townhall.virginia.gov

Fast-Track 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	Inclusion of diazepam rectal gel in emergency drug kits
Date this document prepared	4/6/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Section 540 is amended to allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility.

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 March 25, 2016, the Board of Pharmacy amended 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:

§ 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 legal authority for the Board of Pharmacy to promulgate the proposed regulation

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.

The purpose of the planned regulatory action is to address an urgent problem. Omnicare, a CVS Health Company, provides long term care pharmacy services to a diverse population of skilled nursing patients in Virginia to include sub-acute care for children. Specifically, the children in these facilities suffer from complex physical and neurological diseases and experience frequent seizures. As a result, nurses assigned to these pediatric units need immediate access to Diastat

Rectal gel in their emergency boxes. Limiting the access to this critical medication will most certainly threaten a successful patient outcome up to and including the survival of the patient(s). Unfortunately, current pharmacy regulation 18VAC110-20-550 does not allow a CIV rectal gel to be included in the contents allowed in the emergency box. The company requested the amendment to allow pharmacists to meet the needs of this fragile population. The request for limited access to the drug was approved to protect the health and safety of patients in a long term care facility. Because 18VAC110-20-590 authorizes correctional facilities that employ one or more full-time physicians, nurses, or physician assistants to obtain an emergency kit in accordance with section 540, patients in correctional facilities may also benefit from the inclusion of this drug in an emergency kit.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

This action will not be controversial as it is limited to making a small dosage of a drug that can be life-saving available in an emergency situation.

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.

Section 540 is amended to allow a provider pharmacist, in consultation with medical and nursing staff, to include diazepam rectal gel in an emergency kit maintained in a long-term care facility. The amendment will also allow inmates in correctional facilities to potentially benefit from inclusion of this drug since 18AVC110-20-590 allows for an emergency kit under certain circumstances, consistent with 18AVC110-20-540.

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 advantage to the public is availability of a drug that may be life-saving to a small group of patients. There are no disadvantages.
2) There are no advantages or disadvantages to the public.
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 (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system." There is no restraint on competition as a result of promulgating this regulation.

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 rules, but it appears consistent with federal guidance provided by the Drug Enforcement Administration in the Pharmacist's Manual published by DEA.

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.

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 are no alternative regulatory methods consistent with health and safety of the patients served by long-term care facilities or correctional facilities.

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:	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from

a) fund source / fund detail; and **b) a delineation of one-time versus on-going expenditures**	non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The entities that would be affected would be long-term care facilities or correctional facilities that may have need of a delivery system containing diazepam rectal gel.
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 is no estimate of facilities that would need the drug in their emergency kits.
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 is no costs for the new regulation; it is permissive not mandatory.
Beneficial impact the regulation is designed to produce.	The availability of the diazepam rectal gel will benefit mostly children who receive sub-acute care in skilled nursing facilities and inmates in correctional facilities who may have need for this emergent drug.

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.

There are no less intrusive or less costly alternatives. The proposed regulation is permissive and less restrictive.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

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.

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 list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

540	Sets out requirements for the use and content of an emergency drug kit for a long-term care facility.	Number 2 specifies the contents of the kit to be determined by the provider pharmacist in consultation with the medical and nursing staff of the facility. Current drugs are limited to those administered by injection or inhalation, except for Nitroglycerin SL is permitted. The amendment will add "diazepam rectal gel" as allowable in the kit. *Access to drugs in the emergency kit is restricted to a nurse, pharmacist or prescriber and the content of the kit must be of such a nature that the absence of the drugs would threaten the survival of the patients. Therefore, the Board is satisfied that the addition of diazepam rectal gel will be consistent with public health and safety.* *An amendment to section 540 would also affect section 590, because it would allow correctional facilities to benefit from inclusion of that drug in an emergency kit. 18VAC110-20-590 authorizes such facilities to obtain an*

		emergency kit under certain circumstances, consistent with provisions of 18VAC110-20-540.