townhall.virginia.gov

Final Regulation
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	Implementation of 2021 legislation for pharmacists initiating treatment
Date this document prepared	March 30, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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.

Pursuant to Ch. 214 of the 2021 Acts of Assembly, the Board of Pharmacy amended 18VAC110-21-46 to include the additional drugs and devices that a pharmacist may initiate treatment with and the authority of the pharmacist to dispense controlled paraphernalia or other supplies and equipment in addition to certain drugs and devices.

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.

CDC = Centers for Disease Control and Prevention
FDA = Food and Drug Administration
HIV = human immunodeficiency virus
VIIS = Virginia Immunization Information System

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 March 30, 2023, the Board of Pharmacy voted to adopt final regulations to amend the Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians.

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.

These changes were mandated by Ch. 214 of the 2021 Acts of Assembly.

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."

Virginia Code § 54.1-3303.1(A) states that pharmacists may initiate treatment as described in the Code and as "set forth in regulations of the Board."

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 is intended to solve.

Ch. 214 of the 2021 Acts of Assembly expanded treatment options by pharmacists and required the Board to adopt regulations in furtherance of the act. The General Assembly has decided that these changes are necessary to protect the health, safety, and welfare of citizens; this was not done at the Board's discretion. The regulatory change is solely intended to comply with the statute. It is not intended to solve a particular problem, although the statute was intended to solve a particular problem.

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 changes include: (1) adding, where necessary, controlled paraphernalia or other supplies or equipment to subsections referring to dispensing or administering treatment to patients; (2) adding vaccines included on the Immunization Schedule published by the CDC or that have a current emergency use authorization from the FDA to the list of treatments that may be initiated; (3) adding tuberculin purified protein derivative for tuberculosis testing to the list of treatments that may be initiated; (4) adding controlled substances for the prevention of HIV, including for pre- and post-exposure prophylaxis, to the list of treatments that may be initiated; and (5) requiring pharmacists providing vaccines to report such administration to the VIIS as required by Va. Code § 32.1-46.01.

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 primary advantages to the public are access to care through a local pharmacy, allowing some patients to get immediate care without having to schedule an appointment with a practitioner. There are no disadvantages to the public.
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 to promulgate regulations pursuant to § 54.1-3303.1. 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 changes to previously reported information.

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's 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
Va. Society of Healthsystem Pharmacists	Appreciates the Virginia legislature and the Board's work on these new allowances that will benefit citizens by increasing access to care.	The Board appreciates the support.
Caitlin Prather	Changes will increase access to care and move the state closer to ending the HIV epidemic.	The Board appreciates the support.

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
110-20-150	Previous stage looked as though all of 110-20-150(I) was	This section is no longer part of Action 5861, implementation	150(I) was created by the stages of Action 5604. (See the proposed stage, Action 5604/Stage 9242.) Action 5861 added,

	added through this action.	of 2021 legislation for pharmacists initiating treatment.	pursuant to Ch. 214 of the 2021 Acts, "controlled paraphernalia, or other supplies or equipment" to (I). The text synced to Town Hall at that stage, however, mistakenly showed that *all* of (I) was added language under Action 5861. (See Action 5861/Stage 9562.) In the final adoption of Action 5604, however, the Board adopted a change in the language of (I) to include "controlled paraphernalia, or other supplies and equipment." (See Action 5604/Stage 9665.) This was the result of competing emergency regulations existing over the last three years, creating a confusing overlap of "new" regulations. While this phrase was not part of the original Action 5604, it was what the Board adopted as final and was published on November 21, 2022. Because the language originally included as new in Action 5861/Stage 9562 is already effective, it is not part of this final adoption of regulations in Action 5861.

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	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
21-46	Lists conditions for which a pharmacist may initiate treatment and provides specific requirements for doing so.	Adds "controlled paraphernalia and other supplies and equipment" to the drugs and devices pharmacists can already initiate treatment with to (A)(6), (B)(1), and (B)(2). Adds the following to the list of treatments a pharmacist can initiate treatment with or administer: • vaccines included on the Immunization Schedule published by the CDC in (A)(7); • tuberculin purified protein derivative for tuberculosis testing in (A)(8); and

		• controlled substances for the prevention of HIV in (A)(9). Requires any pharmacist administering a vaccine under the section to report the administration to the VIIS as required under § 32.1-46.01. The intent and rationale of these changes is to match and comply with the requirements of Ch. 214 of the 2021 Acts of Assembly.