townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Board of Nursing, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC90-27
VAC Chapter title(s)	Regulations Governing Nursing Education Programs
Action title	Use of simulation in nursing education
Date this document prepared	7/21/20

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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 adopted definitions and qualifications for the use of simulation in lieu of direct client care hours in fulfillment of the clinical hour requirements for nursing education programs. Amended regulations will define terms, require faculty supervising clinical practice by simulation to have knowledge and skills in the methodology, and clarify that the 50% limitation on the number of clinical hours that can fulfilled by simulation applies to the hours in different specialties and population groups across the life span.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Mandate and Impetus

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, or board decision). 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for the regulatory action is replacement of a Guidance Document that outlined the essential components and major concepts necessary when using simulation in lieu of direct client care. The document presented research on use of simulation in nursing education and best practices for learning outcomes. It also included prescriptive language that appeared to be requirements best set out in regulation. Accordingly, the Board decided to incorporate some of the essential elements of guidance into Chapter 27.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency'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:…

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

The powers and duties of the Board include oversight of nursing education and approval of programs:

§ 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:

1. To prescribe minimum standards and approve curricula for educational programs preparing persons for licensure or certification under this chapter;
2. To approve programs that meet the requirements of this chapter and of the Board;
3. To provide consultation service for educational programs as requested;
4. To provide for periodic surveys of educational programs;
5. To deny or withdraw approval from educational or training programs for failure to meet prescribed standards;…

§ 54.1-3013. Approval of nursing education program.
An institution desiring to conduct a nursing education program to prepare professional or practical nurses shall apply to the Board and submit evidence that:
1. It is prepared to meet the minimum standards prescribed by the Board for either a professional nursing curriculum or a practical nursing curriculum; and
2. It is prepared to meet such other standards as may be established by law or by the Board.
A survey of the institution and its entire nursing education program shall be made by the administrative officer or other authorized employee of the Board, who shall submit a written report of the survey to the Board. If, in the opinion of the Board, the requirements necessary for approval are met, it shall be approved as a nursing education program for professional or practical nurses.
New nursing education programs shall not be established or conducted unless approved by the Board.

Purpose

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.

As nursing education programs are allowed to use simulation for up to 50% of the required clinical hours, it is essential that those hours are led by faculty with expertise in both the subject matter covered and the use of simulation as a teaching tool. Likewise, simulation should not be the only methodology for clinical experience is a particular specialty or with a particular patient population. Therefore, the amendments are necessary to ensure nursing students are adequately trained to be minimally competent for the health, safety, and welfare of patients during clinical experiences and after licensure.

Substance

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 amendments will: 1) define "direct client care" and "simulation" – terms used in the amended regulations; 2) require faculty who supervise clinical practice by simulation demonstrate knowledge and skills in the methodology; 3) require simulation to account from no more than 50% of the total clinical hours in different clinical specialties and population groups

across the life span; and 4) require knowledgeable faculty to be present during the simulation experience.

Issues

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) The primary advantage to the public is greater assurance that nursing students are adequately trained to be minimally competent in providing clinical care; there are no disadvantages to the public;
2) There are no advantages and disadvantages to the agency or the Commonwealth; and
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 which are reasonable and necessary to administer effectively the regulatory system.*"
The proposed regulation on simulation of clinical training is a foreseeable result of the statute requiring the Board to protect the health and safety of patients in the Commonwealth.

Requirements More Restrictive than Federal

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 are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

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, 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. 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	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.
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.	There are no costs to other agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There is no specified benefit from the regulatory change.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
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.	Practical (LPN) and professional (RN) nursing education programs
Agency's best estimate of the number of such entities that will be affected. 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.	The Board has approved 57 LPN programs and 77 RN programs in Virginia. Nursing education programs are either part of community colleges, universities, large hospital systems, or proprietary businesses. Some of the proprietary businesses are operated by national companies, such as ECPI. Others are more local or regional, but the Board has no estimate of how many would qualify as a small business.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:	The Board does not project any additional costs. Regulatory requirements are clarifying and consistent with current expectations for approved curricula in approved nursing education programs. Simulation, which does require the use

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.	of manikins, is an option to in-person clinical experiences.
Benefits the regulatory change is designed to produce.	Greater clarify and consistency in the utilization of simulated clinical experiences.

Alternatives to Regulation

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.

Since up to 50% of the clinical hours in nursing education may be in a simulation experience, amendments to regulation are necessary to ensure that the experience has content and value. There is no alternative that meets the requirement of protecting the public.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

Regulations specify the required curriculum for an approved nursing education program; amendments to regulations are therefore necessary to clarify or specify aspects of such programs.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

N/A

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

The Notice of Intended Regulatory Action and a draft of the regulatory amendments were published on 2/3/20 with comment received until 3/4/20. There was no public comment.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Nursing is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Henrico VA 23233, phone (804) 367-4688, fax (804) 527-4434, email: Elaine.yeatts@dhp.virginia.gov . In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
27-10	Provides definitions for words and terms used in the chapter	The terms “direct client care” and “simulation” are currently used in the chapter, so definitions are added for greater clarity in their usage.
27-60	Sets out the qualifications for faculty to teach in an approved nursing education program	In subsection A, the qualification for nursing faculty supervising the clinical practice of students is amended to clarify that faculty who are utilizing simulation in lieu of direct client care have to meet licensure requirements and provide education of education and experience. Faculty supervising clinical practice by simulation must demonstrate clinical knowledge and skill in that methodology and engage in ongoing professional development in the use of simulation. *The use of manikins to simulate patient care is an evolving field in health care. Nursing faculty supervising clinical training must demonstrate that they not only have knowledge and skill in the clinical experience (i.e., adult cardiac care; pediatrics; labor and delivery), but they must also have knowledge and skill in the technical use of simulation to ensure that the student experience is adequate for patient safety as a post-licensure nurse.*
27-100	Sets out the requirements for a curriculum in direct client care	Subsection D currently provides that no more than 50% of the total clinical hours for any course may be used as simulation. An amendment will clarify that if simulation is used for a course that integrates more than one subject or stage in the life span, the clinical experience through simulation cannot exceed 50% of the total clinical hours in different clinical specialties and population groups. *For example, a course in cardiac care for adults and children would need to have no more than 50% in simulation with manikins for adult care and 50% in simulation with manikins for pediatric care. Likewise, if more than one specialty is included in a single course, the simulated clinical experience would need to have no more than 50% in simulation in each of those specialties.* An amendment is subdivision 4 of subsection D specifies that faculty with education and expertise in simulation and in the applicable subject areas must be present during the simulation experience. *Without appropriate supervision by trained faculty, there is no assurance that the students are being adequately*

		trained or that the clinical experience is providing any assurance of minimal competency. An amendment to subdivision 5 of subsection D adds to the documentation required for all simulated experiences, to include pre-briefing, evaluation of the simulated experience, and the method used to communicate student performance to clinical faculty. *All such documentation should currently be part of the record in a nursing education program, so the additions are considered a clarification of expectation.*