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Final 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	September 24, 2024

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 initiated a rulemaking to amend 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 final 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

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) the name of the agency taking the action; and 3) the title of the regulation.

On September 24, 2024, the Board of Pharmacy amended the Regulations Governing the Practice of Pharmacy.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

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.

Amendments to 18VAC110-20-555(10), (10)(b), (12), (13), and (14)(d) were made at the request of the Registrar and are stylistic edits with no substantive effect on the operation of the section.

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

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

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
Lauren Paul, CVS	Generally supportive of the amendments. Requested clarification that removal of drugs from an ADD is after pharmacist confirmation or permission upon review of a valid prescription or order from a prescriber, but before electronic authorization is received.	The Board has made an additional amendment to 18VAC110-20-555(4)(c) to address this comment and provide the requested clarification.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements

20-555	N/A	There is no requirement. Language has been added as addressed in the column to the right.	Following public comment on the proposed stage, the Board has further amended 18VAC110-20-555(4)(c) to clarify that removal of drugs from an ADD is after pharmacist confirmation or permission upon review of a valid prescription or order from a prescriber, but before electronic authorization is received.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. 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. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
20-555	(4)(a) states that a drug may not be administered 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.	New language groups drugs kept in an ADD that would otherwise stock a stat drug box with drugs 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. As stated in the section above, an additional amendment was added at this stage to clarify that removal of drugs from an ADD is after pharmacist confirmation or permission upon review of a valid prescription or order from a prescriber, but before electronic authorization is received. 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. At the request of the registrar, stylistic changes that do not have a substantive impact on the operation of the regulation were made to 18VAC110-20-555(10), (10)(b), (12), (13), and (14)(d).