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 110-30 – Regulations for Practitioners of the Healing Arts to Sell Controlled Substances**
**Department of Health Professions**
**Town Hall Action/Stage: 4451/7507**
June 23, 2016

## Summary of the Proposed Amendments to Regulation

As mandated by Chapter 117 of the 2015 Acts of the Assembly, the Board of Pharmacy (Board) proposes to promulgate a replacement regulation for an emergency regulation that will expire on June 6, 2017. The emergency and replacement regulations: 1) rearrange portions of the regulation so that classes of fees are grouped together, 2) clarify that required sinks with hot and cold running water must be within 20 feet of the selling and storage area of the facility and may not be in a bathroom or examination room 3) lower fees for initial individual licensure for doctors of medicine, osteopathic medicine or podiatry[1] to sell control substances and 4) institute permit fees for most facilities[2] where practitioners of the healing arts sell controlled substances.

## Result of Analysis

For most proposed changes, benefits likely outweigh costs. For one change, there is insufficient information to ascertain whether benefits outweigh costs for all affected entities.

[1] These entities are practitioners of the healing arts for the purposes of this regulation.

[2] By statute and this regulation, sole practitioners who sell controlled substances must pay individual licensure fees but are exempt from having to pay facility permit fees (although they will have to pay licensure fees).

## Estimated Economic Impact

Many of the Board's proposed regulatory changes, including rearranging regulatory sections and expanding language outlining the requirement for a sink in the immediate vicinity of a facility's controlled substance selling and storage area, do not change current rules or practice. For instance, the Board already requires a sink within 20 feet of the selling and storage area and does not allow that sink to be in a bathroom[3] or an examination room[4]. For these changes, no entities are likely to incur any costs. Interested parties, however, will likely benefit from the additional clarity these changes bring to the regulation.

Before the emergency changes to this regulation became effective, individual practitioners of the healing arts paid $240 to be initially licensed to sell controlled substances and $90 each year to renew that license. Additionally, individuals who missed their renewal date but renewed their license within a year of its expiration date paid a $30 late renewal fee in addition to their regular renewal fee. Individuals who missed their renewal date by more than a year had to pay a $210 reinstatement fee in addition to their renewal fee. Because part of these individual fees were meant to cover inspection of the facility from which individuals would be selling controlled substances, and because the Board instituted facility permit fees that would cover the cost of those inspections instead, the Board proposes to lower half of the individual fees.

Under this proposed regulation, individual licensees will pay $180 for initial licensure to sell controlled substances, $90 to renew their licenses each year, $30 for late renewal and $150 for reinstatement after a license has lapsed for more than a year. Licensees will benefit from these fee reductions as they will either lower individual costs for licensure absolutely and will partially or completely offset new facility permit fees for individual practitioners who are in partnership private practices where partners are responsible for splitting business expenses.

[3] Board staff reports that sinks in bathrooms are not sanitary enough for mixing medications.

[4] Board staff reports that this is not allowed because doctors may need to access the sink when the examination room is occupied by a patient.

The Board also proposes to institute new fees for faculty permits. The fee for an initial permit is $240 and annual renewal of that permit is also $240 so long as the permit is renewed in a timely manner. If business owners renew the their facility permit after the renewal date but within one year, they will have to pay an additional $40; the reinstatement fee for renewing a facility permit more than a year after it lapsed is $240 additional to the on time renewal fee.

Both Chapter 117, and this regulation, exempt sole proprietor practitioners from paying permit fees although they still have to obtain a permit and will have to pay to be individually licensed. Because of this exemption, no sole proprietor practitioner is likely to incur any additional fees, either upon initial licensure/permitting or when they renew their licenses or permits, on account of this proposed change.

Partnership practices with two or three partners[5] will incur net extra costs of $120[6] and $60[7] respectively to be initially licensed/permitted when comparing higher individual licensure fees paid before the emergency stage of this regulation to lower individual fees plus the newly required facility permit paid under this proposed regulation. Partnership practices with four partner practitioners are at a point of indifference because combined fees to be initially licensed/permitted would be the same $960 under the old regulation and under this proposed regulation.

All partnerships with more than four partners and where the business is actually owned by the partners will see cost savings on account of lower combined initial fees under the proposed regulation. Board staff reports that many practices are owned by corporations or hospitals; for those practices, all individual practitioners will see lower

[5] This math is assuming partnerships where the individual partners own the business and will split business expenses.

[6] For a partnership with two doctors licensed to sell controlled substances, the doctors paid a $480 combined to be initially licensed ($240 for each doctor's individual license x 2) under pre-emergency regulation and now pay $600 under the proposed regulation to be initially licensed ($180 for each doctor's individual license plus $240 for the facility license).

[7] For partnerships with three doctors licensed to sell control substances, the doctors paid $720 combined to be initially licensed ($240 for each doctor's individual license x 3) under pre-emergency regulation and now pay $780 under the proposed regulation to be initially licensed ($180 for each doctor's individual license plus $240 for the facility license).

initial licensure costs and the corporation or hospital practice owner will incur the additional facility permit fee.

All licensed practitioners except for sole practitioners, or the businesses that they work for, will incur additional fee costs upon renewal of their facility permits because individual renewal fees remain the same but permit fees need to additionally be paid. There is insufficient information to ascertain whether the benefits of requiring facility permits will outweigh the higher costs that some individuals or businesses will accrue.

### Businesses and Entities Affected

Board staff reports that there are approximately 200 facilities which are permitted to sell controlled substances in the state and that the Board licenses 624 practitioners of the healing arts to sell controlled substances. All of these licensees, all future licensees and all businesses that need facility permits are affected by this proposed regulation.

### Localities Particularly Affected

No locality will be particularly affected by these proposed regulatory changes.

### 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

The facility permit fees in this regulation will raise total fees costs very marginally for some businesses in the Commonwealth. To the extent that those small costs are not passed on to patients in the form of slightly higher cost of care, those businesses will see a very marginal decrease in value.

### 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

Small business partnerships will likely incur additional costs on account of the new facility permit fee in this proposed regulation.

### Alternative Method that Minimizes Adverse Impact

There are no alternatives that would both lower costs and meet the legislative mandate for facility permits.

## Adverse Impacts:

### Businesses:

Physician practices will likely incur additional costs on account of the new facility permit fee in this proposed regulation.

### 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.

amh