



townhall.virginia.gov

Emergency Regulation and 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)	18VAC110-20-10 et seq. 18VAC110-21-10 et seq.
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy Regulations for Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Registration of pharmacy technician trainees and pharmacy technicians
Date this document prepared	9/9/20

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). Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Regulations will: 1) establish the requirements for registration as a pharmacy technician trainee for a person enrolled in a training program and engaging in tasks that may be delegated to a technician; 2) specify the certification examinations that are acceptable for registration as a pharmacy technician; 3) set out the requirement for accreditation of training programs that will become effective on July 1, 2022; and 4) modify other provisions as applicable to changes in the Code of Virginia pursuant to HB1304 and SB830 of the 2020 General Assembly.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

ASHP = American Society of Health-System Pharmacists
NHA = National Healthcareer Association

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

- a) Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.
- b) Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change

Adoption of amendments to regulations by emergency action is required to comply with the second enactment clauses of HB1304 and SB830 of the 2020 General Assembly.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. However, the provisions of subsection B 2 of § 54.1-3321 of the Code of Virginia, as amended by this act, requiring accreditation of a pharmacy technician training program shall become effective July 1, 2022.

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 or Acts and 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 specific statutory provisions for regulations governing registration of pharmacy technician trainees and pharmacy technicians are found in:

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § [32.1-276.3](#), provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § [54.1-2957](#), involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 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 purpose of the regulation is to establish the requirements for registration of a technician trainee and for the education and examination for persons registered as pharmacy technicians to ensure they can perform dispensing functions with the competency necessary for the safety and integrity of prescription drugs.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of Changes” section below.

The substantive provisions of this regulatory action are the addition of section 135, which establishes the requirements for registration as a pharmacy technician trainee for a person enrolled in a training program and engaging in tasks that may be delegated under supervision to a technician, and section 141 which sets out the requirements for registration that will be effective on July 1, 2022, including accreditation of training programs as specified in HB1304 and SB830 of the 2020 General Assembly.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

- 1) The advantage to the public will be more consistent training and examination of pharmacy technicians who play a vital role in filling and dispensing of prescription medications. There will also be accountability to the Board for persons who are performing technician tasks while in training. There should be no disadvantages to the public. Training programs have until July 1, 2022 to become accredited if they are not already.
- 2) There are no advantages or disadvantages to this agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 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. 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.) This proposal is consistent with the agency’s statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

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.

Section 54.1-3321 of the Code of Virginia, as amended by HB1304 and SB830, specifically requires regulations to be promulgated by the Board to register pharmacy technician trainees and

to set requirements for registration of pharmacy technicians as of July 1, 2022. There are no viable alternatives.

**Periodic Review and
Small Business Impact Review Announcement**

This NOIRA is not being used to announce a periodic review or a small business impact review.

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 Elaine Yeatts, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; phone (804) 367-4688; fax (804) 527-4434; Elaine.yeatts@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.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-111			Subsection C is amended for consistency with the revised Code which requires a person to be registered as a

			<p>pharmacy technician trainee in order to perform technician tasks as part of a training program. <i>Previously, it was left to the training program to maintain documentation of a person being enrolled, and there was a limitation on the time he/she could be in training. An amendment to the Code requires registration with the Board and allows a trainee to continue as long as he/she is enrolled in a pharmacy technician training program and "actively progressing toward completion of such program."</i></p>
21-10		<i>Sets out definitions for words and terms used in the chapter</i>	<p>Definitions for ASHP and NHA are added as those acronyms are used in regulation.</p>
21-20		<i>Establishes fees for applicants and registrants</i>	<p>The fee for registration of a pharmacy technician trainee is set at \$20, which is the same fee charged for registration of a pharmacist intern. A trainee registration is good for two years, so there is no renewal fee. Subsection G of 54.1-3321 requires a pharmacy technician trainee to submit an application and a fee specified in regulations of the Board.</p>
21-40		<i>Sets out grounds for unprofessional conduct</i>	<p>Currently, the pharmacist in charge (PIC) in a pharmacy is responsible for ensuring that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current. Since trainees will now be registered, they are included in that responsibility for the PIC. Failure to do so may constitute grounds for disciplinary action.</p>
	21-135	<i>Establishes requirements for registration as a pharmacy technician trainee</i>	<p>Subsection A specifies that prior to engaging in the duties of a pharmacy technician in order to gain pharmacy experience toward completion of a pharmacy technician training program in Virginia, a person must first register with the board as a pharmacy technician trainee.</p> <p>Subsection B specifies that to be eligible to register, an applicant must be enrolled in a pharmacy technician training program. The registration is effective for no more than two years to cover the estimated time period for the trainee to complete the practical pharmacy experience required for completion of the training program and pass the required examination. If the trainee is no longer enrolled in the training program, takes a voluntary break from the program, or is otherwise not actively progressing toward completion of such program, the registration is no longer valid and must be returned to the board immediately.</p> <p><i>Registration authorizes a trainee to perform the functions of a pharmacy technician, but only in the context of a program that is responsible for training. If someone ceases to be enrolled, the registration is invalid.</i></p> <p>Subsection C specifies that a pharmacy technician trainee must be directly monitored by a supervising pharmacist who holds a current active license and assumes full responsibility for the training and supervision of the trainee.</p> <p><i>It is the responsibility of the supervising pharmacist to provide training and to determine the tasks a trainee is</i></p>

			<p><i>competent to perform at any given point during such training.</i></p> <p>Subsection D is similar to other provisions in Pharmacy regulations in that it requires a pharmacy technician trainee to notify the board in writing of any change in address of record within 14 days of such change.</p>
21-140		<i>Sets out the current requirements for registration as a pharmacy technician</i>	<p>Section 140 will remain in effect until July 1, 2022, after which applicants will be required to graduate from an accredited pharmacy technician program.</p> <p>Subsection D is deleted because subsection B of 54.1-3321 specifies passage of a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.</p>
	21-141	<i>Sets the requirements for registration of a pharmacy technician that will be effective July 1, 2022</i>	<p>Section 141 will become effective on July 1, 2022 when completion of an accredited program is effective., as specified in 54.1-3321.</p> <p>Subsection A requires submission of the application fee and an application on a form approved by the board.</p> <p>Subsection B specifies that in order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:</p> <ol style="list-style-type: none"> 1. Completion of a pharmacy technician training program that is: <ol style="list-style-type: none"> a. Jointly accredited by the ASHP and ACPE; b. An accredited training program operated through the Department of Education’s Career and Technical Education program; c. Operated through a federal agency or branch of the military; or d. Accredited by an accreditation body approved by the board. 2. Evidence that the applicant successfully passed a national certification examination administered by PTCB or NHA. <p><i>The specific requirements for registration in regulation mirror the provisions of subsection B of 54.1-3321. At the present time, the only accredited organization is a joint certification program by ASHP and ACPE, but regulations will allow for Board recognition of another accreditation body if one is developed in the future. Pharmacy tech programs in the military are also recognized.</i></p> <p>Subsection C allows a pharmacy technician who has previously practiced in another U. S. jurisdiction to be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.</p> <p><i>Subsection C (2) of 54.1-3321 requires Board regulation to allow for registration by endorsement for someone with previous practice and national certification.</i></p>

			<p>Subsection D allows a person who successfully completed or was enrolled in a Board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022 to still be eligible for registration if he successfully passes a national certification examination administered by PTCB or NHA and submits documentation of such completion or enrollment in a Board-approved pharmacy technician training program and passing examination score.</p> <p><i>The intent of subsection D is to allow eligibility for persons who have not completed all of their training and examination prior to July 1, 2022 so they do not have to start over in an accredited program.</i></p> <p>Subsection E allows a person who passed a national certification examination administered by PTCB or NHA but did not complete a Board-approved pharmacy technician training program prior to July 1, 2022 to obtain registration as a pharmacy technician upon documentation of having passed such examination.</p> <p><i>Subsection C (1) of 54.1-3321 specifically requires Board regulations to allow for eligibility to register for someone who did not complete a board-approved program before July 1, 2022 but passed a certification examination.</i></p>
21-150		<i>Establishes requirements for board approval of a pharmacy technician training program</i>	As of July 1, 2022, all training programs will have to be accredited according to provisions of Section 54.1-3321. Therefore, section 150 will remain in effect until that date.
21-160		<i>Establishes requirements for board approval of examination for technicians</i>	Section 160 is repealed because the required examinations for registration of a pharmacy technician are established by Code in 54.1-3321.
21-170		<i>Sets out the requirements for renewal and reinstatement</i>	Currently, a pharmacy technician who has not held a valid registration for five years or more is required to complete another training program and pass an examination. The amended regulation will allow for reinstatement by passage of an examination, completion of continuing education (equal to four years of hours required for renewal of a pharmacy technician registration), and payment of fees. <p><i>If a technician has been out of practice for five or more years, there must be some evidence of minimal competency. Rather than starting over in a training program, the revised regulation will allow completion of CE and passage of an examination to serve as evidence of current competency.</i></p>
21-180		<i>Sets out requirements for continuing</i>	Subsection E is amended to delete the requirement for "original" documentation and allow for copies of

		<i>education for a pharmacy technician</i>	documents to be provided as evidence of continuing education.
--	--	--	---