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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20 18VAC110-21 18VAC110-30 18VAC110-50
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy; Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians; Regulations for Practitioners of the Healing Arts to Sell Controlled Substances; Regulations Governing Wholesale Distributors, Manufacturers, Third-Party Logistics Providers, and Warehousers
Action title	Increase in fees
Date this document prepared	September 26, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

The Board must begin amending regulations to ensure it obtains sufficient operating funds for future years. Under the current fee structure, the Board will carry a negative balance of $(688,083) for FY2026.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

N/A

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation, (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for this action was a projection of fees and expenditures for the Board of Pharmacy. The mandate for this action is Virginia Code § 54.1-113(B), which requires the Board to adjust fees to ensure that the "fees are sufficient but not excessive to cover expenses."

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(5) requires the Board to "levy and collect fees . . . sufficient to cover all expenses" of the Board. Virginia Code § 54.1-2400(6) states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The Board last initiated a fee increase in 2017, which became effective in 2020. The previous fee increase prior to that was initiated in 2001 and became effective in 2002. The Board instituted one-time fee reductions three times prior to the 2017 action.

Because salaries comprise the bulk of costs for any board within the agency, the five compounded state salary increases instituted since FY2020 have accelerated the need for a fee increase for the Board. When the General Assembly enacts salary increases, general fund state agencies receive allocations through the budget process to cover the increase. DHP, as a special fund agency, receives no such

allocation and must ultimately increase fees on licensees to cover the difference. Fee increases impacting the Board include:

- 5% total salary increase in FY2020;
- 5% salary increase on June 10, 2021;
- 5% salary increase on July 10, 2022;
- 5% salary increase on June 10, 2023; and
- Future 2% salary increase on December 10, 2023.

Additional operational changes affecting available funds include: an increase in licensee counts (FY2020: 37,640; FY2023: 45,486); regulated categories added to the Board's jurisdiction (in 2019 the Board began registering nonresident third-party logistics providers, nonresident warehousers, limited-use physician selling drugs; in 2021 began registering pharmacy technician trainees); an increase in disciplinary cases received by the Board (2018: 651 cases; 2023: 878); and an increase in the number of FTEs (2018: 12 FTEs; 2023: 14 FTEs). It should be noted that the number of FTEs has not increased consistent with the increase in workload for the Board. If the number of FTEs had increased at a rate consistent with operational workload increases, the Board would have between 20 and 21 FTEs.

Without adequate revenue to support inspections of pharmacy facilities, licensing, and disciplinary functions, work to protect the public by regulating, licensing, and disciplining the pharmacy workforce under the Board will slow. This will deprive the citizens of the Commonwealth with needed and safe pharmacy services. Additionally, should inadequate revenue cause a backlog of disciplinary cases, public health and safety may be at risk by permitting practitioners actively committing drug diversion or unprofessional conduct to continue practicing unencumbered for months while awaiting review and adjudication of disciplinary matters.

The Board's actual cash balance for FY2023 is $2,270,363. The estimated **FY2024** cash balance, reflecting a projected revenue of $5,073,521 and expenditures of $5,897,757, will be **$1,446,128**. The estimated **FY2025** cash balance, reflecting a projected revenue of $5,208,210 and expenditures of $6,220,274, will be **$434,063**. The estimated **FY2026** cash balance, reflecting a projected revenue of $5,346,940 and expenditures of $6,469,085, will be **-$688,083**. The estimated **FY2027** cash balance, reflecting a projected revenue of $5,489,832 and expenditures of $6,727,849, will be **-$1,926,100**.

The Medical Cannabis Program, scheduled to move to the Virginia Cannabis Control Authority on January 1, 2024, is not factored into this action or included in the fiscal considerations noted here.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The Board will consider an increase in fees for all regulated practitioners and entities. The Board will develop fee structures that will address the deficit in Board funding for the Board to consider prior to adoption of proposed regulations. The Board will adhere to DHP Policy 76-90.05, Principles for Establishment of Fees, in determining amendments.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small

businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board cannot collect fees unless those fees are set forth in regulation. There are no alternatives.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia, describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.