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Fast-Track Regulation
Agency Background Document

Agency name	Board of Nursing, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC90-21
Regulation title(s)	Regulations for Medication Administration and Immunization Protocol
Action title	Title change
Date this document prepared	9/20/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board has amended the title to clarify the content and intent of the regulation. There were no other changes needed in the chapter.

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.

N/A

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 18, 2018, the Board of Nursing amended 18VAC90-21-10 et seq., Regulations for Medication Administration and Immunization Protocol.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

As required by Executive Order 14 (2018), the Board of Nursing conducted a periodic review of this chapter. The amendment is technical in nature, does not change current procedure, and has no impact on the public. Therefore, it is not expected to be controversial.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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, which provides the Board of Nursing the authority to promulgate regulations to administer the regulatory system and authorization for delegation to an agency subordinate:

> ***§ 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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …*

In the Drug Control Act, § 54.1-3408 has numerous subsections authorizing unlicensed persons in certain settings to administer certain drugs, provided they have been properly trained. For example, subsection I states: "*This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing…"* To provide a regulatory structure for such training programs, the Board promulgated Chapter 21. (Chapter 21 was carved out of Chapter 20 during the Regulatory Review of all regulations in 2014.)

Likewise, subsection L of § 54.1-3408 provides: "*A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present…."* The protocol for such immunization is found in section 50 of Chapter 21.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The regulatory change is consistent with the principle of regulations that are clearly written and easily understandable. The current title of the regulation may be confusing to persons who think it applies to medication administration by licensed persons. It is necessary to retain the current chapter because its provisions protect the health and safety of the public, but the title is amended to be more descriptive of its content.

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.

The title is changed from Regulations for Medication Administration and Immunization Protocol to Regulations for Training Programs for Medication Administration by Unlicensed Persons and Immunization Protocol.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) There are no advantages or disadvantages to the public; the amendment is technical and clarifying.
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 regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There is no applicable federal requirement.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs or savings resulting from the change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	N/A

For all agencies: Benefits the regulatory change is designed to produce.	N/A

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	No costs
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	There are no entities impacted.
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.	N/A
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	N/A
Benefits the regulatory change is designed to produce.	The amendment is technical and clarifying.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The amendment does not change the substance of the chapter; there is no alternative.

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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no alternative regulatory methods for changing the title other than promulgating a regulatory action.

Public Participation

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.

Detail of Changes

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
		Current title: Regulations for Medication Administration and Immunization Protocol	Changing title to: Regulations for Training Programs for Medication Administration by Unlicensed Persons and Immunization Protocol *The amendment is clarifying and not substantive; it does not change the current regulation in any way. It does avoid any confusion with regulation of persons who are licensed or registered and who are authorized to administer medication – especially those medication aides who administer medications in assisted living facilities.*