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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Response to petitions for rulemaking
Date this document prepared	12/11/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Board acted on a petition for rulemaking to permit a pharmacist to dispense a quantity of a Schedule VI drug greater than the face amount prescribed, up to the total amount authorized in refills. Currently a pharmacist may not dispense more than the specific quantity prescribed at each dispensing and may not exceed that quantity by taking authorized refills into consideration. The Board voted unanimously to accept the petition for rulemaking authorizing a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding certain drugs, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills.

The Board acted on another petition for rulemaking to amend 18VAC110-20-540, 18VAC110-20-550 and 18VAC110-20-555 to authorize the use of automated dispensing devices in nursing homes in lieu of manual emergency drug kits and stat-drug boxes.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Statement of final agency action

Please 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 December 11, 2017, the Board of Pharmacy adopted amendments to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 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 specific authority of the Board to regulate the practice of pharmacy is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also

control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.
8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Granting the pharmacist authority to dispense a quantity of a Schedule VI substance greater than the amount initially noted on the prescription would benefit patients and prescribers with greater flexibility and improved medication adherence. A pharmacist would be able to use his/her professional judgment about whether to dispense in conformity with the prescribed amount and dosage. Such flexibility will enable a pharmacist to more easily synchronize the patient's medications, allowing prescription to run out on the same date and reducing the patient's visits to the pharmacy.

Allowing the use of electronic devices for emergency and stat boxes is becoming a standard for acute long-term care facilities, as such devices can minimize diversion and direct access for staff to the correct location for first dose administration.

Both changes are reasonable accommodations in the practice of pharmacy that will benefit the health and safety of patients without jeopardizing the integrity and efficacy of the drug supply in the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The Board promulgate regulations in response to two petitions for rulemaking to:

1) Amend 18VAC110-20-320 to authorize a pharmacist, when deemed appropriate in his professional judgement and upon request by the patient, to dispense a quantity of a Schedule VI drug, excluding psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or drugs of concern, in excess of the specific quantity prescribed for a dispensing, not to exceed the total amount authorized in refills; and
2) Amend sections 540, 550, and 555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box or an emergency kit.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

1) The primary advantage to the public is more flexibility in obtaining Schedule VI drugs. If a consumer is prescribed a drug for a chronic condition and has a certain number of refills on the prescription, he may prefer to get the total quantity dispensed rather than having to come back or reorder when the drug is due to be refilled. The advantage to residents of nursing homes and other entities in which stat or emergency drugs are maintained would be drugs used for non-routine administration would be more readily available through an automated dispensing device. There are no disadvantages to the public;
2) There are no advantages or disadvantages to the agency; and
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system.*" Additionally, the Code of Virginia requires:
The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered…
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
The proposed regulations are permissive and less restrictive and do not represent any restraint on competition.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family and family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

In the process of adopting final regulations, the Board realized that the amendments to section 320 only referring to refills, but the intent of the action was to allow a pharmacist to *dispense or* refill a quantity of Schedule VI drugs up to the total amount authorized, taking all refills into account. The intent was to include initial dispensing, not just the refill of a Schedule VI drug.

The Department of Corrections is authorized to maintain certain drugs in certain quantities in an emergency drug kit. It has requested that they be allowed to maintain the intranasal formulation of naloxone in those kits. The Board determined that the drug could be added to subsection A of section 540, which was already being amended in this action.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

The proposed regulation was published on September 4, 2017 with a public comment period ended on November 3, 2017. There was a public hearing on September 26, 2017; no comment was received orally, electronically, or in writing.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
320	Sets out requirements for dispensing and refilling of Schedule III through VI prescriptions	Amendments to subsection B will allow a pharmacist, using professional judgement and upon request by the patient, to refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration. There would be an exception for drugs classified as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or drugs of concern as defined in § 54.1-2519. *The proposal is permissive for the pharmacist who must use his professional judgment. It is also an option for the patient for his convenience and flexibility.* **In the final action:** **The title of section 320 was amended to include dispensing since the rules in that section include initial**

		dispensing as well as refilling. The word "dispensing" was added to the amended subsection B.
540	Sets out requirements for an emergency drug kit.	Amendments to section 540 would allow a nursing home to store drugs used for emergency administration in an automated drug dispensing system or, as is currently allowed, in an emergency kit. *Storage in an automated dispensing system would have to be compliant with provisions of section 555 for such devices. Use of an automated dispensing device is controlled and secure but less cumbersome than the opening and then resealing and returning of an emergency kit back to the pharmacy for restocking.* **In the final action:** **The content of the emergency drug kit was amended to include the intranasal spray formulation of naloxone. The drug is critically needed for staff, patients, residents or inmates to counteract exposure to drugs that may cause an overdose.**
550	Sets out requirements for a stat-drug box.	Stat-drug boxes are used for first doses when therapy needs to be initiated prior to the receipt of ordered drugs from the pharmacy. Amendments will allow stat drugs to be stored in an automated dispensing system and will permit the provider pharmacist to determine the appropriate quantity of drugs in consultation with medical and nursing staff of the nursing home. *As with an emergency kit, the stat-drug box can be cumbersome to enter, reseal, and return to the pharmacy for restocking. Also, there is a limitation on the number of drugs that can be maintained in a stat-drug box. The proposed regulation allows more flexibility to meet the needs of residents.*
555	Sets out requirements for use of an automated dispensing device (ADD)	Currently, a nursing home that does not have an in-house pharmacy must obtain a controlled substance registration in order to have an ADD. An amendment will specify that a controlled substance registration is not required if the ADD is used exclusively for emergency or stat purposes. *This is consistent with advice from the Drug Enforcement Administration.* Number 4 is amended to include use of an ADD as a stat-drug box in the provision stating that a drug cannot be administered to a patient until a pharmacist has reviewed the prescription order and authorized access for a particular patient. *Drugs from a stat box (or ADD used for stat drugs) are those that have been prescribed for a patient, so the pharmacist must review the order before the drug is removed from the device for patient safety.*