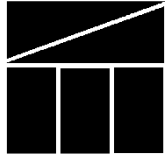


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 110-20 – Regulations Governing the Practice of Pharmacy
Department of Health Professions
Town Hall Action/Stage: 4789/8101
December 13, 2017

Summary of the Proposed Amendments to Regulation

Pursuant to Chapters 55 and 58 of the 2017 Acts of the Assembly, the Board of Pharmacy (Board) proposes to amend their regulation to allow the issuance of controlled substances registration to: “1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training and 2) an entity for the purpose of establishing a bona fide practitioner-patient [relationship] for prescribing when treatment is provided by telemedicine in accordance with federal rules.” These proposed regulatory amendments will replace emergency amendments that became effective May 8, 2017 and that are currently set to expire on November 7, 2018.

Result of Analysis

Benefits likely outweigh costs for all proposed changes.

Estimated Economic Impact

In 2017, Chapters 55 and 58 became law. As reported by the Board of Pharmacy, Chapter 55¹:

“Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for

¹ <http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=818>

use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the controlled substance registration, provided that the entity possessing the controlled substance registration maintains records in accordance with regulations of the Board of Pharmacy.”

Chapter 58²:

“Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment³, for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of

² <http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=819> and <http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=839>

³ Board staff reports that instrumentation can include physical medical equipment to do such things as measure blood pressure, temperature, etc. or may include the ability to connect via Skype so that the practitioner can meet face to face virtually with patients, depending on the applicable standard of care.

telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration.”

Both of these Chapters contain language requiring the Board to promulgate emergency regulations to implement their mandates. The Board promulgated emergency regulations that became effective May 8, 2017 and that are currently set to expire on November 7, 2018.

The Board now proposes to promulgate regulatory amendments to replace the emergency amendments that are currently in place. The proposed language is identical to the emergency language that is currently effective. In addition to allowing the issuance of controlled substances registration to entities listed in Chapters 55 and 58, the Board’s proposed regulation sets rules for record keeping as required by Chapter 55. Specifically, “persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal...” will have to maintain records that include: 1) the prescriber’s standing order authorizing the trained individual to dispense naloxone; 2) invoices or other records showing receipt of naloxone⁴; 3) a manual or electronic log that records the name, strength, lot, expiration date and quantity of naloxone transferred from the controlled substances registration location to the off-site training location along with the date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services; and 4) records for dispensing of naloxone that when and to whom naloxone was dispensed. Records will have to be filed chronologically and maintained for at least two years.

Individuals who newly qualify for controlled substances registration, and who choose to get and maintain that registration, will incur an initial fee of \$90 and a renewal fee of \$90 every year thereafter. Additionally, individuals who are subject to the record keeping requirements proposed by the Board in this action will incur some record keeping costs that include time spent compiling records and, if records are in paper, copying costs. These costs will likely be outweighed by the benefits that will accrue to individuals who overdose on opioids and may have their lives saved because they have easier access to naloxone. Individuals in Southwest Virginia, where psychiatric and other medical services are less readily available, will likely

⁴ These records can be maintained electronically.

benefit disproportionately from this proposed regulation and the statutory changes that authorize and require it.

Businesses and Entities Affected

This regulatory action will affect all individuals who will newly qualify for controlled substances registration as well as the patients they may help. Board staff reports that there are 1,168 controlled substances registrants in the Commonwealth but that it is likely that only a few registrations have been issued under the emergency regulation that this proposed regulation will replace.

Localities Particularly Affected

Localities in Southwest Virginia will particularly benefit from this proposed regulation.

Projected Impact on Employment

These proposed regulatory changes are unlikely to affect employment in the Commonwealth.

Effects on the Use and Value of Private Property

These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs

These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition

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.”

Costs and Other Effects

No small businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact

No small businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Adverse Impacts:

Businesses:

No businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Localities:

Localities in the Commonwealth are unlikely to see any adverse impacts on account of these proposed regulatory changes.

Other Entities:

No other entities are likely to be adversely affected by these proposed changes.

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 Number 17 (2014). 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(C): 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 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.