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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)	18VAC110-21
VAC Chapter title(s)	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	2022 Pharmacists initiating treatment
Date this document prepared	June 25, 2024

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.

Chapters 790 and 791 of the 2022 Acts of Assembly expanded the conditions for which pharmacists can initiate treatment. The legislation additionally required that the Board of Pharmacy promulgate emergency regulations to be effective within 280 days of enactment. The Board did so and the emergency regulations are currently in effect. The emergency regulations amended previously existing emergency regulations promulgated pursuant to 2020 and 2021 legislation regarding pharmacists initiating treatment. Additionally, in 2023 the General Assembly again expanded the conditions for which pharmacists can initiate treatment and again required the Board to promulgate emergency regulations, which it did.

This final action will replace the emergency regulations from the 2022 legislation with identical permanent regulations. The permanent regulations replacing the 2020 and 2021 emergency regulations previously became effective.

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
HIPAA = Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d *et seq.*

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 25, 2024, the Board adopted final regulations amending 18VAC110-21, 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.

Chapters 790 and 791 of the 2022 Acts of Assembly required the Board to promulgate regulations to implement the provisions of the legislation in enactment clause 2.

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 sets forth the ability for pharmacists to initiate treatment for certain diseases and conditions "in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and 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.

The purpose of the proposed regulations is to ensure that a pharmacist who initiates treatment for patients follows protocols that would render such treatment to be a low risk for patient harm. The rules establishing treatment protocols, appropriate notification of primary care providers, obtaining patient histories, and providing appropriate counseling of patients are necessary to ensure the health and safety of patients who receive treatment from pharmacists.

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 changes to the existing emergency regulations are a requirement in 18VAC110-21-46(A) to require the pharmacist to have a bona fide pharmacist-patient relationship with the patient the pharmacist initiates treatment with. In addition, nicotine replacement therapy and other tobacco-cessation therapies are added as drugs and therapies with which a pharmacist can initiate treatment for an adult 18 years of age or older. Subsection B is added to Section 46, which allows a pharmacist to initiate treatment for patients three years of age and older by administering vaccines included on the Immunization Schedule published by the CDC, vaccines for COVID-19, and tests for COVID-19 and other coronaviruses. Additionally, the amendments ensure that practitioners will be provided notification of initiation of treatment with a patient even if no method exists to send the notification electronically in a manner compliant with HIPAA. Finally, the amendments require the treating pharmacist to obtain a patient history and, in the case of administration of vaccines to a minor, provide the minor's parent or guardian that the minor should visit a pediatrician annually.

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 healthcare for certain diseases and conditions at more locations, including patients' local pharmacy. 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. 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'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.

No public comment was received.

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.*

No changes have been made since the previous stage.

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 new requirements
21-46	Current emergency regulation addresses ability of pharmacists to initiate treatment based on 2020 and 2021 legislation.	The first change to Subsection A requires the pharmacist to have a bona fide pharmacist-patient relationship with the patient the pharmacist is initiating treatment with. A 10 is added to permit pharmacists to initiate treatment for patients 18 and over with nicotine replacement and other tobacco-cessation therapies. Subsection B is added to allow pharmacists to initiate treatment for patients aged 3 and older by administering vaccines included on the Immunization Schedule published by the CDC, vaccines for COVID-19, and tests for COVID-19 and other coronaviruses. Subsection C 2 is amended to ensure that notifications will be sent from a treating pharmacist to a patient's primary care provider without a requirement that the primary care provider be equipped to receive the information electronically in a manner that is compliant with HIPAA. Subsection C 5 is added to require a pharmacist initiating treatment to obtain a patient history, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration. Subsection C 6 is added to require a pharmacist administering a vaccine or vaccines to a minor to provide a written notice to the minor's parent or guardian that the minor should visit a pediatrician annually. Subsection D is added to permit the services described in 18VAC110-21-46 to be provided via telemedicine in compliance with requirements of § 54.1-3303 and consistent with the standard of care. The additions will improve timely access to care for patients who can receive vaccinations, tests, and certain controlled substances without the time and

		expense of traveling to a doctor or nurse practitioner for an office visit or an emergency department after normal office hours. The rationale for these amendments to the emergency regulations is to mirror the statutory language enacted by the legislature in Chapters 790 and 791 of the 2022 Acts of Assembly.