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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
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Therapeutic interchange and adaptation regulations pursuant to SB418
Date this document prepared	June 16, 2026

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).

Pursuant to Ch. 888 of the 2026 Acts of Assembly (SB418), the Board of Pharmacy will promulgate regulations to facilitate changes contained in the legislation, which permit a pharmacist to perform a therapeutic interchange by substituting a drug with another drug in the same therapeutic class that the pharmacist believes will have a similar therapeutic effect and adverse-reaction profile when administered in a therapeutically equivalent dose as the prescribed drug.

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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."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 mandate for this action is Ch. 888 of the 2026 Acts of Assembly (SB418).

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(6) specifically 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."

Virginia Code § 54.1-3408.06 (effective July 1, 2026) allows pharmacists to perform therapeutic interchanges provided, among other things, "the substitution is made in accordance with Board regulations." Additionally, enactment clause 2 of Ch. 888 of the 2026 Acts of Assembly states that "the Board of Pharmacy shall promulgate regulations in accordance with this act, which shall include determination of which therapeutic classes of drugs are eligible for therapeutic interchange and which therapeutic classes shall be prohibited."

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 General Assembly determined that these amendments are essential to protect the health, safety, or welfare of citizens by passing SB418, which became Ch. 888 of the 2026 Acts of Assembly, and in that legislation directing the Board of Pharmacy to promulgate regulations.

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 of Pharmacy will promulgate regulations to facilitate changes contained in the legislation, which permit a pharmacist to perform a therapeutic interchange by substituting a drug with another drug in the same therapeutic class that the pharmacist believes will have a similar therapeutic effect and adverse-reaction profile when administered in a therapeutically equivalent dose as the prescribed drug. The regulations will address appropriate circumstances for initiation of a therapeutic interchange and will determine which therapeutic classes of drugs are eligible for therapeutic interchange and which therapeutic classes shall be prohibited. The regulations will also address record-keeping requirements and notification requirements specific to therapeutic interchanges.

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.

There are no alternatives to regulation. The Board was directed by the General Assembly to promulgate regulations on this subject.

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 Matt Novak, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or matthew.novak@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.