townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Board of Nursing, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC90-60-10 et seq.
Regulation title(s)	Regulations Governing the Registration of Medication Aides
Action title	Allowance for subcutaneous administration of certain medications
Date this document prepared	May 19, 2016

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 110 is amended to clarify that medication aides are not allowed to administer by subcutaneous route except for insulin medications, glucagon or auto-injectable epinephrine.

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.

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 May 17, 2016, the Board of Nursing amended 18VAC90-60-10 et seq., Regulations Governing the Registration of Medication Aides by a fast-track action.

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 (6), which provides the Board of Nursing 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: …

§ 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 (§ 2.2-4000 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…

In addition, there is statutory authority for the board to approve training and curriculum for medication aide programs and to establish standards of conduct:

§ 54.1-3005. Specific powers and duties of Board.

In addition to the general powers and duties conferred in this title, the Board shall have the following specific powers and duties:
17. To register medication aides and promulgate regulations governing the criteria for such registration and standards of conduct for medication aides;
18. To approve training programs for medication aides to include requirements for instructional personnel, curriculum, continuing education, and a competency evaluation;

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 amended regulation will clarify that subcutaneous administration of medication is not within the scope of practice for a medication aide, with the exception of three medications essentially used for emergencies and as taught in the medication aide curriculum. The proposal will ensure that medication aides, who are not trained or deemed competent to do so, do not inappropriately administer drugs by a subcutaneous route. Since medication aides work solely in assisted living facilities, specific regulations are necessary to protect a very vulnerable population in a facility where it is unlikely that another health care provider is present.

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 is using the fast-track process because the change will ensure that medication aides can administer certain medications that may be life-saving for a resident in an assisted living facility. Therefore, the Board would like to promulgate those amendments as soon as possible. There should be no opposition to the amendment, so a fast-track action is appropriate.

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 110 is amended to clarify that medication aides are not allowed to administer by subcutaneous route except for insulin medications, glucagon or auto-injectable epinephrine. An exception for insulin and glucagon is already listed for administration by intramuscular or intravenous routes, but it is more appropriately a subcutaneous administration.

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 is residents of assisted living facilities, which are the only settings in which medication aides are used, is the ability for trained individuals to be able to administer a potentially life-saving drug. There are no primary disadvantages to the public.
2) The primary advantage to the Board of Nursing is the clarification about whether medication aides may administer by a subcutaneous route. Such administration is not taught in the training programs and is not part of the curriculum, with the exception of limited rescue medications.
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 (§ 2.2-4000 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 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.

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 regulatory flexibility. The Board is mandated by law to establish the standards of conduct for medication aides and to approve their training and educational curriculum.

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**	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. 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.	There are no costs of the new regulation to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Registered medication aides who work in assisted living 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: 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 6,000 registered medication aides. They work in small businesses and also for large corporations that operate assisted living facilities.
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 costs.
Beneficial impact the regulation is designed to produce.	More clarity in the regulation and the inclusion of auto-injectable epinephrine will be beneficial.

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 viable alternatives that meet the essential purpose of protecting the health and safety of a vulnerable population.

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 follow the instructions in the text following the three chart templates below.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
110	Sets out the standards of practice for a registered medication aide	Subsection B of section 110 is amended to specify that subcutaneous administration of medication is not permissible with the exception of insulin, glucagon or injectable epinephrine. The curriculum for registered medication aide includes the administration of auto-injectable epinephrine and an 8-hour module on administration of insulin and glucagon. It does not include administration of any other drugs by a subcutaneous route; and therefore, such administration is not within the scope of practice of a

		medication aide. The curriculum may be viewed at: http://www.dhp.virginia.gov/asp/Nursing/MARevisedCurriculumAdoptedbyBoard20130521.pdf Other than the 68 hours of training in an approved program, and completion of a DSS course in direct client care, medication aides have no other formal education or training. They practice in assisted living facilities where medications may be self-administered or provided by a medication aide, typically without supervision or oversight by a licensed health care provider (nurse) in the facility. Therefore, their practice is limited to the acts for which they are specifically educated and have demonstrated competency.