110-23.

18VAC110-20-350. Special packaging.
The Board will consider repeal of this section and rely on the statute.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.
An amendment may add pharmacist's initials to filling record for automated counting devices or dispensers to verify process as stated in subsection A.
Amendments to add language from Guidance Document 110-16 will be considered.
There is a need to clarify #4 in subsection C and to change "second" to "subsequent" lots.
The Board may also need to add a requirement that the manufacturer's expiration date be recorded on the filling records used for automated counting devices to allow inspectors to verify that the calculated expiration date has been done correctly.

18VAC110-20-360. Issuing a copy of a prescription that can be refilled.
The Board will check with the Drug Enforcement Administration on consistency with its requirements and may consider striking some of subsection B.

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.
An amendment may add provisions of Guidance Document 110-20.

18VAC110-20-395. Purchase of drugs.
An amendment is necessary to allow for a non-licensed warehouse to sell to pharmacy through intra-company sales.

18VAC110-20-400. Returning of drugs and devices.
An amendment will add hospitals as referenced in § 54.1-3411.1.

18VAC110-0-410. Permitted physician licensed by the board.
An amendment will add "pharmacy" terms to listed in subsection A. There may need to be additional sections added to the list for compliance.

18VAC110-20-425. Robotic pharmacy systems.
The Board will consider elimination of the requirement for an application and approval of a robotic pharmacy system and include the requirements for such a system in regulation. Among the rules to be determined would be packaging standards for drugs stored in robotics and consistency with USP standards.

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.
The Board will consider a request to add suture kits and anesthesia kits to list of items that can be stored outside the pharmacy
Subsection D is being interpreted inconsistently, so it needs to be clarified.
The Board will consider a requirement for monthly drug reviews similar to long term care, if patient stays longer than 30 days, such as in acute psychiatric hospitals.

18VAC110-20-450. After-hours access to the pharmacy.
The rules for after-hours access to pharmacy are now in conflict with JCHAO standards, so the Board will consider revision or repeal of this section. If retained, the Board may need to develop some alternative language for a night cabinet.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.
Amendments may be added to:

- Require a pharmacist to check drugs before leaving the pharmacy to be stocked on the floor.
- Require maintenance of manual delivery records for at least 2 years, but allow the records to be kept off-site.
- Allow the audit records to be kept off-site, rather than in the pharmacy.
- Require records to be maintained for Schedule VI, as well as II-V.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.
The Board may track the language in 555 (5) related to requiring a pharmacist to check delivery orders before they leave the pharmacy. It may require maintenace of records of filling for Schedule VI and auditing records of Schedule VI, but allow pharmacies to keep these records off-site.
There needs to be clarification of what a "sample of administration" means in 5 c (all drugs dispensed from each device within 24 hours or all dispensed to a particular patient within 24

hours or all of a drug dispensed within 24 hours). Amendment may be made to retain all records required by this section for 2 years.

18VAC110-20-500. Licensed emergency medical services agencies program.
Amendments will be considered to: 1) require a pharmacist to check before sealing the drug kit used by EMS agencies; 2) allow for 1:1 exchange of drugs without having to have the controlled substance registration; 3) allow for fluids to be outside the drug box. The regulation should also include similar language regarding methods of sealing box as found in 18VAC110-20-540 and 18VAC110-20-550.

18VAC110-20-520. Drugs in long-term care facilities.
This section needs to be moved into Part XII.
The Board will consider a request to allow floor stocking of over-the-counter medications in LTC facilities.

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.
The Board will consider an issue relating to the need to dispense a limited quantity of a drug that is listed on discharge orders from a hospital that does not specify quantity or duration of order.
There needs to be reference to section 210, which provides the rules for disposal of drugs.

18VAC110-20-550. Stat-drug box.
This section needs to be amended by incorporating language from guidance document 110-11 to clarify that a stat-drug box may only be provided to those facilities that use nurses to access these drugs, so assisted living facilities that use med aides to administer could have a stat-drug box, if they have a nurse on duty for accessing the box.
Amendments may be made to allow greater quantities of doses, increase the number of drugs per therapeutic class, or allow oral Schedule II drugs.

18VAC110-20-555. Use of automated dispensing devices.
The Board may require maintenace of records of filling for Schedule VI and records for auditing Schedule VI, but may allow pharmacies to keep these records off-site.
Amendment may be made to retain all records required by this section for 2 years.
The Board may amend to allow override capability of dispensing devices for emergency drugs, particularly in a long term care environment which is located within a hospital.

18VAC110-20-570. Drugs in infirmaries/first aid rooms.
Subsection D may be deleted as it pertains to administration of over-the-counter drugs, which are not regulated by the Board of Pharmacy.
The definition of "emergency" may be rewritten for greater clarity.
The term "controlled drug" should be changed to "controlled substance".

18VAC110-20-580. Humane societies and animal shelters.
An amendment will specify that the record of training for persons at a humane society or animal shelter should be maintained at the facility.
It also should be clarified that drugs must only be stored or administered at permitted facility.

18VAC110-20-590. Drugs in correctional institutions.
The Board must provide a definition of a correctional facility, to include various types.
Regulations should allow for the use of other types of forms to accompany returned drugs to the pharmacy; it is currently restricted to drug administration record.
Regulations should allow the number of drugs per therapeutic class and the number of doses in stat box and emergency box to be increased, especially for alcohol withdrawal in correctional facilities.
It may be clarified that only jails with infirmaries may stock tetanus or vaccines with a controlled substances registration.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.
Federal regulations will be checked to ensure that these regulations are still consistent

Part XV. Medical Equipment Suppliers

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.
Amendments may be added to require inspection prior to issuance, and require that on any change of location of drug stock or remodeling, the supplier will have to make application and be inspected.
The Board will also consider including requirements for how far in advance the opening inspection can occur and that drugs cannot be stocked prior to inspection, similar to language in section 140 for pharmacies.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.
The Board will look at:

- The need for requiring the responsible party to send in the old CSR registration if there is a change in the responsible party.
- Current technology regarding standards for alarming to include hard-wired systems and battery operated alarms (similar to changes in sections 180)
- Clarification about who may access controlled substances and therefore, qualify as responsible party- may include prescribers, nurses, pharmacists & pharmacy techs, so the requirement that it be a practitioner "authorized to administer" would need to be revised.
- Striking the language about other persons designated to have access in an emergency situation.
- Clarification of who may qualify as supervising practitioner to include physician assistants and nurse practitioners with prescriptive authority.

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.

In order to conduct a thorough review of pharmacy regulations, the Board assigned the task to an Ad Hoc Committee on Regulatory Review to recommend changes for clarity and consistency with changes in pharmacy education and practice. Board members comprising the committee were joined by representatives of chain drug stores, pharmacy schools, the Virginia Pharmacists Association, hospital pharmacies, correctional institutions, EMS agencies, pharmaceutical manufactures, and a consumer organization – all of whom were invited to participate in the discussion of each regulation and to provide suggested changes.

In its announcement of periodic review, the Board requested comment on whether there is a need for amendments for consistency with changes in pharmacy practice and patient care. In order to address issues that have been raised and to clarify current regulations, the Board must proceed with a Notice of Intended Regulatory Action to accomplish the purpose of its periodic review of regulations.

Family impact

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

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