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Fast-Track Regulation 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	Exemption of analytical laboratories from alarm requirements
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 this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board of Pharmacy will exempt analytical laboratories from alarm requirements contained in 18VAC110-20-710(F)(6). The Board has also corrected language regarding animal shelters in the same exemption.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) that the agency has “adopted final amendments” to the regulation; 3) the name of the agency taking the action; and 4) the title of the regulation. A suggested statement is, “On [insert date] the Board/Department of [insert name] adopted final amendments to the [title of regulation(s)].”

On June 16, 2026, the Board of Pharmacy adopted final amendments to the Regulations Governing the Practice of Pharmacy.

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.”

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

Historically, analytical laboratories were covered by a patchwork of requirements regarding alarm systems. The Board of Pharmacy intends to unify treatment of these laboratories reduce requirements in a manner that maintains protection of the public.

This regulatory change is expected to be noncontroversial and is appropriate for the fast-track rulemaking process because the changes reduce requirements for some analytical laboratories and ensure those that are not currently subject to alarm requirements will continue to be exempt.

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.”

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The rationale for this action is to consistently exempt alarm requirements for a specific type of laboratory in the state. This regulatory change is essential to protect the health, safety, and welfare of citizens because it ensures analytical laboratories are not subject to unneeded requirements. The goals of this regulatory change are unification of requirements for analytical laboratories and the problems the change is intended to solve are uneven application of exemption from certain requirements for analytical laboratories.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The Board has amended 18VAC110-20-710(F)(6) to exempt "analytical laboratories" from the list of locations that do not need to adhere to the alarm requirements in the section. In addition, the Board has amended the phrase "humane societies" to "animal shelters" for consistency with the authorization in Virginia Code § 54.1-3423(E) and 18VAC110-20-580.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

- 1) There are no primary advantages or disadvantages to the public.
- 2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system . . . Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations.

"Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no expected costs, savings, fees, or revenues to the agency from this regulatory change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	None.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no expected costs, savings, fees or revenues to localities from this regulatory change.
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Benefits the regulatory change is designed to produce.	There are no expected benefits to localities from this regulatory change.
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Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	This will affect those analytical laboratories that have been subject to the alarm requirements of Section 710.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are currently 21 analytical laboratories holding controlled substance registrations.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no costs.
Benefits the regulatory change is designed to produce.	None.

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.

This requirement is currently in regulation. To create an exemption, the Board must file a regulatory action.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

(1) This amendment already reduces compliance requirements. (2) No schedules or compliance requirements exist. (3) No schedules or compliance requirements exist. (4) No design or operational standards exist. (5) The agency cannot exempt small businesses from public safety requirements without severe detriment to the public.

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.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

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 and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

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 to Matt Novak, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233; by email to matthew.novak@dhp.virginia.gov; by fax to (804) 527-4434. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or

agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-710	Contains security requirements for holders of a controlled substance registration, including alarm requirements.	The Board amended the reference to “humane societies” in subsection F 6 to “animal shelters.” Virginia Code § 54.1-3423(E) and 18VAC110-20-580 reference animal shelters. This change was made for consistency. The Board added “analytical laboratories” to the list of entities exempt from compliance with the alarm requirements contained in section 710. Other entities already exempted from these requirements have authority to possess Schedule II – VI medications with no detriment to public health or safety. Therefore, the Board believes exemption of analytical laboratories, of which only 21 are registered with the Board as holders of controlled substance registrations, can also be exempted from this requirement without detriment to public health or safety.