townhall.virginia.gov

Proposed 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 for Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	Initiation of Treatment by Pharmacists
Date this document prepared	3/16/22

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.

Proposed regulations in section 150 of 18VAC110-20 and in section 46 of 18VAC110-21 are amended to include the additional drugs and devices that may be initiated by a pharmacist and the authority to dispense controlled paraphernalia or other supplies or equipment in addition to certain drugs and devices, in accordance with provisions of Chapter 214 of the 2021 Acts of the Assembly. Section 46 was added by an emergency regulatory action in 2020; the additions to implement the 2021 legislation include:

1) Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, *controlled paraphernalia* as defined in § 54.1-3466, *and other supplies and equipment* available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-

pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

2) Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;

3) Tuberculin purified protein derivative for tuberculosis testing; and

4) Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

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.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Adoption of amendments to regulations by emergency action is required to comply with the second enactment of HB2079 of the 2021 General Assembly.

3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.

This proposed action is necessary to replace 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 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 mandate for regulations governing the initiation of treatment by pharmacists with certain drugs and devices is found in 54.1-3303.1 as amended in 2021 in HB2079:

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs ~~and~~, devices*, controlled paraphernalia, and other supplies and equipment* to persons 18 years of age or older 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:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; ~~and~~

6. ~~Medications~~ *Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter,* covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug*, device, controlled paraphernalia, or other supplies or equipment;*

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;

8. Tuberculin purified protein derivative for tuberculosis testing; and

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

C. A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

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 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 is the addition of section 46 in Chapter 21, Regulations for the Licensure of Pharmacists and Registration of Pharmacy Technicians. Subsection A sets out the listing of drugs and devices a pharmacist is authorized to initiate 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 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.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale

for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No impact
For all agencies: Benefits the regulatory change is designed to produce.	No impact

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None

Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Persons likely to be affected by the amendments would be pharmacists in retail settings who are authorized to initiate treatment for a customer of the pharmacy
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 15,326 licensed pharmacists, but there is no estimate of the number who would be directly affected. Pharmacists are not licensed by specialty (compounding, radiopharmaceutical, hospital, etc.), nor are they identified by work setting. There are 1789 pharmacies, but that includes all types of pharmacies – some of which would not be dispensing directly to a consumer.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There should not be additional costs relating to recordkeeping, counseling, or privacy as the protocols are similar to those already required by state and/or federal law.
Benefits the regulatory change is designed to produce.	Amendments will offer practitioners broader authority to administer drugs and devices and guidelines for safely administering such drugs and devices and offer the public more options for safe treatment.

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 54.1-3303.1 of the Code of Virginia specifically required regulations to be promulgated by the Board in order for pharmacists to be authorized to initiate treatment with certain drugs and devices. There are no viable alternatives.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There is no alternative to adoption of requirements, as it is mandated by Chapter 214 of the 2021 Acts of the Assembly.

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.

There was a comment period from January 17, 2022 to February 16, 2022; there was no public comment.

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.

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, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

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 Erin Barrett, 9960 Mayland Drive, Henrico, 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.

Table 1: Changes to Existing VAC Chapter(s)

Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
110-20-150	Section 150 establishes the physical standards for a pharmacy permitted by the Board.	In addition to the changes promulgated pursuant to the 2020 legislation, Subsection I is amended to include the dispensing of controlled paraphernalia or other supplies or equipment. *The workgroup, comprised of physicians and pharmacists, that developed regulations and protocols in 2020 felt that pharmacists should be able to dispense paraphernalia and other equipment (i.e., needles and syringes for diabetic patients), but that was not expressly authorized by the 2020 legislation. It was corrected in 2021 in HB2079, so those items are added in section 46.*

New chapter-section number, if applicable	Change, intent, rationale, and likely impact of new requirements
110-21-46	In addition to the changes promulgated pursuant to the 2020 legislation, the following were added to section 46: 1) In subsections A and B, controlled paraphernalia or other supplies or equipment were added to drugs and devices as items that a pharmacist may dispense without prescription from a practitioner. *See explanation for amendment to 110-20-150 above.* 2) There were three additions to the listing of dispensed drugs in HB2079, so they are included in subsection A in this emergency action:

	• Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration; • Tuberculin purified protein derivative for tuberculosis testing; and • Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention. *The additions will improve timely access to care from many adults who can receive vaccinations or certain controlled substances without the time and expense of a doctor/nurse practitioner visit.* 3) In subsection B, there is a requirement to report vaccine administration to the Virginia Immunization Information System. *The regulatory requirement is consistent with Subsection C of 54.1-3303.1 which specifies that:* *A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01*

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current emergency requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
18VAC110-21-46(B)(2)		Currently, a pharmacist must notify the patient's primary health care provider of initiation of treatment with a drug or device, excluding controlled paraphernalia or other supplies or equipment.	In 18VAC110-21-46(B)(2), the Board added "controlled paraphernalia, or other supplies or equipment" to the list of treatment types that require the pharmacist to contact the patient's primary health care provider. This change has been made because the Board interprets the notification requirement in Virginia Code § 54.1-3303.1(B) to apply to "controlled paraphernalia, or other supplies or equipment" as provided in HB2079 (Ch. 214 of the 2021 Special Session I) because these terms were added to Virginia Code § 54.1-3303.1(A), which identifies the scope of the provision. This was intended to be part of the Emergency Regulations, but was inadvertently omitted.