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Periodic Review and Small Business Impact Review Report of Findings

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-410
VAC Chapter title(s)	Regulations for the Licensure of Hospitals in Virginia
Date this document prepared	October 28, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Acronyms and Definitions

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

"Board" means the State Board of Health.

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 or 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.

Va. Code § 32.1-12 gives the Board the responsibility to make, adopt, promulgate, and enforce such regulations as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia. Va. Code § 32.1-127 requires the Board to adopt regulations that include minimum standards for (i) the construction and maintenance of hospitals and certified nursing facilities to ensure the environmental protection and the

life safety of its patients, employees, and the public; (ii) the operation, staffing and equipping of hospitals and certified nursing facilities; (iii) qualifications and training of staff of hospitals and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions; (iv) conditions under which a hospital may provide medical and nursing services to patients in their places of residence; and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals and certified nursing facilities. Subsection B of Va. Code § 32.1-127 further details the specific provisions to be included in the regulation.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

No alternative was considered because the General Assembly required the Board to adopt regulations governing the licensure of hospitals and promulgating regulation is the least burdensome method to accomplish this statutory mandate.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency’s response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The Board did not form an informal advisory group for the purposes of assisting in the periodic review.

Commenter	Comment	Agency response
R. Brent Rawlings, Virginia Hospital & Healthcare Association	Commenter requests retention of the regulation; speaks in generally favorable terms about the necessity of the regulation for the protection of the public health, safety, and welfare and for the economic performance of important governmental functions; comments that the regulation is generally clearly written and easily understandable, and provides suggestions for improvement: (1) Section 60. Consider defining “premises” and “grounds” or streamline the definitions by creating a combined “campus” definition. (2) Section 20. “Surgery” is not defined in 12 VAC 5-410-10 as stated in this section. (3) Section 110. Consider requiring licenses issued by the Commissioner include the	The Board notes the general support for the regulation and the request for consideration of amendments. The Board will initiate a fast-track regulatory change for those changes it anticipates will be noncontroversial for 12VAC5-410. The Board agrees that separate regulatory chapters should be promulgated for the different classifications of hospitals, though this change would likely be unsuccessful if the fast-track regulatory process were used, so it intends to initiate a standard regulatory action for that change.

	<p>number of approved operating rooms as well.</p> <p>(4) Section 170. Ownership. Consider addressing ownership for hospitals with entity forms other than corporations such as LLCs.</p> <p>(5) Section 443. Conform newborn service levels to the levels created by the American Academy of Pediatrics</p> <p>(6) Section 470 and Parts IV and V of 12 VAC5-410. With regards to outpatient surgical hospital regulations, we recommend removal of these sections and consider establishing a new chapter specifically for outpatient surgical hospitals to include the current regulations.</p>	
<p>James C. Sherlock</p>	<p>The commenter contends that the 12VAC5-410 are not in conformity with Va. Code § 32.1-127 and applicable executive orders. The commenter suggests incorporating Medicare and Medicaid regulations by reference and removing substantially similar Virginia provisions.</p>	<p>The Board notes this comment and will address reducing or eliminating the duplicative provisions in the planned standard regulatory action to create separate regulatory chapters for the different classifications of hospitals.</p>

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

This regulation is necessary for the protection of public health, safety, and welfare because it requires hospitals to meet minimum standards for personnel, clinical and nonclinical services, treatment of patients, and facility safety. These standards protect members of the public who utilize hospital services. There is room for improvement on the clarity and understandability of the regulation.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.

In the short term, the Board has decided to amend the regulation to incorporate statutory/legislative mandates that have been inadvertently omitted, to update regulatory provisions to include current clinical and industry practices, and to update licensing processes and procedures. In the mid- to long-term, the

Board intends to repeal 12VAC5-410 and replace it with at least two regulatory chapters: one for hospitals that only provide outpatient services and one for hospitals that may provide inpatient and outpatient services. Through this repeal-and-replace effort, the Board hopes to more closely align the hospital licensure program with the federal certification program to reduce confusion for both regulants and the public.

Small Business Impact

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 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.

There is a continued need for the regulation as the Board is mandated to regulate hospitals. The Board did not receive complains or comments concerning the regulation from the public. The regulation is of moderate complexity, which is not an unexpected outcome given the overall complexity of the healthcare industry. The regulation does not conflict with federal law or regulation, though it currently does not meet all state mandates, which prompted the Board to decide to amend the regulation to remedy this. The regulation has been incrementally amended as changes to the Code of Virginia occurred; however, more comprehensive changes to the regulation are needed to reflect changes in the health care industry, technology, and economic conditions, including those that impact small businesses. The Board is not aware of any general hospital that would meet the definition of "small business"; to the extent there may be outpatient surgical hospitals that meet this definition, that classification of hospital already has fewer regulatory requirements by comparison to general hospitals.