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: 4938 / 8270**
June 14, 2018

## Summary of the Proposed Amendments to Regulation

The Board of Pharmacy (Board) proposes to raise fees.

## Result of Analysis

The benefits likely[1] outweigh the costs for the proposed amendments.

## Estimated Economic Impact

*Background*

Fees charged to applicants and licensees of the Board of Pharmacy have not increased since December 2002.[2] During that period, there have been three reductions in renewal fees (2005, 2006 and 2009), while the rate of price inflation has been 33 percent.[3] The number of regulated entities has substantially increased in recent years (12,861 in 2002 to 37,608 in 2018); so the need for additional staff (six in 2002 to 12 in 2018) has increased costs to the Board.

[1] This is not 100 percent certain. See Analysis subsection for discussion.

[2] This applies to fees that existed in 2002. There have been new fees introduced since then. Verification fees for the pharmacy professions were added in 2015 (http://townhall.virginia.gov/L/ViewAction.cfm?actionid=3444), and permit fees for practitioners selling controlled substances were added in 2017 (http://townhall.virginia.gov/L/ViewAction.cfm?actionid=4451).

[3] This rate of inflation is calculated using the Gross Domestic Product: Implicit Price Deflator. See https://fred.stlouisfed.org/series/GDPDEF

Additionally, the cost of inspections has increased, as have expenditures for investigation and adjudication of disciplinary cases. Enforcement inspection and investigative hours have increased from 7,179.30 in Fiscal Year (FY) 2002 to 13,220.30 in FY 2017. The number of cases adjudicated have increased from 269 in 2002 to 651 in 2017. Additionally, the Board's share of allocated expenditures has grown as costs to the Department of Health Professions (DHP) have increased. For example, in FY 2002, information technology (IT) costs were approximately $300,000; in FY 2017, IT costs were $1.84 million.[4]

Code of Virginia § 54.1-113.A (commonly called the Callahan Act)[5] states that:

> Following the close of any biennium, when the account for any regulatory board within the Department of Professional and Occupational Regulation or the Department of Health Professions maintained under § 54.1-308 or 54.1-2505 shows expenses allocated to it for the past biennium to be more than 10 percent greater or less than moneys collected on behalf of the board, it shall revise the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

In FY2017, the Board's expenditures were $3,272,687, while its revenues were $3,293,583. DHP projects that expenditures for FY2018 will be $3,745,630 and revenues will be $3,131,895. Thus, total expenditures for the biennium are projected to be $7,018,317, with revenues projected at $6,425,478. The projected expenditures are 9.2 percent higher than the projected revenues. This being less than 10 percent, the mandate to raise fees via the Callahan Act is not yet triggered. Nevertheless, DHP does anticipate that expenditures will continue to rise faster than revenues, necessitating higher fees to cover costs.

*Proposal*

The Board proposes to increase 110 different fees in this regulatory action, primarily those paid by pharmacists, pharmacies, pharmacist interns, and pharmacy technicians. In addition, the Board is also proposing fee increases for practitioners of the healing arts and wholesale manufacturers, distributors, and warehousers. The minimum dollar value of the

[4] All data (other than inflation rate) provided by Department of Health Professions.

[5] See https://law.lis.virginia.gov/vacode/title54.1/chapter1/section54.1-113/

proposed fee increases is $5,[6] while the maximum dollar value of the proposed fee increases is $230.[7]

The majority of the fees would increase by approximately thirty percent.[8] For the fees that result from an inspection, the Board plans to increase the current fees to an amount to offset the actual costs of enforcement. There are 91 separate fees that would be subject to the roughly thirty percent fee increase.[9] For pharmacists, these cover such areas as initial application fees, annual renewal fees, late fees, reinstatement fees, facility change and inspection fees, and the innovative program approval fee. For practitioners of the healing arts, these cover initial application fees, annual renewal fees, late fees, and reinstatement fees. For manufacturers and distributors, these cover application fees, renewal fees, late fees, and reinstatement fees.

The Board also proposes to increase the fee for facility permits where practitioners of the healing arts sell controlled substances, from $40 to $50. In addition, the Board proposes to repeal several fees related to humane society permits; these fees are no longer assessed since these facilities now pay a controlled substance registration fee. With the proposed fee increases, the DHP projects that the Board will have sufficient revenue to offset expenditures by June 30, 2021.

*Analysis*

DHP points out that without adequate revenue to support inspections of pharmacy facilities, licensing and discipline functions, applicants for licensure or pharmacy permits cannot be approved in a timely manner. This may slow the growth of pharmacy services for the citizens of the Commonwealth. In addition, sufficient funding is needed to carry out the investigative and disciplinary activities of the board without creating significant delays in both activities. If there is a substantial backlog of disciplinary cases, public health and safety may be at risk by allowing

[6] Several fees are proposed to increase from $15 to $20 (the pharmacy intern registration fee, the late fee for an inactive pharmacist license, and the late fee for approval of a pharmacy technician training program), or from $10 to $15 (the late fee for approval of a repackaging training program, and the duplicate license or registration fee).

[7] Some fees would increase from $270 to $500; these include the pharmacy permit application fee and the permit for a physician who is licensed to dispense drugs. This latter fee was just introduced in 2017. See http://townhall.virginia.gov/l/ViewAction.cfm?actionid=4451.

[8] The actual percentages range from 28.57 percent to 33.33 percent for those fees that are increasing by approximately 30 percent.

[9] For a more complete list of the proposed fee increases, see http://townhall.virginia.gov/L/ViewXML.cfm?textid=12504.

practitioners guilty of drug diversion, unprofessional conduct, or careless security to continue in practice for several months awaiting a review and adjudication of an investigative report. Thus, there are both clear benefits and clear costs introduced by the fee increases.

It is not 100 percent certain whether or not the benefits exceed the costs. Since regulation of professions is not a market good, there is not an obvious market price at which speedier license processing and disciplinary investigations are valued. Nevertheless, since the proposed fee increases bring fees to approximately the same level as 15 years ago once inflation is taken into consideration, the benefits likely outweigh the costs.

## Businesses and Entities Affected

The proposed amendments affect all entities and individuals that are regulated by the Board, including: 1,857 pharmacies, 14,714 pharmacists, 1,848 pharmacy interns, 14,552 pharmacy technicians, 140 pharmacy technician-training programs, 727 physicians selling controlled substances, 175 physician selling drugs locations, 10 pilot programs, 2 repackaging training programs, 66 restricted manufacturers, 47 warehousers, 116 wholesale distributors, 1,196 business controlled substance registrants, 9 continuing education course providers, 19 limited use pharmacy technicians, 258 medical equipment suppliers, 335 non-resident medical equipment suppliers, 26 non-resident outsourcing facilities, 732 non-resident pharmacies, 749 non-resident wholesale distributors, 29 non-restricted manufacturers, and 1 permitted physician.[10]

## Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

## Projected Impact on Employment

The proposed fee increases are not likely to significantly affect employment, but may at the margin discourage the creation of a limited number of positions at affected firms.

## Effects on the Use and Value of Private Property

The proposed fee increases moderately increase costs for affected businesses, and would have a commensurate moderate effect on their value.

[10] Data source: Department of Health Professions

## 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 fee increases raise costs for small pharmacies and other small businesses.

### Alternative Method that Minimizes Adverse Impact

If decision makers were to decide that not all current functions of the Board were necessary, or necessary to perform at the frequency or speed supported by the revenue that would be raised by the proposed fee increases, then smaller fee increases could potentially be set.

## Adverse Impacts:

### Businesses:

The proposed fee increases raise costs for pharmacies, pharmacy technician-training programs, repackaging training programs, manufacturers, warehousers, wholesale distributors, continuing education course providers, medical equipment suppliers, outsourcing facilities, and physician practices that sell drugs.

### Localities:

The proposed fee increases would not likely significantly adversely affect localities.

### Other Entities:

The proposed fee increases would not likely significantly adversely affect other entities.

## 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.