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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	9/9/20

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 the subject matter, intent, and goals of this 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 or changes. If applicable, generally describe the existing regulation.

Regulations set out listing of drugs and devices that may be initiated by a pharmacist 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.

N/A

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change

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

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

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 or Acts and 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. 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 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 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.

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.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

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.

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.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

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. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

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, and (iii) the potential impacts of the regulation.

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 Elaine Yeatts, 9960 Mayland Drive, Suite 300, Richmond, 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.

Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	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.	Subsection I is added as a requirement for a pharmacy in which a pharmacist would be initiating treatment with, dispensing, or administering drugs and devices pursuant to § 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 the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq. *Since pharmacists are currently required to offer consultation on prescriptions, they must already have an area or place in the pharmacy where patient privacy can be protected if the pharmacist is initiating treatment with one of the specified drugs or devices.*
	110-21-46	Sets out new requirements, consistent with 54.1-3303.1 for a pharmacist who may initiate treatment with, dispense,	Subsection A enumerates the drugs and devices with which a pharmacist may initiate treatment for a patient. 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

		or administer the following drugs and devices to persons 18 years of age or older	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 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. *The listing of drugs and devices in subsection A and the limitation of persons age 18 or older are specified in subsection A of 54.1-3303.1 of the Code.* Subsection B sets out the rules a pharmacist must follow in initiating such treatment: 1. Follow the statewide protocol adopted by the board for each drug or device. *As specified in the second enactment of HB1506, the Board was required to adopt protocols for each of the drug categories in subsection A. Those protocols were developed by a Workgroup consisting of members of the Boards of Pharmacy and Medicine and staff of the Department of Health, using their professional expertise and experience and information gleaned from other states and national organizations. Minutes and agenda materials for the Workgroup meetings on 7/21/20 and 8/17/20 may be found at: https://townhall.virginia.gov/L/Meetings.cfm?BoardID=30&time=PastYear* 2. Notify the patient's primary health care provider that treatment has been initiated 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 drug being initiated is an injectable or self-administered hormonal contraceptive or a prenatal vitamin, the pharmacist shall also notify the patient's obstetrician or gynecologist. 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. *The requirements for notification, counseling about the benefits of a relationship with a primary health care provider, and the specific consultation associated with initiating treatment with injectable or self-administered hormonal contraceptives are specifically set out in subsection B of 54.1-3303.1. The Workgroup recommended that the regulation include notification to an OB-GYN is the patient is receiving pre-natal vitamins or contraception because it is important for that practitioner to be aware of those prescriptions.* 3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions: a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time. *Since initiation of treatment is the provision of medical care, the regulation for maintenance of patient records is consistent with regulations for medical practitioners such as MDs and DOs. Pharmacists who bill through CMS typically have to maintain patient records for 10 years, so the requirement for six years would not be burdensome.* 4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq. *In the second enactment of HB1506, the Board was specifically mandated to promulgate regulations for compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.*