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# Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5-220-10 <i>et seq.</i>
VAC Chapter title(s)	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	Promulgation of Fee Schedule
Date this document prepared	October 20, 2023

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*.

### **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.

Chapter 1271 of the 2020 Acts of Assembly made extensive revisions to Article 1.1 (§ 32.1-102.1 *et seq.*) of Chapter 4 of Title 32.1 of the Code of Virginia, which governs the Certificate of Public Need program in VDH. The amendments removed the prior statutory cap on fees and included authority for the State Board of Health to establish a fee schedule for the applications that it receives. This regulatory action creates a fee schedule for the COPN program and revises the fee cap on applications.

# **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.

"Agency" means the Virginia Department of Health.

"Board" means the State Board of Health.

"COPN" means Certificate of Public Need.

"ICF/IID" means intermediate care facility for individuals with intellectual disabilities.

"RHPA" means regional health planning agency.

"SHSP" means the State Health Services Plan.

"VDH" means the Virginia Department of Health.

### **Statement of Final Agency Action**

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 approved these Fast Track amendments to the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220) on December 15, 2023.

### **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 the ORM procedures, "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."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

Chapter 1271 (2020) made extensive revisions to Article 1.1 (§ 32.1-102.1 *et seq.*) of Chapter 4 of Title 32.1 of the Code of Virginia, which governs the COPN program in VDH. Va. Code § 32.1-102.2(A)(5) previously granted the Board the authority to establish a fee schedule for COPN applications, but the fees were capped at "the lesser of one percent of the proposed expenditure for the project or \$20,000"; this fee cap was created in 1996 and was an increase from the prior fee cap of \$10,000. With the amendments introduced by Chapter 1271 (2020), the authority to establish a fee schedule has been renumbered as Va. Code § 32.1-102.2(A)(5), expanded to include registration applications, and removed the fee cap. Chapter 1271 (2020) also increased the review interval for the SHSP (formerly the State Medical Facilities Plan) from four years to two years and placed new requirements on VDH to have a publicly available electronic inventory of COPN-authorized capacity. These changes require an additional two FTEs and the Board is establishing a new fee schedule to support the existing COPN program, the new program obligations, and the new FTEs.

It's anticipated that this action will be noncontroversial and appropriate for the fast-track process because:

- the fee being charged for registration applications is nominal;
- the fee being charged for COPN applications retains a fee cap (though it has been adjusted higher) and still utilizes a formula of the lesser of 1.5 percent of the proposed project expenditure or the fee cap; and

 the changes to the fee schedule proposed in this action were developed with robust stakeholder engagement.

# 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.

This regulation is promulgated under the authority of Va. Code §§ 32.1-12 and 32.1-102.2(A)(4). Va. Code § 32.1-12 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."

Va. Code § 32.1-102.2(A)(4) states that the Board shall promulgate regulations that are consistent with this article and "...[m]ay establish a schedule of fees for applications for certificates or registration of a project to be applied to expenses for the administration and operation of the Certificate of Public Need Program[.]"

### 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 is intended to solve.

The rationale or justification of the regulatory change is that the COPN program should be primarily, if not entirely, supported by fee revenue rather than general funds. The specific reasons the regulatory change is essential to protect the health, safety, or welfare of citizens is that the continued financial health of the COPN program ensures that the healthcare marketplace is not characterized by unneeded medical facilities or equipment and that charity care is being provided to indigent patients. There is a minimum patient volume needed to ensure continued competency of staff providing care, which is a consideration of COPN programs staff when evaluating COPN requests; COPNs are also conditioned on the provision of a prescribed amount of charity care to indigent patients, which allows healthcare to be accessible to more patients. The goals of the regulatory change are to ensure that VDH receives sufficient revenue to support its COPN program and the mandated activities that the COPN program carries out. The problem the regulatory change is intended to solve is to update a fee cap that has not been changed in over 20 years and to create a fee for the registration process that currently lacks one.

# 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.

<u>12VAC5-220-10. *Definitions.*</u> Repeal of the definition for "application fee."

<u>12VAC5-220-105</u>. *Requirements for registration of the replacement of existing medical equipment*. Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

<u>12VAC5-220-110. *Requirements for registration of certain capital expenditures.*</u> Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

#### 12VAC5-220-125. Fee schedule.

A new section; creates a fee schedule for COPN applications and registration applications.

#### 12VAC5-220-180. Application forms.

Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

#### 12VAC5-220-355. RFA project application forms.

Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-125.

### 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.

The primary advantages to the public are a sufficiently funded COPN program that can regulate the healthcare marketplace, that maintains and updates the SHSP, and that monitors compliance with charity care conditions on COPNs. The primary disadvantage to the public is the assessment of higher fees for COPN projects if the project cost is in excess of \$1.33 million. The primary advantages to VDH and the Commonwealth are that the COPN program will have sufficient fee revenue to support its current staff, the two new FTEs, and the new mandates that the COPN program must meet. There are no primary disadvantages to the Commonwealth. There are no other pertinent matters of interest to the regulated community, government officials, and the public.

# **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

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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

The two licensed nursing homes operated by the Department of Veterans Services, the licensed general hospital operated by Virginia Commonwealth University (VCU) Health Systems Authority, the general hospital operated by the University of Virginia (UVA) Medical Center, and any state agency wishing to begin a project that would require either a COPN or registration with the COPN program are particularly affected by this proposed regulatory change.

#### Localities Particularly Affected

The County of Bedford, Lee County Hospital Authority, and Chesapeake Hospital Authority may be particularly affected by this proposed regulatory change since Bedford operates a nursing home and the two hospital authorities operate a licensed general hospital each and would be particularly affected by this proposed regulatory change. Additionally, any locality wishing to begin a project that would require either a COPN or registration with the COPN program would be particularly affected by this proposed regulatory change.

#### Other Entities Particularly Affected

Any person wishing to begin a project that would require either a COPN or registration with the COPN program are particularly affected by this proposed regulatory change.

### Economic Impact

Consistent with § 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 the proposed change versus the status quo.

#### Impact on State Agencies

For your agency: projected costs, savings, fees or	There are no projected costs, savings, or
revenues resulting from the regulatory change,	revenue loss resulting from the regulatory
including:	change.
a) fund source / fund detail;	change.
· · · · · · · · · · · · · · · · · · ·	Fac colculations are based on the overage
b) delineation of one-time versus on-going	Fee calculations are based on the average
expenditures; and	annual number of projects and project costs for
c) whether any costs or revenue loss can be	SFYs2015-2020 due to the variability in the
absorbed within existing resources	number of project applications and capital
	expenditure costs observed by the COPN
	program after the start of the COVID-19
	pandemic in 2020. The data for SFYs2021-2023
	do not reflect anticipated typical COPN
	expenditure and revenue, and therefore were not
	utilized in these fee calculations.
	The SFY2020 budget to administer the COPN
	program was \$981,368. COPN application fee
	revenue in SFY2020 was \$1,022,030, a 4.1%
	margin (\$40,662) over budget. The SFY2024
	budget includes an additional two FTEs for the
	COPN program to provide support to the
	production of the State Health Services Plan and
	production of the State Health Services Fian and

	to provide community outreach and education on the COPN program; therefore, there is not sufficient revenue from the current fee structure to support the COPN program. The annual number of COPN applications cannot be accurately predicted and the number of applications received for SFY15-SFY20 has varied from a low of 38 applications to a high of 61 applications.
	In SFY1995 (the year before the last increase in COPN application fees), the average proposed capital expenditure for a proposed COPN project was \$3,132,053 (range \$0 - \$54,524,000) and the average COPN application fee was \$6,215 (range \$0 - \$10,000). In SFY1995, only 37% of COPN application fees were at the maximum allowed. In SFY2020, the average proposed capital expenditure for a proposed COPN project was \$9,100,992 (range \$0 - \$155,764,458) and the average COPN application fee was \$15,254 (range \$1,000 - \$20,000). In SFY2020, 63% of projects seeking COPN authorization had estimated capital costs greater than \$2,000,000.
	With the inclusion of two new FTEs, the COPN program budget's "annual revenue target" is now \$1,704,141. Item 300 of the State Budget provides that any COPN application fees in excess of the amount required to operate the COPN program (less than one month's operating expenses) shall be provided to RHPAs as supplemental funding, which in a year with an average number of expected applications would result in \$52,432 (\$74,622 less than one month's operating expenses) being provided to the RHPAs.
	The projected fees resulting from the regulatory change are a fee of \$70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of \$1,600 and maximum of \$44,000) for all other projects.
	The projected total revenue resulting from the regulatory change is at least \$1,704,141 annually, which is an increase of \$682,471 compared to SFY2020's fee revenue.
<i>For other state agencies</i> : projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for other state agencies. The projected costs for other state agnecies are identical to those being assessed on other entities, which is a fee of \$70 for registration and a fee of 1.5% of the estimated

	capital expenditure for the project (with a minimum of \$1,600 and maximum of \$44,000) for all other projects.
For all agencies: Benefits the regulatory change	VDH will have sufficient fee revenue to support
is designed to produce.	its COPN program activities and staff.

#### Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for localities. The projected costs for localities are identical to those being assessed on other entities, which is a fee of \$70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of \$1,600 and maximum of \$44,000) for all other projects.
Benefits the regulatory change is designed to produce.	VDH will have sufficient fee revenue to support its COPN program activities and staff.

#### Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	The individuals, business, or other entities likely to be affected by the regulatory change are any that seek to apply for a COPN for a project or for registration of qualified projects. This potentially includes hospitals, nursing homes, ICF/IIDs, and some physician offices.
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:	There are 103 general hospitals, 73 outpatient surgical hospitals, 8 psychiatric hospitals, 289 nursing homes, 61 ICF/IIDs, and 22,874 doctors of medicine.
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.	There is not data available about how many doctors of medicine operate a physician's office and how many of that number would be engaging in services or utilizing equipment that would require either registration or a COPN; however, it is likely that all doctors of medicine would qualify as a small business if they did operate a physician's office, unless the physician's office is owned by a health system or other larger entity that is not a small business. Over SFYs2015- 2020, COPN requests from physician groups make up an average of 18.8% of all requests (an average of 8.8 requests per year).
All projected costs for affected individuals, businesses, or other entities resulting from the	There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for affected

regulatory change. Be specific and include all costs including, but not limited to: 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.	individuals, businesses, or other entities. The projected costs are a fee of \$70 for registration and a fee of 1.5% of the estimated capital expenditure for the project (with a minimum of \$1,600 and maximum of \$44,000) for all other projects.
Benefits the regulatory change is designed to	VDH will have sufficient fee revenue to support
produce.	its COPN program activities and staff.

# 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.

There are no viable alternatives to the regulatory change as the Board has no other method other than the promulgation of regulations to create a fee schedule.

# **Regulatory Flexibility Analysis**

Consistent with § 2.2-4007.1 B 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.

There are no alternative regulatory methods. The Board is required by the General Assembly to regulate the COPN program. The Board has no other method other than the promulgation of regulations to create a fee schedule.

# **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.

Consistent with § 2.2-4011 of the Code of Virginia, 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

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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.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in 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: <u>https://townhall.virginia.gov</u>. Comments may also be submitted by mail, email or fax to Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233; email:regulatorycomment@vdh.virginia.gov; fax: (804) 527-4502. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

### **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.

#### Table 1: Changes to Existing VAC Chapter(s)

Current chapter- section number	New chapter- section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
220-10	N/A	This section contains the definitions for 12VAC5-220.	<ul> <li>Change: The Board is proposing to remove the definition of "application fee".</li> <li>Intent: The intent of this change is to remove the previous application fee requirements from the definitions section</li> <li>Rationale: The rationale of this change is that there is no need to keep this outdated definition because a fee schedule is being created.</li> <li>Likely Impact: The likely impact of this change is that the regulation will not contain conflicting information.</li> </ul>
220-105	N/A	This section contains the requirements for the registration of the	<b>Change:</b> The Board is proposing to add language to require the payment of a \$70 fee for registrations.

		replacement of existing	
		medical equipment.	<b>Intent:</b> The intent of this change is to require a fee for the registration of medical equipment.
			<b>Rationale:</b> The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to collect an fee for registration of equipment and collection of a fee will partially offset administrative costs to the agency for processing registration applications.
			<b>Likely Impact</b> : The likely impact of this change is that regulants will now pay a fee to register medical equipment.
220-110	N/A	This section contains the requirements for the registration of certain capital expenditures.	<b>Change:</b> The Board is proposing to add language to require the payment of a \$70 fee for registrations.
			<b>Intent:</b> The intent of this change is to require a fee for the registration of certain capital expenditures.
			<b>Rationale:</b> The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to collect a fee for the registration of certain capital expenditures and collection of a fee will partially offset administrative costs to the agency for processing registration applications.
			<b>Likely Impact:</b> The likely impact of this change is that regulants will now pay a fee to register medical equipment.
N/A	220-125		<ul> <li>Change: The Board is proposing to create a new section for the fee schedule. This new section:</li> <li>Increases the fee percentage from 1% to 1.5% of the total capital expenditure;</li> <li>Increases the minimum and maximum fee caps to \$1,600 and \$44,000;</li> <li>Requires a \$70 registration fee for certain capital expenditures and medical equipment and services; and</li> <li>Prescribes a \$50 dishonored payment fee as authorized by Va. Code § 2.2-4805.</li> </ul>
			Intent: The intent of this change is to update the fees for the COPN program.

		<ul> <li>Rationale: The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and these amounts are calculated to achieve that goal.</li> <li>Likely Impact: The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.</li> </ul>
220-180	This section contains the application requirements for a certificate of public need.	Change: The Board is proposing to remove the previous fee language and add a cross-reference to the new fee schedule in 12VAC5-220-125. Intent: The intent of this change is to update the COPN fees.
		<b>Rationale:</b> The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly authorizes the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and that the fees should be located in a single regulatory section and cross-referenced.
		<b>Likely Impact:</b> The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.
220-355	This section contains the application requirements for an RFA project.	<b>Change:</b> The Board is proposing to remove the previous fee language and add a cross-reference to the new fee schedule in 12VAC5-220-125. <b>Intent:</b> The intent of this change is to
		<b>Rationale:</b> The rationale for this change is that Chapter 1271 of the 2020 Act of Assembly permits the Board to change the fee amounts in order to ensure sufficient operating costs for the COPN division and that the fees should be located in a single regulatory section and cross-referenced.
		<b>Likely Impact:</b> The likely impact of this change is that VDH will have sufficient fee revenue to support its COPN program activities and staff.