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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; 18VAC110-21
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy; Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Initiation of Treatment by Pharmacists
Date this document prepared	June 6, 2022 Amended July 18, 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.

Regulations amended by the Board set out listing of drugs and devices that may be used by a pharmacist to initiate treatment for a patient over the age of 18, as well as the requirements to follow a protocol, notify a primary care provider, maintain patient records, and protect patient privacy.

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.

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 6, 2022, the Board of Pharmacy adopted final amendments to 18VAC110-20, Regulations Governing the Practice of Pharmacy, and 18VAC110-21, Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians to comply with 2020 legislation regarding pharmacists initiating treatment.

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.

Adoption of amendments to regulations by emergency action was required to comply with the second enactment clause of HB1506 of the 2020 General Assembly. As specified, the amendments include provisions for ensuring patient privacy, notification to the patient's primary care provider, and counseling with the patient.

Adoption of proposed regulations is necessary to replace the emergency regulations currently in effect.

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 states that a pharmacist may initiate treatment for certain diseases and conditions "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's intended to solve.

The purpose of the amendments is to ensure that a pharmacist who initiates treatment for patients follows a protocol that would render such dispensing to be low risk for patient harm. The rules establishing protocols, appropriate notification of primary care providers, maintenance of records, and patient privacy are necessary to ensure this activity protects the health and safety of patients who receive such 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 provision in the proposed regulation is the addition of section 46 in Chapter 21, Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians. Subsection A sets out the listing of drugs and devices a pharmacist is authorized to use to initiate treatment under Code section 54.1-3303.1. Subsection B sets out the requirements for such initiation of treatment, including adherence to established protocols, notification to medical providers, maintenance of records, and protection of patient privacy.

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 access to certain prescription drugs and devices directly from a pharmacist rather than being required to go to a health care practitioner with prescriptive authority and incur additional cost. There should be no disadvantages to the public. A pharmacist who follows the protocols established for initiation of treatment would be providing drugs and devices that are considered to be low risk for any patient harm.
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 requirements that are more restrictive than federal requirements. The second enactment clause of HB1506 (2020) required that regulation include a requirement for compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq. in the initiation of treatment by a pharmacist.

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.

The proposed regulations were published in the Virginia Register on January 3, 2022. The Comment period opened at that time and remained open until March 4, 2022. A public hearing was held on February 7, 2022. The Board received no comments on Town Hall, at the public hearing, or from direct contact.

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.*

There have been no changes 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	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
20-150			Subsection I is added to establish the physical standards for a pharmacy in which a pharmacist would be initiating treatment with, dispensing, or administering drugs and devices pursuant to Virginia Code § 54.1-3303.1 and 18VAC110-21-46. The pharmacy must be configured in such a way that the consultation required for initiating treatment can protect patient confidentiality and comply with HIPAA requirements.
	21-46		Section 46 sets out new requirements for the initiation of treatment by pharmacists. Subsection A enumerates the drugs and devices with which a pharmacist may initate treatment for a patient. The listing of drugs and devices in subsection A and the limitation of treatment to persons 18 or older are specified in Virginia Code § 54.1-3303.1(A). Subsection B sets out the rules a pharmacist must follow in initiating such treatment. The second enactment clause of HB1506 of the 2020 Session required the Board to adopt protocols for each of the drug categories listed in Virginia Code § 54.1-3303.1(A). Those protocols were developed by a workgroup which consisted of members of the Boards of Pharmacy and Medicine and staff of the Department of Health, using their professional expertise, experience, and information taken from other states and national organizations. Minutes and agenda materials for the workgroup meetings on July 21, 2020 and August 17, 2020 are available on Town Hall. Subsection B also sets out requirements related to notification, counseling about the benefits of a relationship with a primary healthcare provider, and the specific consultation associated with initiating treatment with injectable or self-administered hormonal contraceptives. These requirements are also specified in Virginia Code § 54.1-3303.1(B). The workgroup recommended that the regulation include notification to an OB-GYN if the

			patient is receiving prenatal vitamins or contraception. The workgroup felt it was important for the practitioner to be aware of those prescriptions. Subsection B further specifies record requirements related to initiation of treatment. This regulation is consistent with record keeping regulations for medical practitioners such as MDs and DOs. It is also necessary because the initiation of treatment by a pharmacist is the provision of medical care. Pharmacists who bill through CMS typically have to maintain patient records for 10 years, so the requirement to maintain records for 6 years should not be burdensome. Finally, Subsection B requires that the services are performed in a manner that protects patient confidentiality and complies with HIPAA. This was a specific requirement in the second enactment clause of HB1506.