Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20
Regulation title	Regulations of the Board of Pharmacy
Action title	Floor stock in correctional institutions
Date this document prepared	3/27/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The purpose of the proposed regulatory action is to allow a correctional facility to maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and to be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. The floor stock must be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

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 26, 2014, the Board of Pharmacy adopted amendments to 18VAC110-20-10 et seq., Virginia Board of Pharmacy Regulations.

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 to control prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 goal of the amended regulation is a less burdensome requirement for drugs in correctional facilities that will facilitate more efficient medical care for the patients who are inmates in those facilities. In modifying regulation 18VAC110-20-590, the Board adopted a requirement for floor stock of controlled substances that have little or no potential for abuse or diversion. Therefore, the proposed change will accommodate better patient care without jeopardizing public health and safety.

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?

The Board has opted to use the fast-track process because: 1) the amended regulation is less restrictive; 2) it was supported unanimously and without discussion by board members; and 3) it will not be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

The substantive change to existing regulation is an allowance for a correctional facility to be able maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock must be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

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 of the regulatory action is cost and time savings to correctional facilities and provider pharmacies as they strive to meet the medical needs of inmates in the system. The purpose for the requirement can be accomplished with a less burdensome and costly regulation that assures public protection. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) There are no other pertinent matters of interest.

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.

The proposed regulation does not affect any locality.

Regulatory flexibility analysis

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.

Since the intent is to promulgate a less burdensome and costly regulation, there are no alternative methods for accomplishing the objective as requested by the Department of Corrections.

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.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	Correctional facilities would be affected.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	The Board has no estimate of the number; none would be considered small businesses since all are government entities.
Benefits expected as a result of this regulatory proposal.	Facilitation of medical care for inmates would be a benefit of the proposal. There would also be some cost and opportunity savings by the ability to maintain floor stock to be administered pursuant to a valid order rather than having to receive these bulky drugs in a stat box provided by the provider

	pharmacy or transfer the inmate to a local hospital to receive the drugs.
Projected cost to the state to implement and enforce this regulatory proposal.	There would be no cost to implement.
Projected cost to localities to implement and enforce this regulatory proposal.	There would be no cost to localities.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	There would be no cost to affected entities. As stated above, there may be some cost-savings for correctional facilities that choose to maintain floor stock.

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.

In order to accommodate the request from the Department of Corrections for a less intrusive and less costly requirement, the Board of Pharmacy must amend section 590 which sets our provisions for drugs in correctional facilities.

Family impact

Please assess the impact of the proposed 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.

The proposed regulatory action does not affect the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. 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.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

590	Sets out the requirements for correctional facilities in the storage, administration and security of prescription drugs	The primary change to section 590 is the addition of a new subsection C, which provides that: A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and shall be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution. *The Department of Corrections has requested authorization to maintain floor stock of controlled substances that are used in patient care, as listed in the regulation. These drugs may be maintained in accordance with an order from a prescriber and would be available to be only administered by a person authorized to administer drugs. While they are "controlled substances" and require a prescription from a prescriber, they are not drugs subject to abuse or diversion. Floor stock of these substances is allowed in other types of institutional settings, so the Board believes the allowance for correctional facilities is reasonable and in the best interest of patients.* Amendments to subsections A and D are clarifying and necessary for consistency with all provisions in section 590.