Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Nursing; Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC90-60-10
Regulation title	Regulations Governing the Registration of Medication Aides
Action title	Administration of glucagon
Date this document prepared	3/27/08

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 amendment allows an exception to the prohibition for medication aides in assisted living facilities to mix, dilute or reconstitute drugs for the dilution or mixing of glucagon.

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.

The Board of Nursing adopted the amendments to 18VAC90-60-10 et seq., Regulations Governing the Registration of Medication Aides on March 18, 2008.

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 responsibility to promulgate regulations, establish renewal schedules and to levy fees:

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

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…

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.

An amendment to section 110 will allow medication aides to mix, dilute or reconstitute glucagon. When regulations were written, it was agreed that medication aides would not have the education and training to mix, dilute or reconstitute drugs in an assisted living facility. The one exception to that prohibition was insulin, because it is essential for health and safety of residents for aides to be able to care for those with diabetes. If a medication aide is trained and authorized to administer insulin for diabetic residents in assisted living, they must also be able to administer glucagon, which is a rescue drug for such patients. The fact that glucagon must also be reconstituted or diluted was overlooked in the original drafting. Therefore, the amendment is essential to protect the health and safety of diabetic residents in assisted living facilities where medication aides are used to administer drugs.

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 determined that a fast-track process is appropriate because there is no controversy with this action. It will correct an omission in the initial regulations which became effective July 1, 2007. A medication aide who administers insulin for diabetic residents in an assisted living facility must also be able to administer glucagon, which is a rescue drug for such patients, so this action is necessary for patient safety.

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.)

Subsection B currently prohibits a medication aide from mixing, diluting or reconstituting two or more drug products, with the exception of insulin. The amendment will add an exception for glucagon.

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 of the amendment may be that it will facilitate the ability of medication aides to care for diabetic residents of assisted living facilities. There are no disadvantages, since medication aides receive training in mixing glucagon in their educational programs.

2) There are no disadvantages to the agency or the Commonwealth.

3) There is no other pertinent matter of interest related to this action.

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.

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	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 some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There will be no on-going expenditures related to this action.
Projected cost of the regulation on localities	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals affected by this regulation would be persons who are registered as medication aide.
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.	There are currently 76 registered medication aides; it is not required for med aides to be registered to administer drugs in assisted living until December 31, 2008. It is unknown how many may currently be administering insulin.
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 for compliance. Training in dilution of insulin and glucagon is already part of the 68-hour program.

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 only alternative would be to require every assisted living facility that has a diabetic resident to hire a nurse for the administration of insulin and, if necessary, glucagon. That alternative would be prohibitive for many smaller facilities and would be problematic if a current resident developed diabetes and the only person available to administer drugs was a medication aide. The facility would either have to dismiss the resident or quickly hire a nurse for that resident.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family or family stability.

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	Proposed change and rationale
110	n/a	Currently, subsection B says: A medication aide shall not: 1. Transmit verbal orders to a pharmacy; 2. Make an assessment of a client or deviate from the medication regime ordered by the prescriber; 3. Mix, dilute or reconstitute two or more drug products, with the exception of insulin; *The amendment will add glucagon to the exception for insulin.*