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(s)	18VAC110-20-10 et seq. 18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Periodic review
Date this document prepared	3/25/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 25, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to an agency subordinate,* will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Amendments are being considered for Chapters 20 and 50 to address current issues with practice, to clarify certain requirements, and to incorporate provisions currently found in guidance

documents. The intent is to update the regulations and to streamline requirements where possible.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and establish renewal schedules:

> *§ 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 and Chapter 25 of this title…*

The specific authority to control prescription drugs in the Commonwealth 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

Purpose

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, please explain any potential issues that may need to be addressed as the regulation is developed.

Regulation of the practice of pharmacy is both complex and essential to public health and safety. The Board takes seriously its statutory responsibility to ensure the safety, integrity and efficacy of prescription drugs in the Commonwealth. At the same time, the practice of pharmacy is constantly changing as new technologies become available. To incorporate efficiency and cost-effectiveness, rules for pharmacy practice must be changed while balancing the assurances that controlled substances are dispensed in a manner that protects from medication error and diversion that is harmful to the patient and the community.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

As part of the periodic review, the Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 25, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to an agency subordinate,* will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Amendments to the following sections of Chapter 20 (or the new chapter 25) will be considered in the promulgation of proposed regulations:

PART I. General Provisions.

18VAC110-20-10. Definitions

- Modifying definition for "robotic pharmacy system."

18VAC110-20-20 Fees

- Changing the renewal for pharmacist licenses and pharmacy technician registrations to a date different from December 31st, but retain the facility renewal dates for facilities. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-21 Public address

- Adding requirement for notification to the board if there is a name change and specify documentation that must be submitted. Consider a specific timeframe for notification.

18VAC110-20-25 Unprofessional conduct

- Adding failure to submit corrective action related to inspection deficiency within a specified time frame.
- Adding dispensing any controlled substance with the intent or knowledge that it will be used otherwise than medicinally, for accepted therapeutic purposes, or with the intent to evade any law with respect to the sale or use of such drug.

PART II. Licensure Requirements for Pharmacists.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Specifying a timeframe for validity of law exam score to 3 years, consistent with requirements for record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee rather than the current active renewal fee.

- Revising terms "reactivate" and "reinstate" for correct and consistent usage.

18VAC110-20-90 Requirements for continuing education (CE)

- Accepting additional inter-professional continuing education.
- Changing wording in (B) (2) from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of continuing education.
- Requiring a portion of the 15 required hours to be live or real-time interactive continuing education.

18VAC110-20-100 Approval of continuing education programs

- Deleting ability for board to approve CE programs.

PART III. Requirements For Pharmacy Technician Registration.

18VAC110-20-102 Criteria for approval of training programs

- Including requirement for training program approval number to be printed on certificate awarded by training program.
- Requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Changing "certificates" to "documentation" in both sentences of subsection D.

PART IV. Pharmacies.

18VAC110-20-110 Pharmacy permits generally

- Specifying minimum number of hours pharmacist-in-charge (PIC) must practice at the location listed on the pharmacy permit application
- Requiring minimum number of years of experience for pharmacist-in-charge eligibility.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Requiring an inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Allowing Board to rescind pharmacy permit if not opened within 60 days of issuing permit.

18VAC110-20-150 Physical standards for all pharmacies

- Specifying acceptable refrigeration facilities based on Center for Disease Control guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient.

18VAC110-20-190

- Amending physical requirements for a prescription department's enclosure.
- Amending requirement for locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

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

- Adding language from Guidance Document 110-40 regarding dispersion of Schedule II drugs.

PART VI. Drug Inventory and Records.

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

- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

PART VII. Prescription Order and Dispensing Standards.

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- Separating subsections A and B from the rest of the regulation.
- Addressing concern in subsection B by the Virginia Pharmacist Association with pharmacists not being provided adequate pharmacy technician support.
- Reviewing appropriateness of requiring pharmacists to not return a forged prescription.
- Regarding subsection F and on-hold prescriptions, revising requirement for pharmacy to pull the originally filed prescription and refile it.
- Adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Addressing concerns with white bagging and brown bagging.
- Revising section 275 for more clarity.

18VAC110-20-277 Prescription Requirements

- Adding new regulation in section 277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

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

- Clarifying that a requirement for a signature to be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Considering whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

Adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

PART VIII. Labeling and Packaging Standards for Prescriptions.

18VAC110-20-355 Pharmacy repackaging of drug; records required; labeling requirements

Amending requirement for how to identity pharmacist verifying accuracy of the process.

PART X. Unit Dose Dispensing Systems.

18VAC110-20-425 Robotic Pharmacy Systems

- Streamlining robotic pharmacy system regulations by striking #5 and simplifying #4.
- Strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

In #2, consider changing "practitioner" to "prescriber"

18VAC110-20-490 Automated devices for dispensing and administration of drugs

- Streamlining requirements for automated dispensing devices in hospitals.
- Clarifying that drug for emergency use may include drugs for first doses.
- Clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530 Pharmacy's responsibility to long-term care facilities

Allowing a pharmacy providing services to a long-term care facility to provide prescription information of Schedule VI drugs to a "back-up" pharmacy without constituting the transfer of a prescription. In addition to section 530, the Board will also consider amending section 515 on Remote prescription order processing for hospitals and long-term care facilities and section 360 on Issuing a copy of a prescription that can be filed or refilled to address this same issue..

18VAC110-20-550 Stat-drug box

- Clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarifying that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

Considering whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amending regulation based on recent amendments to §54.1-3423; changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers (MES)

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Adding requirement that applications must include name of responsible party
- Requiring MES to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Adding language from Guidance Document 110-19 for MES to transfer prescriptions.
- Adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

18VAC110-20-710 Requirements for storage and security for controlled substance registrants

- Amending schedules to include Schedule I

The Board considered whether there is a better method for identifying the responsible pharmacist as initials are required 23 times throughout regulations of the Board. It is likely the Board review all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

18VAC110-50-40 Safeguards against diversion of drugs

- Amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Expanding ability to issue limited use for other entities such as third party logistic providers if law passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

18VAC110-50-80 Minimum qualifications, eligibility, and responsible party

- Requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.

For consistency, the Board will consider requirements similar to those in sections 70 through 140 for manufacturers.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Regulation Committee of the Board of Pharmacy conducted a thorough review of regulations and recommended a number of amendments. Each section was discussed for clarity and the need to amend to address any issues or inconsistencies with its provisions. Staff of the Board also brought recommendations for amendments. In some cases, the Committee did not recommend amendments but identified the need for additional research and review.

For example, in section 50, the Committee considered striking subsection B to eliminate language for "first" professional degree; staff was asked to do further research on implications of this recommendation. At a subsequent meeting, staff recommended that reference to a "first" professional degree should remain; curricular elements of a non-traditional PharmD program are not identical to that of traditional programs; many schools of non-traditional PharmD programs rely on state licensure, but licensure requirements vary among the states.

The Committee also discussed amendments to regulation (such as the ability to carry over hours of continuing education) but concluded that a statutory change would be necessary. The Committee attempted to identify every regulatory section that should be included in the NOIRA document in order to solicit public comment on any intended regulatory change.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including 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 hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

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 Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on 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. A regulatory panel will not be used as the amendments will be drafted by the Regulation Committee of the Board in an open meeting.

Periodic review and small business impact review report of findings

If this NOIRA is the result of a periodic review/small business impact review, use this NOIRA to report the agency's findings. 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 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

1) Summary of comments on the Notice of Periodic Review

Commenter	Comment	Agency response

Jon Horton, Sentara Norfolk General	Asks to consider addition of Tech-Check-Tech in regulations for unit dose dispensing systems. Allowance for a pharmacy technician (instead of the pharmacist) to check the work of another technician, if the technician checking has met certain criteria.	Board has approved an innovative pilot process for a similar system; effectiveness of the pilot will be measured before consideration of inclusion in regulation.
Jamin Engel Sentara RMH Medical Center	Asks for regionalization of hospital compounding of sterile products.	Regionalization of compounding would be considered outsourcing by federal and state law. Newly promulgated regulations would allow a hospital system to create an outsourcing facility that could be permitted to perform sterile compounding for health care institutions under a common ownership.
Tim Musselman	Consider the following: 1) An amendment to the requirement for a secure prescription department in instances where the department and the entire location are closed and secured at the same time. 2) An amendment to require employers to provide adequate technician support.	1) The Board is considering an amendment to the requirement in response to the comment (see section 190). 2) Regulations place the responsibility for determining the number of technicians to be employed, but in reality, that decision is typically left up to management and not in control of the pharmacist. The Board does not believe it has the authority to require pharmacies to hire a certain number of pharmacists or technicians.
Jill McCormack National Association of Chain Drug Stores	Asks to revise Chapter 50 for manufacturers, wholesalers and warehousers and the Board's requirements for a pedigree which are now inconsistent with the Federal Drug Quality and Security Act for track and trace.	The Board is aware of the need to amend the regulation; to that end, legislation was introduced in the 2016 Session to amend Virginia law (HB528). Amendments to Chapter 50 will be accomplished by a regulatory action exempt from the APA for conformity with changes in state law.

(2) The Board has determined that the regulation meets the criteria set out in Executive Order 17 (2014), as the regulation of prescription drugs and pharmacy facilities is required by Virginia law and is necessary for the protection of public health, safety, and welfare. In order to ensure that the regulation is clearly written and easily understandable, there are amendments recommended in several sections (see Substance section).

(1) There is a continued need for the regulation; the power and duty of the Board to promulgate regulations is found in § 54.1-3307.

(2) The comments received concerning the regulation from the public were considered; to the extent allowable by law and within the context of public health and safety, changes are recommended.

(3) The Board has discussed the complexity of the regulation and will consider a division of the chapter to address regulation of persons (pharmacists and pharmacy techs and interns) and regulations of the practice of pharmacy;

(4) The Board has reviewed any duplication or conflicts with federal or state law or regulation; amendments will be promulgated consistent with legislation passed in the 2016 General Assembly. Amendments have been made in recent years to ensure consistency with state and federal law.

(5) Chapter 20, Regulations Governing the Practice of Pharmacy has been amended 15 times in the past five years, and there are seven additional actions currently in progress. The Board has been very responsive to the need for regulations to remain current with newer technology, emerging practices and changes in the law. In addition, the Board has statutory authority to approve innovative pilot programs that may not be consistent with regulation but, with proper controls and assessment, may be useful in testing new procedures or technologies. Based on results from some of these pilots, regulations may also be amended.