Virginia Department of Planning and Budget

Economic Impact Analysis

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Department of Health Professions
Town Hall Action/Stage: 5604 / 9242
June 9, 2021

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 731 of the 2020 Acts of Assembly (legislation), an emergency regulation became effective on January 3, 2021, that allows pharmacists to dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with specified requirements.

The emergency regulation will expire on July 2, 2022. Also pursuant to the legislation, the Board of Pharmacy proposes to replace the emergency regulation with an identical permanent regulation.

Background

Amongst other new text, Chapter 731 added the following to the Code of Virginia:

> § 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.

The proposed regulation is essentially identical to the legislative text. As instructed by the legislation, statewide protocols were developed by the Board in collaboration with the Board of Medicine and the Department of Health for all of the drugs and devices listed above. These protocols are currently posted on the Board's website.[1]

> Chapter 731 also added the following to the new § 54.1-3303.1.
>
> 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.

Again, the proposed regulation is essentially identical to the legislative text.

Estimated Benefits and Costs

By mirroring the legislation, the proposed regulation essentially confers the same benefits found in the statute. Namely, by allowing pharmacists to dispense and administer the specified drugs and devices, patients potentially benefit in three ways: 1) saving the time required to obtain and go to a doctor's appointment in order to get a prescription, 2) saving the fees associated with

[1] See https://www.dhp.virginia.gov/Pharmacy/

the doctor's appointment, and 3) reducing the cost of obtaining 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.

Naloxone is an opioid antagonist used for the complete or partial reversal of opioid overdose, including respiratory depression.[2] Epinephrine is used in emergencies to treat very serious allergic reactions to insect stings/bites, foods, drugs, or other substances. Epinephrine acts quickly to improve breathing, stimulate the heart, raise a dropping blood pressure, reverse hives, and reduce swelling of the face, lips, and throat.[3] Enabling pharmacists to administer these drugs without a physician's prescription could potentially be lifesaving in some circumstances.

The protocols jointly created with the Board of Medicine and the Department of Health for the pharmacists to follow should help minimize risk that pharmacists would improperly initiate treatment with, dispense, or administer the specified drugs and devices. The requirement in the new § 54.1-3303.1 that the pharmacist who initiates treatment with or dispenses or administers the specified drugs or devices notifies the patient's primary health care provider, provided that the patient consents to such notification, should help continuity of care. Likewise, the requirements that if: 1) the patient does not have a primary health care provider, the pharmacist counsels 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, and 2) the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist counsels the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears, should help encourage patients to pursue and find appropriate ongoing health care services.

Businesses and Other Entities Affected

There are approximately 8,600 licensed pharmacists with a Virginia address and 1,789 pharmacies in the Commonwealth.[4] It is unclear how many pharmacists and pharmacies will

[2] Source: www.rxlist.com
[3] Source: www.webmd.com
[4] Source: Department of Health Professions

choose to provide this service to their patients. Only those that elect to initiate treatment for patients would be affected by the legislation and proposed amendments to the regulation.

Since the administering of the specified drugs and devices would be optional for pharmacists, the proposal does not produce any costs.

Small Businesses[5] Affected:

The proposed amendments do not appear to adversely affect small businesses.

Localities[6] Affected[7]

Localities with comparatively high opioid addiction rates may be particularly affected in that pharmacists could administer naloxone to someone brought into their pharmacy experiencing an opioid overdose. The proposal does not introduce costs for local governments.

Projected Impact on Employment

The proposed amendments do not appear to substantively affect total employment.

Effects on the Use and Value of Private Property

The legislation and the proposed regulation would likely spur some pharmacists to dispense and administer some, in not all of the drugs and devices specified in the legislation and proposed regulation. This may have a moderate positive impact on the value of the associated pharmacies. The proposed amendments do not affect real estate development costs.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and

[5] Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

[6] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[7] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.