townhall.virginia.gov

Proposed 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 automated dispensing devices stocked solely with emergency or stat use medications from certain requirements of 18VAC110-20-555
Date this document prepared	June 13, 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.

In response to a petition for rulemaking, the Board issued a Notice of Intended Regulatory Action to consider an amendment to section 555 to exempt an automated dispensing device ("ADD") from the requirements of 18VAC110-20-555 when that ADD is exclusively stocked with certain drugs that may be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use. The Board has now adopted proposed regulations to amend 18VAC110-20-555.

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.

ADD = automated dispensing device

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 change was a petition for rulemaking requesting an amendment to regulations for ADDs stocked solely with stat or emergency use drugs. As presented by the petitioner, it would be more secure for such drugs to be stored in an ADD than a "tackle-box" style mechanism which is currently used.

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 Board determined that the petitioner correctly identified a potential hazard in storage of stat or emergency use only medications under 18VAC110-20-540 or 18VAC110-20-550. Stat or emergency use drugs stored in an ADD would contain an electronic record of access to those drugs, while the current tackle-box style storage systems do not. For some facilities, such as nursing homes, ADDs are not used because the only drugs stored on the premises are stat or emergency use medication. Patient and drug security may be increased through utilization of ADDs when exempted from certain requirements that would unacceptably delay the administration of life-saving drugs for patients.

Additionally, the change as adopted by the Board treats stat drugs and drugs that would be kept in an emergency drug kit the same in that the drugs may be accessed prior to receiving electronic authorization from the pharmacist. Under current language, stat drugs are treated differently from drugs that would be

in an emergency drug kit when these drugs are stored in an ADD. Drugs that would be in an emergency drug kit may be accessed prior to receiving electronic authorization from the pharmacist, while stat drugs may not.

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.

18VAC110-20-555 is amended to remove the reference to drugs that would be stocked in a stat drug box from the requirements of 18VAC110-20-555(4)(a). (4)(c) is amended to include drugs that would be included in a stat drug box, thereby treating drugs that would be contained in a stat drug box the same as drugs that would be kept in an emergency kit.

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 security of the drug supply in that diversion of stat-use or emergency medications will be less likely while preserving quick access to these medications. 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. 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.	There are no benefits to state agencies.

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.	This will most likely affect nursing homes in the Commonwealth.
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.	VDH Office of Licensure and Certification, rather than DHP, licenses nursing homes. VDH has not published the number of licensed nursing homes in the Commonwealth. It is unknown how many, if any, would be considered small businesses.
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.	No projected costs. This is a reduction of requirements.
Benefits the regulatory change is designed to produce.	This change is designed to provide fast and trackable access to certain medications used in stat or emergency situations.

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 is no alternative to regulation. Use of ADDs is regulated by the Board. To create the exception requested by the petitioner, the Board must amend the existing regulation.

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.

There are no alternative regulatory methods for the regulation of ADDs. 1) This action already lessens requirements for using ADDs. 2) There are no schedules or deadlines at issue. 3) There are no reporting requirements at issue. 4) There are no established performance standards for small businesses at issue. 5) The Board cannot exempt small businesses from application of the Drug Control Act or Board regulations without harming the public. This is already arguably a reduction for small businesses in compliance.

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 the 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.

Commenter	Comment	Agency response
John Camperlengo, Chief Legal Officer, PharmScript LLC	PharmScript supports the regulatory change because it will eliminate a hurdle to speedy patient care and will lower the risk of patient harm.	The agency agrees and appreciates the support.
Brad McDaniel, Chair, Legislative Committee, Virginia Society of Health-systems Pharmacists	Provides recommendations for additional requirements, including requiring a nurse to remove the medication under a patient profile, only allowing overrides outside of pharmacy service hours, and	While the Board understands the intent behind the comment, the purpose of the petition for rulemaking was to create an ADD exception that operated similar to a stat or emergency use box, which would not have these same requirements. To add the additional requirements to the

	overrides assessed periodically by the pharmacy provider.	exemption would make it less useful to those locations intended to use ADDs solely for stat or emergency use medication.

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	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-555	(4)(a) states that a drug may not be administered	New language groups drugs kept in an ADD that would otherwise stock a stat drug box with drugs

	to a patient from an ADD until a pharmacist has reviewed the prescription order and electronically authorized the access of the drug for that particular patient in accordance with the specific order. (4)(c) allows drugs that would be stocked in an emergency drug kit to be accessed from an ADD prior to receiving electronic authorization from the pharmacist if the absence of the drug would threaten the survival of patients.	kept in an ADD that would be part of an emergency drug kit. Drugs that would be in a stat drug box may be removed from an ADD prior to authorization from a pharmacist if delay in administration of the drug would harm the patient. The intent of this change is to allow facilities to replace tacklebox-style containers of stat drugs with more secure ADDs. Allowing stat-use medications to be stored in and retrieved from ADDs if needed for the health of the patients would limit unauthorized access, provide quick access to needed medications, and electronically record medication access and dispensing.