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Final Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20, <i>et seq.</i> 18VAC110-21, <i>et seq.</i>
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	June 6, 2022

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 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. If applicable, generally describe the existing regulation.

These regulations: (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 Ch. 107 and Ch. 237 of the 2020 Acts of 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
PTCB = Pharmacy Technician Certification Board
PIC = Pharmacist in Charge

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On June 6, 2022, the Board of Pharmacy adopted final amendments to 18VAC110-20 *et seq.*, Regulations Governing the Practice of Pharmacy, and 18VAC110-21 *et seq.*, Regulations for Licensure of Pharmacists and Registration of Pharmacy Technicians, governing pharmacy trainees.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

The Board was required to enact emergency regulations pursuant to the second enactment clauses of [Ch. 107](#) and [Ch. 237](#) of the 2020 Acts of Assembly. Proposed regulations to replace the emergency regulations were approved by the Executive Branch and published on January 3, 2022. This action adopts final regulations to replace the emergency regulations.

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 of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o 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."

The specific legislative authority for this action can be found in Virginia Code §§ 54.1-3300 (which provides a definition of "pharmacy technician trainee") and 54.1-3321 (which requires registration of pharmacy technician trainees by the Board, provides scope of practice, and sets forth training requirements).

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

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 that 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
- The addition of Section 141, which sets out the requirements for registration of pharmacy technician trainees that will be effective on July 1, 2022, including accreditation of training programs as specified in Ch. 107 and Ch. 237 of the 2020 Acts of 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 and increased 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. Training programs have until July 1, 2022 to begin seeking accreditation with pre-candidate status if they have not already. Increased training standards may reduce the challenges faced by pharmacies, particularly in hospitals, of recruiting well-trained pharmacy technicians and protecting patient safety as the scope of pharmacy technicians continually expands. There should be no disadvantages to the public. A disadvantage perceived by some independently-owned pharmacies is the increased cost for participating in the accrediting program. The Board has published an FAQ document regarding training opportunities for independently-owned pharmacies.
- 2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth and of the statutory directive to

implement regulations for the registration of pharmacy technician trainees and requirement of passage of a national examination to register as a pharmacy technician. The Board is authorized under § 54.1-2400 “[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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 promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Commenter	Comment	Agency response
Douglas Schiffman, Rappahannock Center for Education, via Town Hall	The regulations will reduce the number of pharmacy technician training programs and pharmacy technician students. The cost will be prohibitive. There are very few accredited ASHP programs compared to over 100 programs previously approved by the Board of Pharmacy.	Similar legislation and regulation in other states, such as Louisiana, did not result in a drop in the number of pharmacy technician students. Independent pharmacies can still serve as worksites for accredited programs without the independent pharmacies becoming accredited by ASHP/ACPE.

<p>Cheri Garvin, RPh, by letter</p>	<p>Independent pharmacies cannot realistically obtain ASHP/ACPE accreditation due to the cost. Local community colleges do not intend to obtain ASHP/ACPE accreditation due to the cost. Concern regarding how a registered trainee changing jobs would be handled by the Board under the new regulations.</p>	<p>Similar legislation and regulation in other states, such as Louisiana, did not result in a drop in the number of pharmacy technician students. Independent pharmacies can still serve as worksites for accredited programs, such as accredited distance-learning (online) training programs that currently exist nationally, without the independent pharmacies becoming accredited by ASHP/ACPE.</p> <p>The registration of a pharmacy technician trainee will be dependent on that trainee's enrollment in a particular training program. If a pharmacy technician trainee is enrolled in a program run by a pharmacy that also serves as the trainee's worksite, leaving that pharmacy would then invalidate the registration under 18VAC110-21-135(B). The trainee would have to register with the Board when the trainee enrolled in a new program.</p> <p>If the pharmacy technician trainee is enrolled in a program at an educational institution and is employed at a pharmacy that is an approved worksite for hands-on training, the trainee could change approved worksites without invalidating their registration with the Board.</p>
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Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
21-170(D)(1)	Reinstatement applicants must take and pass a national certification exam administered by PTCB or NHA	No passage of the national examination is required for reinstatement applicants who have maintained a national certification	This change lowers barriers to reinstatement for individuals that have maintained their national certification.

Detail of All Changes Proposed in this Regulatory Action

List all changes proposed in this action and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
20-111		Prior to promulgation of emergency regulations, this section allowed a pharmacy technician in training to perform tasks on site for up to nine months before registering with the Board. Pharmacies training pharmacy technicians were required to maintain documentation onsite showing the trainee was enrolled in an approved training program and the start date for the trainee at the pharmacy.	Subsection C is amended for consistency with the revised Code, which requires a person to be registered as a pharmacy technician trainee in order to perform technician tasks as part of a training program. An amendment to the Code requires registration with the Board immediately (rather than after nine months) and allows a trainee to continue as long as he or she is enrolled in a pharmacy technician training program and “actively progressing toward completion of such program.” A trainee registration may not exceed 2 years under the regulation.
21-10		Sets out definitions for words and terms used in the chapter.	Definitions of ASHP and NHA are added because those acronyms are used in the amended and new regulations.
21-20		Establishes fees for applicants and registrants.	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 valid for two years. No renewal provision is necessary. Va. Code § 54.1-3321(G) requires a pharmacy technician trainee to submit an application and a fee as specified in regulations of the Board.
21-40		Sets out grounds for unprofessional conduct, including that the 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.	Under the amendment, the PIC is also required to ensure that any pharmacy technician trainees are properly registered. Failure to do so may constitute grounds for disciplinary action.
	21-135		Subsection A specifies that a person must register with the Board as a

			<p>pharmacy technician trainee prior to engaging in the duties of a pharmacy technician in order to gain experience toward completion of a pharmacy technician training program.</p> <p>Subsection B specifies that an applicant must be enrolled in a pharmacy technician training program to be eligible to register as a trainee. The registration is effective for no more than two years, which covers the estimated time period for a trainee to complete the practical pharmacy experience required by 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 the program, the registration is no longer valid and must be returned to the Board immediately. Registration authorizes a trainee to perform the functions of a pharmacy technician, but only while enrolled in a program responsible for training pharmacy technicians. If a registrant is no longer enrolled, the registration is invalid.</p> <p>Subsection C specifies that a supervising pharmacist who holds a current active license must directly monitor a pharmacy technician trainee. That licensed pharmacist assumes full responsibility for the training and supervision of the trainee. It is the responsibility of the supervising pharmacist to provide training and to determine the tasks that a trainee is competent to perform at any given point in the training. This is similar to the requirement for a pharmacist supervising a pharmacy intern.</p> <p>Subsection D is similar to other provisions in the Board's regulations in that it requires a registered 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		Sets out the current requirements for registration as a pharmacy technician.	Section 140 will remain in effect until July 1, 2022, after which applicants will be required to graduate from an

			<p>accredited pharmacy technician program, which includes any programs seeking accreditation and currently in pre-candidate status. Subsection D is deleted because Va. Code § 54.1-3321(B) requires passage of a national certification examination administered by the PTCB or NHA.</p>
	<p>21-141</p>	<p>Sets the requirements for registration as a pharmacy technician that will be effective July 1, 2022.</p>	<p>Section 141 will become effective on July 1, 2022.</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, to be registered as a pharmacy technician, an applicant shall provide evidence of the following:</p> <p>(1) Completion of a pharmacy technician training program that is: (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.</p> <p>(2) Evidence that the applicant successfully passed a national certification examination administered by PTCB or NHA.</p> <p>The requirements for registration in this regulation mirror the provisions of Va. Code § 54.1-3321(B). At the present time, the only accredited organization is a joint certification program by ASHP and ACPE, but this regulation will allow the Board to recognize other accrediting bodies if they are developed in the future. Pharmacy technician programs provided by the military are also recognized.</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</p>

			<p>documentation of previous practice and having passed a national certification examination administered by PTCB or NHA. Va. Code § 54.1-3321(C)(2) requires Board regulation to allow for registration by endorsement for someone with previous practice and national certification.</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 be eligible for registration if that person successfully passes a national certification examination administered by PTCB or NHA and submits documentation of completion or enrollment in a Board-approved training program and documentation of a passing examination score. The intent of this subsection is to allow persons who have not completed all of their training and taken the examination prior to July 1, 2022 to be eligible for registration as a pharmacy technician without having to start over in an accredited program.</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 the examination. Va. Code § 54.1-3321(C)(1) requires that the Board promulgate regulations to allow individuals who did not complete a board-approved program before July 1, 2022 but passed a certification examination eligibility for registration as a pharmacy technician.</p>
21-150		Establishes requirements for Board approval of a pharmacy technician training program.	This regulation will no longer be effective as of July 1, 2022. On that date all training programs must be accredited according to the provisions of Va. Code § 54.1-3321, which includes any programs seeking

			accreditation and currently in pre-candidate status.
21-160		Establishes requirements for Board approval of examination for technicians.	Section 160 is repealed because the required examinations for registration of a pharmacy technician are established in Va. Code § 54.1-3321.
21-170		Sets out the requirements for renewal and reinstatement of a pharmacy technician registration. 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 reinstatement following passage of an examination, completion of continuing education equal to four years of hours required for timely renewal of a registration, and payment of fees. 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 allows completion of continuing education and passage of an examination to serve as evidence of current competency.
21-180		Sets out requirements for continuing education for a pharmacy technician.	Subsection E is amended to delete the requirement that the technician provide "original" documentation and allow the technician to provide copies of documents as evidence of continuing education.