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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) Chapter citation(s)	18VAC110-21
VAC Chapter title(s)	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Periodic review
Date this document prepared	3/15/22

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The Board will amend the regulation. The Board has identified at least two sections that it will consider for amendments:

- Section 80, to include a prohibition on taking the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions; and to authorize the Board to delegate to the National Association of Boards of Pharmacy the review and granting of testing accommodations for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act.
- Section 90 to require Foreign Pharmacy Graduate Equivalency Examination prior to obtaining pharmacist license through endorsement or score transfer.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

The impetus for this regulatory action is implementation of recommendations from the Board’s periodic review of regulations. A General Notice was published with comment on the report of results requested from January 17, 2022 to February 25, 2022. No comment on this chapter was received.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency’s overall regulatory authority.

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 (§ [2.2-4000](#) et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. 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.).

The statutory authority for the Board to promulgate regulations to regulate the practice of pharmacy is found in:

§ 54.1-3307. Specific powers and duties of Board.

A. 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 that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

- 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 statutory authority for the Board to promulgate regulations to regulate pharmacists and pharmacy technicians is found in:

§ 54.1-3310. Unlawful to practice without license.

Except as prescribed in this chapter or by Board regulations it shall be unlawful for any person to practice pharmacy, or to engage in, carry on, or be employed in the dispensing, or compounding of drugs within this Commonwealth unless licensed by the Board as a pharmacist. The possession by any person in any place of a miscellaneous stock of drugs shall be prima facie evidence that such person is practicing pharmacy.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

- 1. The entry of prescription information and drug history into a data system or other record keeping system;*
- 2. The preparation of prescription labels or patient information;*
- 3. The removal of the drug to be dispensed from inventory;*
- 4. The counting, measuring, or compounding of the drug to be dispensed;*
- 5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;*
- 6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;*
- 7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and*
- 8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.*

B. To be registered as a pharmacy technician, a person shall submit :

- 1. An application and fee specified in regulations of the Board;*
- 2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and*
- 3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.*

C. The Board shall promulgate regulations establishing requirements for :

- 1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;*
- 2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and*
- 3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.*

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other

than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The amendments being considered are necessary to protect public health and safety by ensuring that persons licensed as pharmacists are sufficiently prepared and competent to dispense controlled substances, administer immunizations, supervise technicians, and other duties relating to care and treatment of patients.

Substance

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

The Board will amend the regulation. The Board has identified at least two sections that it will consider for amendments:

- Section 80, to include a prohibition on taking the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions.
- Section 80, to authorize the Board to delegate to the National Association of Boards of Pharmacy (NABP) the review and granting of testing accommodations for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act.

- Section 90 to require FPGEC prior to obtaining pharmacist license through endorsement or score transfer and delete exemption from FPGEC in subsection D. A FPGEC is the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Graduate Equivalency Examination and Test of English as a Foreign Language Internet-Based Test, and that a foreign pharmacist’s education meets comparable requirements to pharmacists educated from US pharmacy colleges.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

Licenses issued by the Board of Pharmacy are mandated by Chapter 33 of Title 54.1 of the Code of Virginia. There are no alternatives for implementation of the mandates other than the promulgation of reasonable regulations that are enforceable and protect the public health and safety.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; (804) 367-4688; FAX (804) 527-4434; erin.barrett@dhp.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<https://townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://commonwealthcalendar.virginia.gov/>). Both oral and written comments may be submitted at that time.