



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-410
Regulation title(s)	Regulations for the Licensure of Hospitals in Virginia
Action title	Update the Regulations to reflect a CMS issued final rule enabling hospitals that are part of a hospital system to have a unified integrated medical staff
Date this document prepared	September 24, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation.

The State Board of Health (Board) proposes to amend 12VAC5-410 et. seq. Regulations for the Licensure of Hospitals in Virginia to reflect changes to federal regulations. The Center for Medicare and Medicaid Services (CMS) revised 42 C.F.R. § 482.22 (b) in 2014 to add § 482.22 (b)(4) which permits a hospital that is part of a hospital system consisting of multiple, separately certificated hospitals to participate in a unified, integrated medical staff that the hospital system utilizes for two or more of its member hospitals, in accordance with state law. The Regulations for the Licensure of Hospitals in Virginia is currently written in a manner that can be interpreted to be more restrictive than the federal regulations. This was not the intent and therefore this regulatory action will amend the regulations to remove restrictions that may be interpreted to be more stringent than federal law.

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.

CMS means the Centers for Medicare and Medicaid Services

OLC means the Office of Licensure and Certification

VDH means the Virginia Department of Health

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.

These amendments to the Regulations for the Licensure of Hospitals in Virginia (12VAC5-410) were approved by the State Board of Health on December 3, 2015.

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.

The regulation is promulgated under the authority of §§ 32.1-12 and 32.1-127 of Chapter 5 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code." Section 32.1-127 of the Code of Virginia directs the Board to promulgate regulations with minimum standards for the construction and maintenance of hospitals, the operation, staffing and equipping of hospitals, qualifications and training of staff of hospitals, conditions under which a hospital may provide medical and nursing services to patients in their places of residence and policies related to infection prevention, disaster preparedness and facility security.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe 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 Center for Medicare and Medicaid Services (CMS) revised 42 C.F.R. § 482.22 (b) in 2014 to add § 482.22 (b)(4) which permits a hospital that is part of a hospital system consisting of multiple, separately certificated hospitals to participate in a unified, integrated medical staff that the hospital system utilizes for

two or more of its member hospitals, in accordance with state law. The Regulations for the Licensure of Hospitals in Virginia is currently written in a manner that can be interpreted to be more restrictive than the federal regulations. This was not the intent and therefore this regulatory action will amend the regulations to remove restrictions that may be interpreted to be more stringent than federal law. This regulatory action will protect the health and welfare of Virginians by ensuring that patients within a hospital setting benefit from the improved efficiency, quality and patient safety made possible through a unified, integrated medical staff.

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?

These amendments simply ensure that the Commonwealth's regulations are not more restrictive than federal regulations. These amendments have also been prepared with input from stakeholders. Therefore, the Department does not expect that this regulatory action will be controversial.

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.

12VAC5-410-210. Clarify the requirement that each hospital have an organized medical staff. Add language which allows hospitals which are a part of a hospital system to have a unified and integrated medical staff. Add subsections to specify the requirements of unified and integrated medical staffs.

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 primary advantage to the agency, the Commonwealth and the public of the proposed regulatory action will be less burdensome regulations. The proposed regulatory action will also lead to improved efficiency, quality and patient safety created through unified and integrated medical staffs. There are no known disadvantages to the agency, the Commonwealth or the public.

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 requirements in this proposal that exceed 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.

No locality will be particularly affected by the proposed regulatory action.

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.

The alternative regulatory methods are not applicable. The regulations are required by the Code and the proposed amendments are attempting to reduce the burden of the existing requirements.

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	None
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Those individuals who serve as the medical staff to hospitals throughout the Commonwealth. Patients served by hospitals throughout the Commonwealth.
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;	There are 106 licensed hospitals and critical access hospitals within the Commonwealth.

b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	
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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.	No projected cost.
Beneficial impact the regulation is designed to produce.	Less burdensome nature of the regulations.

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 other viable alternatives other than the proposed amendments to obtain the objectives of the board.

Public participation notice

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.

Family impact

Please assess the impact of this 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.

The board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. 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.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-410-210		<p>A. Each hospital shall have an organized medical staff responsible to the governing body of the hospital for its own organized governance and all medical care provided to patients.</p> <p>B. The medical staff shall be responsible to the hospital governing board and maintain appropriate standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.</p> <p>C. The medical staff, subject to approval by the governing body, shall develop bylaws incorporating details of the medical staff organization and governance, giving effect to its general powers, duties, and responsibilities including:</p> <ol style="list-style-type: none"> 1. Methods of selection, election, or appointment of all officers and other executive committee members and officers; 2. Provisions for the selection and appointment of officers of departments or services specifying required qualifications; 	<p>A. Each hospital shall have an organized medical staff responsible to the governing body of the hospital for its own organized governance and all medical care provided to patients. <u>Nothing in this provision shall prevent hospitals which are a part of a hospital system from having a unified and integrated medical staff as permitted by 42 C.F.R. § 482.22 (b) (4).</u></p> <p>B. The medical staff shall be responsible to the hospital governing board and maintain appropriate standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.</p> <p>C. The medical staff, subject to approval by the governing body, shall develop bylaws incorporating details of the medical staff organization and governance, giving effect to its general powers, duties, and responsibilities including:</p> <ol style="list-style-type: none"> 1. Methods of selection, election, or appointment of all officers and other executive committee members and officers; 2. Provisions for the selection and appointment of officers of departments or services specifying required qualifications; 3. The type, purpose, composition and organization of standing committees; 4. Frequency and requirements for attendance at staff and departmental meetings;

		<p>3. The type, purpose, composition and organization of standing committees;</p> <p>4. Frequency and requirements for attendance at staff and departmental meetings;</p> <p>5. An appeal mechanism for denial, revocation, or limitation of staff appointments, reappointments and privileges;</p> <p>6. Delineation of clinical privileges in accordance with the requirements of § 32.1-134.2 of the Code of Virginia;</p> <p>7. Requirements regarding medical records;</p> <p>8. A mechanism for utilization and medical care review; and</p> <p>9. Such other provisions as shall be required by hospital or governmental rules and regulations.</p> <p>D. A copy of approved medical staff bylaws and regulations and revisions thereto shall be made available to the OLC on request.</p>	<p>5. An appeal mechanism for denial, revocation, or limitation of staff appointments, reappointments and privileges;</p> <p>6. Delineation of clinical privileges in accordance with the requirements of § 32.1-134.2 of the Code of Virginia;</p> <p>7. Requirements regarding medical records;</p> <p>8. A mechanism for utilization and medical care review; and</p> <p>9. Such other provisions as shall be required by hospital or governmental rules and regulations.</p> <p>D. A copy of approved medical staff bylaws and regulations and revisions thereto shall be made available to the OLC on request.</p> <p>Intent: Clarify that the regulations are not intended to prevent unified and integrated medical staff in hospitals which are a part of a hospital system as permitted by federal regulation.</p> <p>Likely Impact: Greater clarity of the regulations.</p>
--	--	---	---