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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)	12 VAC 5-220
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Date this document prepared	August 9, 2024

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.

"COPN" means Certificate of Public Need.

"VDH" means the Virginia Department 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.

This regulation was promulgated under the authority of §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

§ 32.1-12 of the Code of Virginia grants the Board the legal authority “to make, adopt, promulgate, and enforce such regulations...as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by it, the Commissioner, or the Department.”

§ 32.1-102.2 of the Code of Virginia directs the Board to promulgate regulations that are consistent with Article 1.1 of Chapter 4 of Title 32.1 of the Code of Virginia, which describes requirements for Medical Care Facilities Certificate of Public Need.

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 Code of Virginia requires the Board to adopt regulations governing the COPN program in Virginia, and repealing and replacing the 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.

Commenter	Comment	Agency response
<i>General Comments - Summarized</i>		
18 people via the Virginia Regulatory Town Hall	The regulation serves as a barrier to patients receiving high-quality, affordable health insurance	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulation.
10 people via the Virginia Regulatory Town Hall	The regulation limits the services physicians are able to offer	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulation.
15 people via the Virginia Regulatory Town Hall	The regulation results in increased costs for patients	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulation.
5 people via the Virginia Regulatory Town Hall	The regulation harms small businesses	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections fo the regulation.

5 People via the Virginia Regulatory Town Hall	The regulation is outdated	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulations.
12 People via the Virginia Regulatory Town Hall	The regulation hinders competition	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulations.
8 People via the Virginia Regulatory Town Hall	The regulation supports healthcare monopolies in Virginia	The Board notes the opposition to the regulation. The comments did not provide any suggested amendments to specific sections of the regulations.
17 People via the Virginia Regulatory Town Hall	The regulation should be repealed	The Board notes the comments, but repealing this chapter without a replacement is outside the authority of the Board as the Code of Virginia requires the regulation to exist, whether by amendment or by repeal-and-replace.
8 People via the Virginia Regulatory Town Hall	The regulation should be reformed	The Board notes the request for amendment to the regulation. The comments did not provide any suggested amendments to specific sections of the regulations.
3 People via the Virginia Regulatory Town Hall	COPN should be deregulated	The Board notes the comments, but repealing this chapter without a replacement is outside the authority of the Board as the Code of Virginia requires the regulation to exist, whether by amendment or by repeal-and-replace.
Cynthia Dudley, Trillium Drop-In Center, Inc., via the Virginia Regulatory Town Hall	The regulation does not help psychiatric patients	The Board notes the request for amendment to the regulation. The comments did not provide any suggested amendments to specific sections of the regulations.
2 People via the Virginia Regulatory Town Hall	The regulation is necessary for the protection of the public health, safety, and welfare	The Board notes the support for the regulations.
2 People via the Virginia Regulatory Town Hall	The regulation is necessary for the economical performance of important government functions	The Board notes the support for the regulations.
Brent Rawlings, Virginia Hospital & Healthcare Association, via the Virginia Regulatory Town Hall	The regulation minimizes the economic impact on small businesses	The Board notes the support for the regulations.
Brent Rawlings, Virginia Hospital & Healthcare Association, via the Virginia Regulatory Town Hall	A publicly accessible online library where all relevant COPN information and documents are posted should be created	The Board notes this comment and will take this suggestion under consideration.

<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>Various Code citations should be updated throughout the regulatory text</p>	<p>The Board notes this comment; the Board has approved an action (Action 6301) to update statutory citations throughout 12VAC5-220</p>
<p><i>12VAC5-220-10. Definitions.</i></p>		
<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>(i) The definition of “public hearing” should be revised for clarity (ii) Definitions should be added for the following terms: a. Mental Hospital b. Psychiatric Hospital c. Intermediate Care Facility d. Mental Retardation Facility</p>	<p>The Board notes this comment; the Board has approved an action (Action 6301) to remove “mental hospital” and “mental retardation facility” from 12VAC5-220. The Board will take the remaining suggestions under consideration.</p>
<p><i>12VAC5-220-130. Significant change limitation.</i></p>		
<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>The provisions regarding the review process when a RPHA is not present should be clarified</p>	<p>The Board notes this comment; the Board has approved an action (Action 6301) that addresses the substance of this comment.</p>
<p><i>12VAC5-180. Application forms.</i></p>		
<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>Application forms and regulatory requirements do not accurately reflect the application process in practice and should be updated to bring them into alignment with current practice</p>	<p>Thank you for your comment. The Board will take this suggestion into consideration.</p>
<p><i>12VAC5-220-230. Review of complete application.</i></p>		
<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>The provisions regarding the public hearing process when a RPHA is not present should be clarified</p>	<p>Thank you for your comment. This has been addressed in a recent action amending 12VAC5-220 (action #6301).</p>
<p><i>12VAC5-220-440. Extension.</i></p>		
<p>Brent Rawlings, Virginia Hospital & Healthcare Association , via the Virginia Regulatory Town Hall</p>	<p>The provisions regarding the extension request process when a RPHA is not present should be clarified</p>	<p>Thank you for your comment. This has been addressed in a recent action amending 12VAC5-220 (action #6301).</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 the COPN program ensures that the healthcare marketplace in Virginia is not saturated with unneeded medical care facilities, services or equipment, that charity care is being provided to indigent persons, that new medical care facilities, services or equipment are encouraged in geographic areas not served or not sufficiently served by existing medical facilities, and that there is public input regarding proposed changes to new or existing healthcare services in a community. The regulation is fairly complex due to the subject matter and will require revisions in form and style to make it more easily understandable.

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.

The Board will repeal and replace these regulations to incorporate various statutory and legislative mandates that have been omitted from previous actions, to update the regulation to reflect the current requirements within the *Form, Style and Procedure Manual for Publication of Virginia Regulations* administered by the Virginia Registrar or Regulations, and to consider opportunities for regulatory reduction where possible.

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 the COPN program in Virginia. The nature of many of the comments received were generally focused on the perceived outdatedness and burdens of the COPN program in Virginia. The regulation is complex and difficult to read, making the choice of repeal-and-replace the least burdensome regulatory pathway to update the regulations to make them more readable. 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 through a repeal-and-replace 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. During the most recent licensure renewal period, fourteen general hospitals, 37 outpatient surgical hospitals, and 110 nursing homes self-reported that they meet the definition of “small business”; given that some self-reported small businesses are part of larger health systems or corporations, VDH is unable to ensure the validity of the self-reported data. VDH is unable to quantify how many physician offices qualify as small businesses due to lack of available data (self-reported or otherwise). The Board was not able to identify any alternatives for small businesses that would be more equitable while still protecting the health,

safety, and welfare of the public, and has put forth thoughtful consideration about the burdens of the regulatory requirements that have a cost to regulants.
