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	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Stat-drug boxes in long-term care facilities
Date this document prepared	9/3/09

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 amendments to section 550 will allow a stat-drug box in a long-term care facility to contain doses of Schedule II drugs for the relief of acute pain and will offer more flexibility in the drugs that are maintained in a stat-box, depending on the needs of patients in the facility.

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 September 2, 2009, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy to allow more flexibility for long-term care facilities using stat-drug boxes.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and establish renewal schedules:

> *§ 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 and Chapter 25 of this title…*

The specific authority to control prescription drugs in the Commonwealth 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 purpose of the amended regulation is to address a public health need in many nursing homes that have become "sub-acute hospitals." Nursing homes are seeing an increased number of acute patients with many health complications. Many are admitted post-surgically after an orthopedic procedure (hip replacement, etc.) and the adequate and timely administration of pain medication is critical to their well-being and recovery. Patients who have their pain controlled have fewer complications and heal faster. Patients may be admitted when the pharmacy is not open, and it may take many hours for the prescriber's order to be filled by the provider pharmacy and delivered to the facility for administration. In the best of circumstances, there is a gap of time between the patient's arrival at the nursing home and the delivery of prescription pain medication from the provider pharmacy. By amending the current regulation, the Board has addressed this issue in a manner that is responsive to patient health needs but also retains safeguards against diversion and medication error. Only persons licensed to administer, dispense or prescribe may access a stat box, and a valid prescription or order from a prescriber must be received prior to removal of any drug from the stat-drug box.

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 amendment is being sought by a coalition of nursing homes, provider pharmacies, and professional association serving the long-term care industry. There is a sense of urgency about the need for the amendment to alleviate pain and enhance patient comfort and recovery, and there is consensus about the language being proposed. No opposition is expected.

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.)

The substantive provision is deletion of the prohibition against the stat-drug box in a long-term care facility containing Schedule II drugs.

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 that the inclusion of Schedule II drugs in a stat box in a long-term care facility will allow facilities and physicians to ensure their patients receive pain medications appropriately and expeditiously. There are no disadvantages. Any concern about diversion is addressed by the security measures and accountability required, and only licensed nurses, pharmacists or prescribers can access drugs in a stat box.
2) There are no advantages or disadvantages to the agency or 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 requirements in this proposal more restrictive than federal requirements. A question had been raised as to whether the requirements of the Drug Enforcement Administration (DEA) might be more restrictive and not allow inclusion of Schedule II drugs in a stat-drug box, but the DEA has been consulted and concurred with the change.

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.

None are affected.

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.

There are no regulatory methods that will accomplish the objectives of applicable law.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	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 or entities for necessary functions of regulation. There would be a one-time expense of less than $1,000 for promulgation of the amended rule. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.

Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals affected by the regulation would be patients newly admitted to long-term care who need the timely delivery of drugs for control of acute pain or other conditions. The other entities affected would be licensed nursing homes, assisted living facilities and pharmacies that provide pharmaceutical services to long-term care facilities.
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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	It is unknown how many licensed nursing homes or assisted living facilities would be affected, but all are likely to have a positive effect by being able to provide pain medications to newly-admitted patients in a timelier manner. It is unknown how many provider pharmacies there are; they are licensed as pharmacies, not licensed by the services they provide.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There are no additional costs to the affected individuals or entities. Drugs would be those prescribed for the patient; the amendment would just allow the patient to receive the drug more expeditiously.

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 issue relating to stat-drug boxes was presented to the Board at its meeting on Jun 10, 2009. Beverley Soble, Virginia Health Care Foundation and Wendy Walter, Fairmont Crossing, Amherst, VA requested that the Board consider changing its regulations to allow Schedule II controlled substances to be maintained in the stat boxes for long term care facilities. Ms. Soble stated that nursing homes frequently receive orders for patients on nights and weekends when it is not possible to receive timely medications from pharmacies. Under the best circumstances, i.e. midweek and daytime, there is typically at least a six to eight hour delay in getting an ordered medication. She stated that there are other federal and state standards that are violated if patients are not receiving pain medication in a timely manner. She also stated that she has taken steps to explore all viable options; including obtaining discharge medications when patients are sent from the hospital to the nursing home, and the use of the automated dispensing devices (ADD), but these did not appear viable. Expense was the primary reason for not using an ADD (with the current reimbursement structure), but even if a nursing home could afford an ADD, there is no one place to put it to be geographically accessible because of the distance from the device to

other nursing units. Ms. Soble also stated that they had determined that MD, NC, and WV all allowed Schedule II drugs for first doses in nursing homes.

As a result of the comments, a committee was appointed to work with representatives for nursing homes and long term care pharmacies to develop a recommendation to address this issue. There was a consensus among all those who helped develop the regulatory language that the dosages allowed were sufficient to address the needs of long-term care patients without the risk of storing large quantities of undispensed drugs.

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.

There is no impact to the institution of the family and family stability, except to the extent stress and costs to families relating to admission of a family member to a long-term care facility may be somewhat alleviated by appropriate management of pain and more speedy recovery for those in rehabilitation.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
550	n/a	Sets out requirements for the use of stat-drug boxes to provide for initiating therapy prior to receipt of ordered drugs from a pharmacy.	First, the prohibition against the stat-drug box containing Schedule II drugs is deleted. *The primary goal of those seeking a regulatory change was the deletion of this prohibition to allow inclusion of pain medications that can be administered more quickly to patients who are admitted to nursing homes after surgery or suffering from a debilitating illness.* Second, the proposed amendment allows 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be

			substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient. *The current regulation limits the content of a stat-drug box to no more than one drug in Schedule III through V in each therapeutic class and no more than five doses of each. The amended regulation will allow the provider pharmacy, in consultation with the nursing home or assisted living facility, to determine the content of the box within a limitation of 20 dosage units per schedule. Larger nursing homes with more than one unit of beds are allowed to have multiple stat boxes – sufficient to meet the needs of patients on each unit. Homes with smaller populations should easier be able to meet the needs of any new patients within the 20 dosage units allowed. The decision on the number of stat boxes needed is made by the provider pharmacy and the facility based on acuity of the patient population.*