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	18VAC90-21-10 et seq.
Regulation title	Regulations Governing the Practice of Nursing
Action title	Administration of insulin, glucagon, and epinephrine pursuant to HB1444
Date this document prepared	7/22/13

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Chapter 183 of the 2013 Acts of the Assembly provides that employees of or persons providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may administer insulin, glucagon, and epinephrine pursuant to a written order issued by a prescriber in certain circumstances. The bill also requires the Board of Nursing to promulgate regulations governing training in the administration of epinephrine and glucagon by persons authorized to administer epinephrine and glucagon. Therefore, such training is added to the medication administration training program already set out.

In February of 2014, provisions relating to medication administration and immunization protocols were deleted from Chapter 20 and incorporated into a new Chapter 21. Therefore, the amended regulation is 18VAC90-21-30, rather than 18VAC90-20-390. Additionally, the Board

revised the submission to use the generic term for an Epipen® by substituting the term auto-injectable epinephrine.

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 18VAC90-20-10 et seq., Regulations Governing the Practice of Nursing on July 17, 2013.

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. 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, the second enactment clause of Chapter 183 of the 2013 Acts of the Assembly specifies that: *That the Board of Nursing shall promulgate regulations to implement the provisions of this act relating to medication administration training for the administration of epinephrine and glucagon*.

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 amendments is to include training in the signs of hypoglycemia and the administration of glucagon to the module on training in the administration of insulin. The 32-

hour training program set out in section 390 is used for training unlicensed persons to administer medications in certain facilities as prescribed in subsection L of § 54.1-3408. If a person is authorized to assist with the administration of insulin, he should also be trained in the administration of a rescue dose of glucagon. Since Chapter 183 provides that employees of or persons providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services (DBHDS) may administer insulin, glucagon, and epinephrine pursuant to a written order issued by a prescriber in certain circumstances, training in administration of those drugs is essential to protect public health and safety for persons receiving services in a DBHDS facility.

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?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The amendments are mandated by and necessary to implement the statute. They will not be controversial, and the curriculum already exists for such training.

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.

This action will amend the 32-hours medication administration program to add "signs of severe hypoglycemia and administration of glucagon" to the insulin module. For the purpose of "facilitating client self-administration or assisting with the administration of an Epipen® pursuant to an order issued by the prescriber for a specific client in a facility licensed by the Department of Behavioral Health and Developmental Services under provisions of subsection D of § 54.1-3408," it will also add #5 is added to the curriculum.

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 would be to those persons who are receiving services in a DBHDS licensed facility and who may have diabetes or severe allergies. There are no advantages or disadvantages to the general public.
2) There are no advantages or disadvantages to DHP but there are advantages to DBHDS, which will be able to train and utilize unlicensed persons to administer insulin, glucagon and an Epipen®.
3) There are no other pertinent matters.

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

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 alternative regulatory methods. Adoption of an amended regulation is required by Chapter 183 of the Acts of the Assembly.

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	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 not incur additional costs for email notification to persons on the Public Participation Guidelines mailing lists. There will be no on-going expenditures related to this action.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Affected individuals are unlicensed persons who are employees of or persons providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services who may be required to receive training in administration of insulin, glucagon, and epinephrine.
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.	The agency has no estimate of the number of persons who will be trained, but it is likely to be a small number.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.	Since the number of hours required for a training program is not being increased, there would be no costs associated with this action. The curriculum for training unlicensed persons in administration of glucagon and Epipen® already exists and will not have to be developed.
Beneficial impact the regulation is designed to produce.	Facilities licensed by DBHDS will be able to train persons in administration of certain drugs that may be necessary for persons receiving services in one of its facilities or programs.

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 will accomplish the purpose of compliance with the legislative mandate.

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 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
30	Sets out the general curriculum for a 32-hour training program in medication administration	Section 30 currently includes in #4 training in "facilitating client self-administration or assisting with the administration of insulin" including the cause and treatment of diabetes; the side effects of insulin; and the preparation and administration of insulin. This action will add "signs of severe hypoglycemia and administration of glucagon" since glucagon is specifically mentioned in the legislation and its administration may be essential to rescue an insulin-dependent person. For the purpose of "facilitating client self-administration or assisting with the administration of auto-injectable epinephrine pursuant to an order issued by the prescriber

		for a specific client in a facility licensed by the Department of Behavioral Health and Developmental Services under provisions of subsection D of § 54.1-3408," #5 is added to the curriculum.