townhall.virginia.gov

Proposed 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	3/22/17

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

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. A more detailed discussion is provided in the "Detail of changes" section below.

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 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. 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 this stage 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.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Pharmacies that dispense Schedule VI drugs, provider pharmacies and nursing homes that have automated dispensing devices.
Agency's best estimate of the number of such entities that will be affected. Please 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 1852 pharmacies permitted in Virginia. Not all of those dispense Schedule VI drugs to consumers, so there is no estimate of the number that may be affected. Likewise, there is no estimate of the number of small business; the majority of pharmacies are part of large national chains. There is no estimate of the number of provider pharmacies and nursing homes that may be affected.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no additional costs. Those nursing homes that currently use automated dispensing devices for routine medications would be able to use the same device for non-routine administration. If the emergency kit and the stat box can be replaced by storing drugs in an automated dispensing device, provider pharmacies and nursing homes may be able to reduce costs.
Beneficial impact the regulation is designed to produce.	The benefits of this action are: 1) more flexibility in dispensing Schedule VI medications to the possible benefit of the customer; 2) more availability of drugs for emergency or stat use in nursing homes.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

The petitions requested less burdensome and intrusive alternatives to current regulations, so changes to achieve that purpose must be accomplished by amendments to Chapter 20.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

There is no alternative regulatory method. The requirements for refills and for emergency kit, stat boxes, and automated dispensing devices are set in regulation; enacting any less restrictive requirements necessitates amendments to regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

There was a comment period on the NOIRA from 11/28/17 to 12/28/17.

Commenter	Comment	Agency response
Dale StClair	Reiterated the need and justification for use of automated dispensing devices for emergency and stat box purposes. Provided information from the DEA about whether emergency kits required a separate DEA registration.	The Board concurred with the comments.

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Current section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
320	Sets out requirements for refilling 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.*
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.*
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.*