



Virginia
Regulatory
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Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-410
Regulation title	Rules and Regulations for the Licensure of Hospitals
Action title	Amend sections 420 and 1190
Document preparation date	April 7, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This proposed amendment requires a registered nurse, qualified by education and experience in perioperative nursing, to be present as a circulating nurse in each operating room during surgical procedures conducted in inpatient hospitals and outpatient surgical centers. This amendment is the result of a Petition for Rulemaking received from the Virginia Council for periOperative Nurses (Council).

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 Health adopted these amendments to the hospital and outpatient surgery center licensure regulation at its April 4, 2005 meeting.

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.

This amendment is promulgated under the authority of Section 32.1-127 of the Code of Virginia, which grants the Board of Health the legal authority to promulgate regulations “in substantial conformity to the standards of health, hygiene, sanitation, construction, and safety as is established and recognized by medical and health care professionals and by specialists in the matter of public health and safety.” Therefore, this authority is mandated.

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.

Patient safety in hospitals has come to national attention in recent years as a result of the 1998 National Institute of Health report “To Err Is Human.” The Department believes that adopting these standards will enhance patient safety during surgical procedures, a critical time in patient care.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Please note: If an objection to the use of the fast-track process is received within the 60-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 objection 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 response from hospitals, received as part of the Petition for Rulemaking process, was supportive of registered nurses serving as circulating nurses during surgical procedures. Therefore, the department has determined that the proposed amendments are not controversial and are appropriate for filing via the “fast-track” regulatory process.

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.)

The proposed amendment updates two hospital regulatory sections, 12 VAC 5-410-420 and 1190 respectively, pertaining to surgical practice in inpatient and outpatient surgery centers.

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.*

The Department was approached by the Virginia Council for periOperative Nurses with a Request for Rulemaking to amend section 420 of the Rules and Regulations for the Licensure of Hospitals. To assure consistency between inpatient and outpatient services, the Department proposes adopting a similar standard for outpatient surgery centers as well.

Financial impact

Please identify the anticipated financial impact of the proposed regulation and at a minimum provide the following information:

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	None to minimal. State general funds (0100) and licensure fees fund the hospital licensure program. The regulation already contains standards regarding personnel in operating suites and there is no change to the inspection process. Therefore, this is a one-time expenditure to promulgate this change to the regulation.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	Hospitals providing surgical services and outpatient surgery hospitals
Agency’s best estimate of the number of such entities that will be affected	94 hospitals and 41 outpatient surgery centers
Projected cost of the regulation for affected individuals, businesses, or other entities	Minimal as most hospitals already employ perioperative nurses as circulating nurses.

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.

The hospital and outpatient surgery center licensure regulation address standards regarding surgical services, therefore, promulgating this amendment to the regulation is the only alternative available.

Family impact

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

There is no direct impact on the family.

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.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-410-420	New subsection D	Does not address criteria for circulating nurses	Inserted "A registered nurse, qualified by education and experience in perioperative nursing, shall be present as a circulating nurse in each operating room during surgical procedures. Renummer remaining subsections. Enhances patient safety during surgical procedures.
12 VAC 5-410-1190	New subsection 2	Does not address criteria for circulating nurses	Inserted "A registered nurse, qualified by education and experience in perioperative nursing, shall be present as a circulating nurse in each operating room during surgical

			procedures. Renumber remaining subsections. Enhances patient safety during surgical procedures.
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