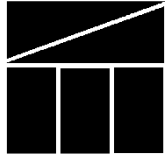


Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes  Not Needed

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

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**18 VAC 105 -20 Regulations of the Virginia Board of Optometry**  
**Department of Health Professions**  
**Town Hall Action/Stage: 4892 / 8222**  
April 27, 2018

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### **Summary of the Proposed Amendments to Regulation**

The Board of Optometry (Board) proposes to promulgate provisions for optometrists' prescribing of controlled substances containing opioids.

### **Result of Analysis**

There is insufficient data to accurately compare the magnitude of the benefits versus the costs.

### **Estimated Economic Impact**

#### *General Opioid Background*

The Department of Health Professions reports that in 2014, for the first time in Virginia, more people died from opioid overdoses than from fatal car accidents. Emergency department visits for heroin overdoses for January to September 2016 increased 89 percent, compared to the same nine-month period in 2015. In the first half of 2016, the total number of fatal drug overdoses in Virginia increased 35 percent, when compared to the same period in 2015, and in 2013, fatal drug overdoses became the number one cause of unnatural death. Many of those who become addicted to heroin started with an addiction to prescription drugs. In order to stem the tide of addiction, the Board believes practitioners need enforceable rules for proper prescribing of drugs containing opioid in treatment of pain to protect the public health and safety.

### *Optometry Background*

The Regulations of the Virginia Board of Optometry include certification for qualified optometrists to treat diseases and abnormal conditions of the human eye and its adnexa and to prescribe and administer certain therapeutic pharmaceutical agents (TPA). The certification is referred to as TPA certification. The TPA that a TPA-certified optometrist may prescribe include a limited number of controlled substances containing opioids. The current regulation does not include any requirements that specifically pertain to opioids.

### *Proposal*

The proposed regulation includes the following provisions:

- A TPA-certified optometrist must consider non-pharmacologic and non-opioid treatment prior to prescribing opioid treatment for patients with acute pain.<sup>1</sup>
- Prior to prescribing an opioid for acute pain, the TPA-certified optometrist must perform a health history and physical examination appropriate to the complaint, query the Prescription Monitoring Program (PMP) as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance abuse.
- When prescribing an opioid, the practitioner must prescribe the lowest effective dose for the fewest number of days, not to exceed a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the patient record.
- The optometrist must carefully consider and document in the patient record the reasons to exceed the equivalent of 50 morphine milligrams per day.
- Naloxone shall be considered for patients when risk factors of prior overdose, substance abuse, or concomitant benzodiazepine are present.
- If another prescription for an opioid is to be written beyond seven days, the patient must be re-evaluated, the need for continued prescribing must be documented in the patient record, and the optometrist must check the patient's prescription history in the PMP.
- The patient record must include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the

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<sup>1</sup> Acute pain is defined as "pain that occurs within the normal course of a disease or condition for which controlled substances may be prescribed for no more than three months."

medication prescribed (including date, type, dosage, strength, and quantity prescribed).

- Due to a higher risk of fatal overdose when opioids are prescribed for a patient also taking benzodiazepines, sedative hypnotics, tramadol, or carisoprodol, a TPA-certified optometrist shall only co-prescribe these substances when there are extenuating circumstances and shall document in the patient record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.
- If an optometrist treats a patient for whom an opioid prescription is necessary for chronic pain,<sup>2</sup> the licensee shall either: (1) refer the patient to a medical doctor who is a pain management specialist, or (2) comply with regulations of the Board of Medicine, 18 VAC 85-21-60 through 18 VAC 85-21-120, if choosing to manage the chronic pain with an opioid prescription.
- Definitions for “acute pain,” “chronic pain,” “controlled substance,” and the “Prescription Monitoring Program” have been added to the regulation.

### *Analysis*

The proposed provisions increase time costs for both TPA-certified optometrists and patients, and recordkeeping costs for the optometry practice. By effectively requiring additional office visits for opioid treatment beyond seven days, fees paid by patients and/or their insurance carriers would increase as well. By discouraging the use of opioids, the proposed provisions may result in some patients experiencing more pain or being in pain for more time than without the proposed requirements.

The proposed requirements are designed, of course, to help reduce opioid addiction and opioid-related deaths. It is not known how successful the provisions would be in achieving those goals. To the extent that the proposals would be successful in reducing opioid addiction and opioid-related deaths, the benefits likely would exceed the costs. If the provisions are ineffective in reducing opioid addiction and opioid-related deaths, then the costs would exceed the benefits.

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<sup>2</sup> Chronic pain is defined as “nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.”

**Businesses and Entities Affected**

The proposed amendments potentially affect the 1,669 TPA-certified optometrists licensed in Virginia, and their practices.<sup>3</sup> All or most of their practices would qualify as small businesses.

**Localities Particularly Affected**

The proposed amendments do not disproportionately affect particular localities.

**Projected Impact on Employment**

The proposed amendments are unlikely to significantly affect employment.

**Effects on the Use and Value of Private Property**

The proposed amendment do not significantly affect the use and value of private property.

**Real Estate Development Costs**

The proposed amendments do not affect real estate development costs.

**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**

The proposed amendments moderately increase time and recordkeeping costs for optometry practices.

**Alternative Method that Minimizes Adverse Impact**

There is not an apparent alternative method that achieves the same policy goal at a lower cost.

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<sup>3</sup> Data source: Department of Health Professions

**Adverse Impacts:****Businesses:**

The proposed amendments moderately increase time and recordkeeping costs for optometry practices.

**Localities:**

The proposed amendments do not adversely affect localities.

**Other Entities:**

The proposed amendments may result in some patients experiencing more pain or being in pain for more time than without the proposed requirements.

**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.