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Proposed Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-30
VAC Chapter title(s)	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
Action title	Implementation of 2021 Periodic Review
Date this document prepared	March 30, 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 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 has promulgated regulations following its periodic review of Chapter 30 to do the following:

- Create requirements similar to other facilities permitted by the Board of Pharmacy to declare hours of operation that the location will be open to service the public and report changes in the hours of operation expected to last more than one week to the Board and the public at least 14 days prior to the anticipated change. The requirements include exemptions for: (1) emergency circumstances beyond the control of the owner or responsible party; and (2) expansion of hours.
- Amend 18VAC110-30-80 to prohibit licenses and permits from being issued to a private dwelling or residence.

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

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 these changes was the [2021 Periodic Review of Chapter 30](#), at the conclusion of which the Board determined it would retain and amend the chapter.

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 § 54.1-3304.1 provides the Board “the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts.” Va. Code § 54.1-3304.1(A).

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.

(1) These regulations need to be amended to ensure patients have sufficient information to know when pharmaceutical services will be available at the location where a practitioner is permitted to sell controlled substances. These regulations additionally need to be amended to prohibit the sale of controlled substances in a licensee’s private residence, which could jeopardize the integrity and security of such substances. (2) Both purposes protect the health, safety, and welfare of citizens by: (a) ensuring patients are aware of changes in hours of any pharmacy services they use, including those run by practitioners of the healing arts; and (b) by ensuring the integrity and security of controlled substances by prohibiting a

practitioner from dispensing from a home or private residence. (3) The regulatory amendments are intended to provide greater clarity for patients of when they can rely on dispensing of controlled substances from a practitioner of the healing arts, similar to patients using a traditional permitted pharmacy which is already subject to these requirements. The regulatory changes are additionally intended to ensure the security and integrity of controlled substances dispensed by a practitioner of the healing arts by prohibiting dispensing from a private dwelling or residence.

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 amendments promulgated by the Board do the following:

- Create requirements similar to other facilities permitted by the Board of Pharmacy to declare hours of operation that the location will be open to service the public and report changes in the hours of operation expected to last more than one week to the Board and the public at least 14 days prior to the anticipated change. The requirements include exemptions for: (1) emergency circumstances beyond the control of the owner or responsible party; and (2) expansion of hours.
- Amend 18VAC110-30-80 to prohibit licenses and permits from being issued to a private dwelling or residence.

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) The primary advantages to the public are knowledge of when controlled substances available via a prescription may be obtained from a practitioner of the healing arts with a license to sell controlled substances, similar to public knowledge of permitted pharmacy hours. There are no 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 and of the directives of Virginia Code § 54.1-3304.1. 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

<p><i>For your agency:</i> 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.</p>	<p>There are no expected costs, savings, fees, or revenues to the agency from this regulatory change.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>There is no benefit to agencies.</p>

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.
Benefits the regulatory change is designed to produce.	There are no expected benefits to localities from this regulatory change.

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.	The individuals affected by this will be those practitioners of the healing arts that obtain a license from the Board of Pharmacy to sell controlled substances and the businesses other than pharmacies obtaining a facility permit to sell controlled substances.
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.	As of December 31, 2022, there were 645 licensed practitioners selling controlled substances and 164 locations at which practitioners sold controlled substances.
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.	None.
Benefits the regulatory change is designed to produce.	The regulatory change is intended to benefit the public by providing the same clarity of open hours for locations that provide controlled substances from a practitioner of the healing arts as provided by pharmacies. Additionally, the amendments are intended to ensure controlled substances are not being sold from a private dwelling, which would be an unsecured location.

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 only way to create the requirement for practitioners of the healing arts providing controlled substances is to amend the existing regulations.

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) There are no compliance or reporting requirements associated with these changes. 2) There are no compliance or reporting requirements associated with these changes. 3) There are no compliance or reporting requirements to consolidate or simplify. 4) There are no performance standards or operational standards in these amendments. 5) The Board cannot exempt small businesses from the requirements included in these regulations because that would eliminate the regulations and pose a harm to the safety and welfare of the public.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

Not applicable.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those

received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

No comments were received.

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.

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, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the 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://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. 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 of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

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 the existing VAC Chapter(s) and the proposed regulation. If the 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	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
30-21		(A) sets forth the requirement that a practitioner of the healing arts that sells controlled substances shall obtain a permit from the Board of Pharmacy.	<p>An obsolete start date has been deleted. Additionally, the first sentence has been edited for clarity and to conform with the usage of terms in the rest of the subsection.</p> <p>The subsection is also amended to include the requirement to designate the operating hours of the location on the application form for a permit.</p>
	30-55	N/A	<p>This new section sets out the requirements for notifying the public and the Board when changes of hours for a permitted facility occur. This section is modeled on 18VAC110-20-135 and contains the same timeframes and notification requirements.</p> <p>Specifically, the new provision requires the practitioner in charge of a permitted facility to provide notice to the public and the Board of any change in operation expected to last more than one week. The practitioner in charge must post the notice in a conspicuous place and notify the Board at least 14 days prior to the closure unless the change is related to emergency circumstances beyond the control of the practitioner.</p> <p>Changes in hours of operation that expand the time the location is open to service the public do not require notification.</p>
30-80		Sets forth inspection requirements of permit holders and certain limitations to the issuance of permits.	<p>New subsection (G) is added to specify that no facility permit shall be issued to a private dwelling or residence for the purpose of selling controlled substances. This is to avoid having a permit to sell controlled substances from an unsecured home.</p> <p>This change will not prevent practitioners from making house calls and providing medication to patients on those visits.</p>