Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Board of Nursing, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC90-20-10 et seq.
Regulation title	Regulations Governing the Practice of Nursing
Action title	Training for administration of gastrostomy tube in DBHDS facilities
Date this document prepared	January 29, 2014

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

HB1759 of the 2013 General Assembly authorizes a person who has successfully completed a training program approved by the Board of Nursing to administer medications via percutaneous gastrostomy tube to person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services (DBHDS).

The key provision of the regulation is the inclusion in Section 390 (content of a medication administration training program) a requirement to complete the curriculum approved by the Department of Behavioral health and Developmental Services for unlicensed persons to administer medication via a gastrostomy tube.

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.

There are no acronyms used.

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.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards including the responsibility 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:

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.

Chapter 114 of the 2013 Acts of the Assembly amended § 54.1-3408 of the Drug Control Act to require adoption of this regulation:

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The intent of the regulatory action in the adoption of emergency regulations is compliance with the statutory mandate of Chapter 114 of the 2013 Acts of the Assembly to "*promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment*." The Act provides for administration of drugs by an unlicensed person to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services (DBHDS) via a gastrostomy tube, provided the unlicensed person has successfully completed a training program "*approved by the Board of Nursing."*

The goal of the amendment to Section 390 is inclusion of a training module in gastrostomy tubes approved by DBHDS, which is designed to ensure that unlicensed persons have adequate competency to administer medications in a manner that protects the health and safety to persons receiving services in a DBHDS-approved program. The training by DBHDS is an addition to the basic content of the curriculum for medication administration training program as authorized in § 54.1-3408 of the Code of Virginia.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The key provision of the regulation is the inclusion in Section 390 (content of a medication administration training program) a requirement to complete the curriculum approved by the Department of Behavioral health and Developmental Services for unlicensed persons to administer medication via a gastrostomy tube.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

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1) The primary advantage of the amendment is better management of clients in facilities licenses by DBHDS who require a gastrostomy tube. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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 is no requirement more restrictive than 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Richmond, VA 23233 or by fax to (804) 527-4434 or to **elaine.yeatts@dhp.virginia.gov.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the *Virginia Register of Regulations* and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (**http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi**). Both oral and written comments may be submitted at that time.

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. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

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	
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.	
Benefits expected as a result of this regulatory proposal.	
Projected cost to the state to implement and enforce this regulatory proposal.	
Projected cost to localities to implement and enforce this regulatory proposal.	
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.	

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 alternatives that would achieve the essential purpose. Administration of drugs via a percutaneous gastrostomy tube requires an understanding of the purpose, technique and possible complications involved. To allow an unlicensed person to perform such administration in a program licensed by the Department of Behavioral Health and Developmental Services (DBHDS), the Drug Control Act (§ 54.1-3408) was amended by the 2013 General Assembly. To protect the health and safety of persons receiving such administration, the Code requires successful completion of a training program approved by the Board of Nursing and an evaluation of the unlicensed person by a registered nurse to demonstrate competency in administration of drugs via percutaneous gastrostomy tube. The training program or module for administration of drugs via a gastrostomy tube is designed for current medication aides in DBHDS facilities who have already completed the medication management curriculum set out in Section 390 of Board of Nursing regulations. Competency of the unlicensed person must be demonstrated in a written test and a skills demonstration by a registered nurse.

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 to the proposed regulatory action that would comply with the mandate of Chapter 114 of the 2013 Acts of the Assembly.

To develop a training program as specified in the Act, the Department of Behavioral Health and Developmental Services (DBHDS) was asked to utilize the expertise of its registered nurses who are familiar with gastrostomy tubes and with client needs in its facilities to develop a training program. The Board of Nursing has amended its requirements for a medication administration curriculum to approve the curriculum developed by DBHDS for the administration of mediations via a gastrostomy tube in DBHDS facilities. The use and management of the curriculum will be the responsibility of DBHDS nurses, who will conduct the training, administer the written test and evaluate the skills and competency of the medication aides. If experience with the training indicates that there is a need for modifications to the training module, DBHDS will be able to make changes as necessary to protect the health and safety of persons within its facilities.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

The NOIRA to replace emergency regulations was published on November 4, 2013 with comment until December 4, 2013. There were no comments received.

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 on the family.

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.

*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.*

The proposed amendment to section 390 is identical to the emergency regulation currently in effect.

Current section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
390	Sets out the content of the curriculum for training in medication administration by unlicensed persons as authorized in § 54.1-3408 of the Drug Control Act.	Subsection B is added to Section 390 to require: *Pursuant to § 54.1-3408 (L), the board requires successful completion of the curriculum approved by the Department of Behavioral Health and Developmental Services for unlicensed persons to administer medication via a gastrostomy tube.* The curriculum and training module approved by DBHDS includes general information about gastrostomy tubes, techniques, infection control, medication administration, physician orders, and the role of the nurse, intervention for complications, and forms for competency evaluations. The training program will be used by registered nurses to train medication aides in DBHDS facilities and may be modified by that Department as experience dictates. It will allow persons with gastrostomy tubes to reside in community facilities in which the full-time services of a registered nurse are not available.