

To Register for the Board of Health Meeting on March 18, 2021

(Either to attend and view the meeting or to speak during the Public Comment Period)

The purpose of these instructions is to help any member of the public who wishes to observe or participate in the Board of Health meeting on March 18 to understand how to do so.

1) Open the link the Online meeting registration:

<https://covaconf.webex.com/covaconf/onstage/g.php?MTID=e18fa4134c27dffce8b004bf156b885e9>.

The screenshot shows the Cisco Webex registration page for the Board of Health Meeting. The page includes the following elements:

- Event Information:** Board of Health Meeting - 9am. Registration is required to join this event. If you have not registered, please do so now.
- Event status:** Not started ([Register](#))
- Date and time:** Thursday, June 4, 2020 8:00 am Eastern Daylight Time (New York, GMT-04:00) ([Change time zone](#))
- Duration:** 7 hours
- Description:** (Empty)

By joining this event, you are accepting the Cisco Webex [Terms of Service](#) and [Privacy Statement](#).

The registration form includes the following fields:

- First name:
- Last name:
- Email address:
- Event password:

The 'Join Event Now' button is disabled, and a message states: "You cannot join the event now because it has not started."

A modal window is open, titled "Try the new Webex web app!". It lists the following benefits:

- ✓ Nothing to install
- ✓ Simple and intuitive
- ✓ Ideal for participants who do not need to present

A [Learn more](#) link is provided at the bottom of the modal.

2) Click on the link that says, "Register" It is in blue and on the line that starts with "Event Status".

Event Information: Board of Health Meeting - 9am

Registration is required to join this event. If you have not registered, please do so now.

Event status: Not started ([Register](#)) 

Date and time: Thursday, June 4, 2020 8:00 am
Eastern Daylight Time (New York, GMT-04:00)
[Change time zone](#)

Duration: 7 hours

Description:

3) This will prompt you to register for the event. Please enter your name and email address on the registration form. (Note: this information will not be retained after the meeting and will only be used for purposes of making sure people who want to connect to the meeting or speak at the meeting can do so.)



Register for Board of Health Meeting - 9am

Please complete this form to register for the event. An asterisk (*) indicates required information.

English

Please answer the following questions.

* First name:	<input type="text"/>	* Last name:	<input type="text"/>
* Email address:	<input type="text"/>	* Phone number:	<input type="text"/>
* Confirm email address:	<input type="text"/>		

Are you a member of the media?:
 Yes
 No

If yes, what media outlet are you with?:

If you would like to sign up to speak during the public comment period please place a check next to the topic you would like to speak about::

- Regulations for Licensure of Nursing Homes 12VAC5-371
- Regulations Governing Newborn Screening Services 12VAC5-71
- Regulations for the Licensure of Hospitals 12VAC5-410
- State EMS Plan
- Other

If you chose Other for the public comment period, please list the topic::

Submit

- 4) If you want to speak during the public comment, choose one of the items on the list in the bottom center of the screen and check the box for the topic you want to speak on. If you do not want to speak during the meeting, but just watch, do not check any of those boxes. When you are finished entering registration information and choosing a topic to speak on (if appropriate) click the “Submit” button in the bottom right.



Register for Board of Health Meeting - 9am

Please complete this form to register for the event. An asterisk (*) indicates required information. [English](#)

Please answer the following questions.

* First name:	<input type="text" value="Bob"/>	* Last name:	<input type="text" value="Smith"/>
* Email address:	<input type="text" value="bob.smith@google.com"/>	* Phone number:	<input type="text" value="1"/> <input type="text" value="804-867-5309"/>
* Confirm email address:	<input type="text" value="bob.smith@google.com"/>		

Are you a member of the media?:
 Yes
 No

If yes, what media outlet are you with?:

If you would like to sign up to speak during the public comment period please place a check next to the topic you would like to speak about::

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- Regulations for the Licensure of Hospitals 12VAC5-410
- State EMS Plan
- Other

If you chose Other for the public comment period, please list the topic::



- 5) Once you have clicked “Submit” that will lead you to the final screen and then you are finished.



Registration Confirmed

Thank you for registering.

You are now registered for the event: **Board of Health Meeting - 9am**

You will receive a confirmation email message that contains detailed information about joining the event.

The event will start at 8:00 am New York Time on June 4, 2020.
Please join the event on time.

Invite a Friend

To invite a friend to this event, enter your friend's email address.

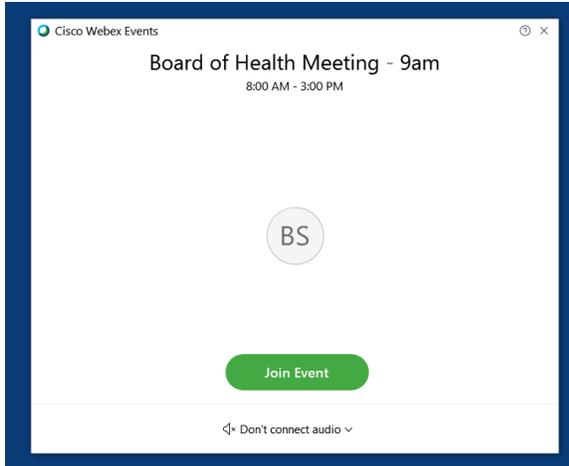
Set Up Webex Events

To participate in fully interactive events, please click [here](#) for setting up Webex Events on this computer.

The playback of UCF (Universal Communications Format) rich media files requires appropriate players. To view this type of rich media files in the event, please check whether you have the players installed on your computer by going to [Verify Rich Media Players](#).

To view system requirements, go to www.webex.com.

JOINING THE MEETING



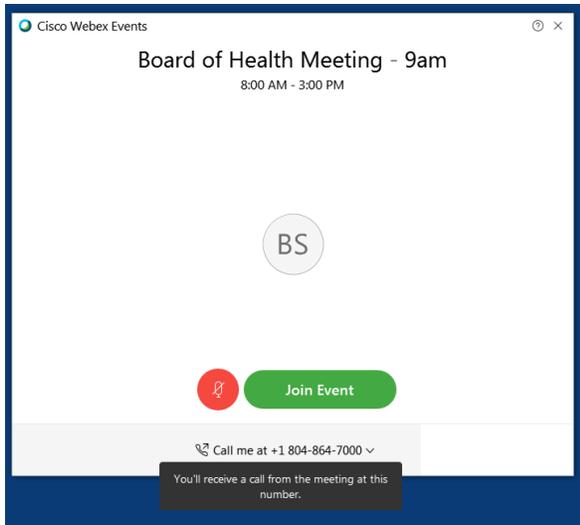
On the day of the meeting, you will click in the email to join the meeting.

You will need to enter your name as it appeared on the registration in order to join.



You should select the "CALL ME AT" option to connect for audio. DO NOT select the call in nor use computer audio options.

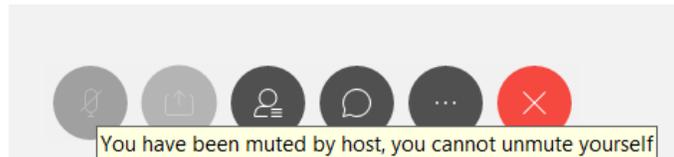
Enter your 10 digit phone number and click the blue check mark.



Click Join Event.

You will receive a phone call from the meeting platform.

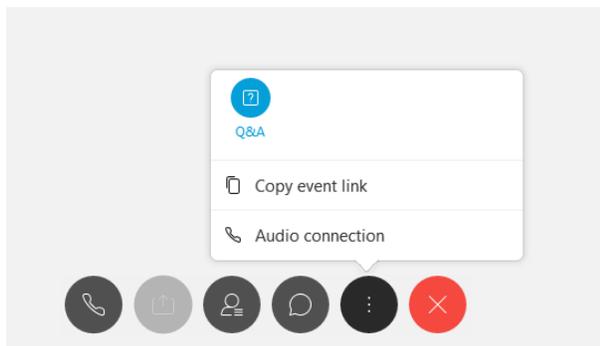
You will be prompted to press 1 when you answer the phone to connect.



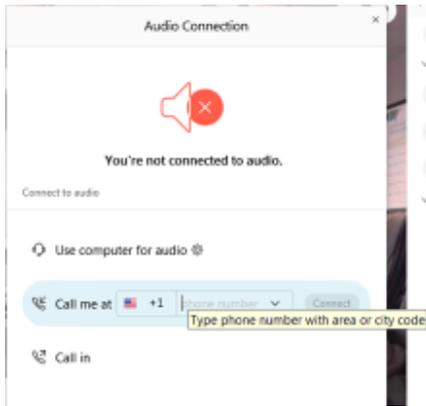
Note that you will be automatically muted when you join the meeting. You cannot unmute yourself to be heard during the meeting until the host unmutes you. This will occur during the public comment period for those who have signed up to do so.

Audio settings:

In order to facilitate public comment, you will need to use your phone to dial in. It is very important that you follow these instructions to merge your phone and computer identification. This will allow you to be unmuted to speak during public comment if you have signed up.



If you have joined the meeting without having WebEx call you, you will need to change the audio settings. Click on the "MORE" control button and select audio connection. **DO NOT** use the call-in option nor the computer audio option.



You will change the type of connection and select “CALL ME AT”. Enter your 10 digit phone number and click CONNECT. Press 1 when prompted on the incoming phone call.

**State of Board of Health
Agenda
March 18, 2021 – 9:00 a.m.
VIA WEBEx**

Call to Order and Welcome	Faye Prichard, Chair
Introductions	Ms. Prichard
Review of Agenda	Alexandra Jansson
Approval of December 3, 2020 Minutes	Ms. Prichard
Commissioner’s Report <i>COVID-19 Update</i>	M. Norman Oliver, MD, MA State Health Commissioner
Break	
Regulatory Action Update	Joe Hilbert Deputy Commissioner for Governmental and Regulatory Affairs
Public Comment Period	
Break	
<u>Regulatory Action Items</u> Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations 12VAC5-220 (Fast Track Amendments)	Rebekah Allen, JD Senior Policy Analyst Office of Licensure and Certification
Legislative Update – 2021 General Assembly	Mr. Hilbert
Budget Update	Stephanie Gilliam Deputy Director for Budget Office of Financial Management
Appointment of Nominating Committee	Ms. Prichard
Other Business	
Adjourn	

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**State of Board of Health
December 3, 2020 – 9:00 a.m.
Virtual Meeting – WebEx**

Due to COVID-19, this meeting was conducted in an all-virtual environment.

Members Present: Faye Prichard, Chair; Gary Critzer, Tommy East; James Edmondson; Elizabeth Harrison; Linda Hines, RN; Anna Jeng, ScD; Patricia Kinser, PhD; Wendy Klein, MD; Benita Miller, DDS; Holly Puritz, MD; Jim Shuler, DVM; Stacey Swartz, PharmD; Katherine Waddell; and Mary Margaret Whipple.

VDH Staff Present: Dr. Norm Oliver, State Health Commissioner; Dr. Laurie Forlano, Deputy Commissioner for Population Health; Joe Hilbert, Deputy Commissioner for Governmental and Regulatory Affairs; Mylam Ly, Policy Analyst; Dr. Parham Jaber, Chief Deputy Commissioner for Public Health and Preparedness; Alex Jansson, Policy Analyst; Mike McMahon, Acting Deputy Commissioner for Administration; Maria Reppas, Director of the Office of Communications; John Ringer, Director of Public Health Planning and Evaluation; Stephanie Gilliam, Deputy Director for Budget; Tammie Smith, Public Relations Coordinator; Richard Watson, Video Conference Engineer; Brad Bradley, Public Health Preparedness Systems Manager; Dwayne Roadcap, Director, Office of Drinking Water; Heather Board, Acting Director, Office of Family Health Services; Consuelo Staton, MEd., State Resource Mothers Program Coordinator, Office of Family Health Services.

Other Staff: Robin Kurz, Senior Assistant Attorney General; Grant Kronenberg, Assistant Attorney General.

Call to Order

Ms. Prichard called the meeting to order at 9:15am.

Introductions

Ms. Prichard welcomed those in attendance to the meeting. Ms. Prichard then started the introductions of the Board members and VDH staff present.

Review of Agenda

Mr. Hilbert reviewed the agenda and the items contained in the Board's virtual binder.

Proclamation for Bruce Edwards

Ms. Prichard read a proclamation in honor and remembrance of former Board of Health Chair, Bruce Edwards. It was adopted by consensus.

Approval of September 3, 2020 Minutes

Dr. Puritz made the motion to approve the minutes from the September 3, 2020 meeting with Dr. Klein seconding the motion. The minutes were approved unanimously by roll call vote.

Commissioner's Report

Dr. Oliver provided the Commissioner's Report to the Board. He discussed the novel coronavirus (COVID-19) situation and response:

- Disease Burden and Transmission
- Testing
- Containment
- Long Term Care Facilities
- Community Mitigation
- Communications
- Vaccination
- Funding Allocation

There was discussion concerning when a vaccine would be available and plans for distribution and prioritization, the importance of consistent and clear messaging, and best practices for the general public as numbers of cases rise and preventative measures continue.

Wastewater Surveillance for COVID-19

Dr. Jeng presented an overview of the wastewater surveillance project in the Hampton Roads area with HRSD staff Kyle Curtis and VDH staff Marcia Degen from the Office of Environmental Health Services. This project has involved monitoring wastewater for COVID-19 markers to track and evaluate the spread of COVID-19.

Regulatory Action Update

Mr. Hilbert reviewed the summary of all pending VDH regulatory actions. Since the September 2020 meeting the Commissioner has approved the two following regulatory actions on behalf of the Board while the Board was not in session:

- Certification of Community Health Workers (12VAC5-402) – Notice of Intended Regulatory Action – Approved NOIRA
- Regulations Governing Vital Records – (12VAC5-550) Final Action Withdrawn

Mr. Hilbert advised the Board that there are 13 periodic reviews in progress:

- Virginia Emergency Medical Services Regulations (12VAC5-66)
- Regulations for the Repacking of Crabmeat (12VAC5-165)
- Regulations Governing Eligibility Standards and Charges for Medical Services to Individuals (12VAC5-200)
- Methodology to Measure Efficiency and Productivity of Health Care Institutions (12VAC5-216)
- Regulations of the Patient Level Data System (12VAC5-217)
- Rules and Regulations Governing Outpatient Data Reporting (12VAC5-218)
- Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220)
- Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information (12VAC5-407)

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- Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees (12VAC5-408)
- Regulations for the Licensure of Hospitals in Virginia (12VAC5-410)
- Regulations Governing the Virginia Physician Loan Repayment Program (12VAC5-508)
- Guidelines for Virginia General Assembly Nursing Scholarships (12VAC5-510)
- Regulations for Identification of Medically Underserved Areas in Virginia (12VAC5-540)

Public Comment Period

Following a short break, there was one public speaker who had signed up, but was not present at the meeting. There were no public comments.

Regulations of Waterworks (12VAC5-590) – Final Amendments

Mr. Roadcap presented the final amendments. The purpose of this action is to amend the *Waterworks Regulations* to update and clarify the requirements for waterworks to follow in construction, operation, and treating, monitoring, and testing drinking water that are necessary to protect public health and ensure they provide reliable, safe drinking water to Virginians.

Since promulgation by the Board of Health in 1993, sections of the *Waterworks Regulations*, primarily the definitions (12VAC5-590-10) and Part II, have been amended as needed to incorporate federal requirements in the *Safe Drinking Water Act* (42 USC § 300f *et seq.*) and National Primary Drinking Water Regulations (40 CFR Parts 141, 142, and 143). VDH completed the most recent amendment in November 2016 to incorporate the requirements in the Revised Total Coliform Rule (RTCR), 40 CFR §§ 141.851 through 141.861, in the *Waterworks Regulations*. VDH made these amendments through “exempt” regulatory actions that were necessary for the state to retain primary enforcement responsibility for waterworks in Virginia. See § 2.2-4006 A 4 of the *Code of Virginia*. From 1993 to the present, the balance of the *Waterworks Regulations* have remained unchanged.

The VDH Office of Drinking Water, the Waterworks Advisory Council, and a Regulatory Advisory Panel consisting of waterworks stakeholders, collectively recommend that Parts I and III of the current *Waterworks Regulations* be updated in the areas of waterworks’ permitting, design, and construction, and Part II be amended to clarify operating requirements and improve overall readability. As part of the agency’s effort to clarify and improve the readability of the *Waterworks Regulations*, VDH also addressed consistent use of defined terms and technical terms across the entire document. The regulatory action follows these recommendations and also incorporates the following: current water treatment technologies; current monitoring and control technologies; changes to water consumption patterns resulting from shifts in consumer use and water-saving plumbing fixtures; changes to source water quality and availability due to increased water demands; and new state laws and regulations governing source water supply planning and withdrawal.

Ms. Hines made a motion to approve the final amendments to the Regulations of Waterworks with Dr. Jeng seconding the motion.

There was discussion around how many problems with waterworks have occurred in the past several years.

The motion was approved unanimously by roll call vote.

Regulations for Adult Comprehensive Sickle Cell Clinic Network (12VAC5-191) – Fast Track Amendments

Ms. Board presented the fast track amendments. The purpose of this regulation is to be in compliance with the Code of Virginia and to implement an adult comprehensive sickle cell clinic network. Sickle cell disease (SCD) is a group of inherited, lifelong blood disorders that affects the red blood cells. In the United States, SCD disproportionately affects African Americans and those with a Hispanic background. Throughout the world, the disease affects those from the Middle East, Italy and Greece. Sickle cell affects every organ in the body. Complications include severe pain, stroke, acute chest syndrome, organ damage, and in some cases premature death. Increased sickle cell-related mortality has been shown in 18-30 year olds, with the highest rate of acute care encounters and re-hospitalizations in this age group compared to the older group of patients who would be expected to have increased illness and complications due to advancing age. According to VDH data, the rate of emergency department (ED) visits for sickle cell disease in Virginia was highest among the 18-30 age group at 53.8 ED visits per 10,000 ED visits and 53.1 ED visits per 10,000 ED visits in 2018 and 2019 respectively.

The short-term goal of this regulatory change is the establishment of an adult comprehensive sickle cell clinic network. The long-term goal is a reduction in the rate of ED visits for adults with sickle cell in the 18-30 age group and an increase in the number of adults who continue into specialty care and establish a medical home with a specialty care provider.

Dr. Puritz made a motion to approve the fast track amendments to the Regulations for Adult Comprehensive Sickle Cell Clinic Network with Dr. Jeng seconding the motion.

The motion was approved unanimously by roll call vote.

Regulations for Certification of Doulas (12VAC5-403) – Proposed Amendments

Ms. Board presented the proposed amendments. The purpose of this regulation is to be in compliance with the Code of Virginia and to provide standardized doula certification requirements in the Commonwealth of Virginia. Certification requirements for state-certified doulas shall reflect national best practices pertaining to community-based doula training and certification.

Individuals practicing as state-certified doulas will have attained the required training, through entities approved by the Board of Health, to provide coaching, outreach, and navigation services to Virginia's most hard-to-reach pregnant women to ensure that disadvantaged populations are equipped with the knowledge to receive the most appropriate medical and social supports to meet their needs. A standardized doula certification model is also beneficial to supporting and maintaining the doula workforce. This regulatory action will ensure that the content is clearly written.

Mr. Edmonson made a motion to approve the proposed amendments to the Regulations for Certification of Doulas with Mr. Critzer seconding the motion.

There was discussion about the intent of the regulations and input from stakeholders, what a curriculum might look like, what organizations would be able to certify, the certification in other states, and the impact on practicing doulas if they are not certified (e.g. would they be able to enter the hospitals with patients).

After discussion the motion to approve was withdrawn and a motion to send back the regulations for further development was made by Mr. Edmonson. The motion was seconded by Dr. Shuler.

The motion was approved 13 to 2 by roll call vote.

Board of Health Annual Report/Plan for Well-Being Update

Dr. Forlano presented an update on the Plan for Well-Being (The Plan). The Plan outlines a path for improving the health and well-being of Virginians through four aims, 13 goals, and 29 measures.

Of the 29 measures, 15 show improvement, when compared to baseline measures, although at different degrees. Of these, three measures (Disability-Free Life Expectancy, Percent of High School Graduates Enrolled in an Institution of Higher Learning, and Teen Pregnancy Rates) have exceeded the goal that was originally set forth in The Plan. The remaining 14 measures have evidenced little to no change, or have decreased further away from the intended goal.

Over the next year, a Plan for Well-Being 2.0 will be developed.

Dr. Klein made a motion to approve and accept the annual report with Dr. Kinser seconding the motion.

The motion passed unanimously by roll call vote.

Legislative Update

Mr. Hilbert presented the legislative update from the 2020 General Assembly Special Session. He highlighted bills that would have an impact on VDH's work. Subject areas included the following:

- Bills That Passed
 - Outbreak/Communicable
 - Disease Data Reporting
 - Patient
 - Visitation Policies
 - Immunity from Civil Liability for Certain Health Care Providers
- Bills That Failed
 - Testing Prioritization
 - Immunization Restrictions
 - Board

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- and Commissioner's Emergency Rulemaking Authority
- Other
- Appropriation Act Language

Mr. Hilbert also provided the Board with an update concerning the status of the policy recommendations that it submitted to the Governor in September, 2020.

Budget Update

Ms. Gilliam presented the budget update from the 2020 General Assembly Special Session. She described the COVID-19 response CARES funding and the cooperative budget that funds the local health departments. She discussed the budget amendments that came out of the Special Session and the instructions provided for consideration of reinstating any funding if available.

Ms. Gilliam also provided the Board with a description of budget amendment requests submitted by VDH to the Administration for possible inclusion in the Governor's Budget Bill that will be considered by the 2021 General Assembly.

Other Business

There was no other business discussed.

Adjourn

Meeting adjourned at 2:48pm.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

M. NORMAN OLIVER, MD, MA
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: February 17, 2021

TO: State Board of Health

FROM: Rebekah E. Allen, JD
Senior Policy Analyst, Office of Licensure and Certification

SUBJECT: Fast Track Action – Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations – Promulgation of Fee Schedule

Enclosed for your review are proposed amendments to Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220).

Chapter 1271 (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 (COPN) program. Chapter 1271 removed the 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, the action will remove the definition of “application fee”, replaces the repealed definition with a new section number 95 that sets out the fee schedule for COPN applications and registration applications, and updates the regulatory text for internal consistency with the new fee schedule.

The State Board of Health is requested to approve the Fast Track Action. Should the State Board of Health approve the Fast Track Action, the amendments will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed regulatory text will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. A 30-day public comment period will begin. Fifteen days after the close of the public comment period, the regulation will become effective.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-220-10 <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	February 19, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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 (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.

Enter statement here

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 Executive Order 14 (as amended, July 16, 2018), “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.”

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

Chapter 1271 (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 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 Acts of Assembly), 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 Acts of Assembly) 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 is anticipated that this action will be noncontroversial and therefore appropriate for the fast-track process because:

- the fee being charged for registration applications is nominal; and
- 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 one percent of the proposed project expenditure or the fee cap.

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 §§ 32.1-12 and 32.1-102.2(A)(4) of the Code of Virginia. 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’s 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 flooded with 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 is 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.

12VAC5-220-10. Definitions.
Repeal of the definition for “application fee.”

12VAC5-220-95. Fee schedule.
A new section; creates a fee schedule for COPN applications and registration applications.

12VAC5-220-105. Requirements for registration of the replacement of existing medical equipment.
Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-95.

12VAC5-220-110. Requirements for registration of certain capital expenditures.

Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-95.

12VAC5-220-180. Application forms.

Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-95.

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

Specifies that the registration has to be accompanied by the fee prescribed in 12VAC5-220-95.

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 disadvantages to the public is the assessment of higher fees for COPN projects if the project cost is in excess of \$2 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

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "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

No other state agencies are particularly affected by this proposed regulatory change.

Localities Particularly Affected

No localities are particularly affected by this proposed regulatory change.

Other Entities Particularly Affected

No entities are particularly affected by this proposed regulatory change.

Economic Impact

Pursuant to § 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 change versus the status quo.

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources 	<p>There are no projected costs, savings, or revenue loss resulting from the regulatory change.</p> <p>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 SFY2021 budget includes an additional two FTEs for the COPN program to provide support to the production of the State Health Services Plan 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 in just the last five years has varied from a low of 38 applications to a high of 61 applications.</p> <p>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.</p> <p>With the inclusion of two new FTEs, the COPN program budget's "annual revenue target" is now \$1,189,849. Setting the maximum COPN application fee at \$60,000 will be just \$4,751</p>
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	<p>short of target in a year with the lowest expected number (38) of COPN applications and would exceed the target in a year with an average number (46) of expected applications by \$244,743. Item 300 of the State Budget provides that any COPN application fees in excess of the amount required to operate the COPN program (less 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 \$145,589 (\$244,743 less one month's operating expenses) being provided to the RHPAs.</p> <p>The projected fees resulting from the regulatory change are a fee of \$70 for registration and a fee of 1% of the estimated capital expenditure for the project (with a minimum of \$1,000 and maximum of \$60,000) for all other projects.</p> <p>The projected total revenue resulting from the regulatory change is at least \$1,189,489 annually, which is an increase of \$167,819 compared to SFY2020's fee revenue.</p>
<p><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.</p>	<p>None.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>VDH will have sufficient fee revenue to support its COPN program activities and staff.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>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 assess on other entities, which is a fee of \$70 for registration and a fee of 1% of the estimated capital expenditure for the project (with a minimum of \$1,000 and maximum of \$60,000) for all other projects.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>VDH will have sufficient fee revenue to support its COPN program activities and staff.</p>

Impact on Other Entities

<p>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.</p>	<p>The individuals, business, or other entities likely to be affected by the regulatory change are any that seek to apply for a COPN or for registration of qualified projects. This potentially includes hospitals, nursing homes, ICF/IIDs, and some physician's offices.</p>
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<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>There are 104 general hospitals, 65 outpatient surgical hospitals, 8 psychiatric hospitals, 283 nursing homes, 61 ICF/IIDs, and 37,567 doctors of medicine.</p> <p>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. Over the past five years, COPN requests from physician groups make up an average of 18.8% of all requests (an average of 8.8 requests per year over the last five years).</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:</p> <ul style="list-style-type: none"> 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. 	<p>There are no projected savings, fees or revenues resulting from the regulatory change resulting from the regulatory change for affected individuals, businesses, or other entities. The projected costs are a fee of \$70 for registration and a fee of 1% of the estimated capital expenditure for the project (with a minimum of \$1,000 and maximum of \$60,000) for all other projects.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>VDH will have sufficient fee revenue to support its COPN program activities and staff.</p>

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

Pursuant to § 2.2-4007.1B 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.

As required by § 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 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: <https://townhall.virginia.gov>. 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.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-	New chapter-	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
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section number	section number, if applicable		
12VAC5-220-10	N/A	<p>12VAC5-220-10. Definitions.</p> <p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Acquisition" means an expenditure of \$600,000 or more that changes the ownership of a medical care facility. It shall also include the donation or lease of a medical care facility. An acquisition of a medical care facility shall not include a capital expenditure involving the purchase of stock. See 12VAC5-220-120.</p> <p>"Amendment" means any modification to an application that is made following the public hearing and prior to the issuance of a certificate and includes those factors that constitute a significant change as defined in this chapter. An amendment shall not include a modification to an application that serves to reduce the scope of a project.</p> <p>"Applicant" means the owner of an existing medical care facility or the sponsor of a proposed medical care facility project submitting an application for a certificate of public need.</p> <p>"Application" means a prescribed format for the presentation of data and information deemed necessary by the board to determine a public need for a medical care facility project.</p> <p>"Application fees" means fees required for a project application and application for a significant change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost increase for the project or \$20,000.</p> <p>"Board" means the State Board of Health.</p> <p>"Capital expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is not properly chargeable as an expense of</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-10. Definitions.</p> <p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Acquisition" means an expenditure of \$600,000 or more that changes the ownership of a medical care facility. It shall also include the donation or lease of a medical care facility. An acquisition of a medical care facility shall not include a capital expenditure involving the purchase of stock. See 12VAC5-220-120.</p> <p>"Amendment" means any modification to an application that is made following the public hearing and prior to the issuance of a certificate and includes those factors that constitute a significant change as defined in this chapter. An amendment shall not include a modification to an application that serves to reduce the scope of a project.</p> <p>"Applicant" means the owner of an existing medical care facility or the sponsor of a proposed medical care facility project submitting an application for a certificate of public need.</p> <p>"Application" means a prescribed format for the presentation of data and information deemed necessary by the board to determine a public need for a medical care facility project.</p> <p>"Application fees" means fees required for a project application and application for a significant change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost increase for the project or \$20,000.</p> <p>"Board" means the State Board of Health.</p> <p>"Capital expenditure" means any expenditure by or in behalf of a medical care facility that, under</p>

	<p>operation and maintenance. Such expenditure shall also include a series of related expenditures during a 12-month period or a financial obligation or a series of related financial obligations made during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made in behalf of a medical care facility by any person. See definition of "person."</p> <p>"Certificate of public need" means a document that legally authorizes a medical care facility project as defined herein and which is issued by the commissioner to the owner of such project.</p> <p>"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Commissioner" means the State Health Commissioner who has authority to make a determination respecting the issuance or revocation of a certificate.</p> <p>"Competing applications" means applications for the same or similar services and facilities that are proposed for the same planning district or medical service area and which are in the same review cycle. See 12VAC5-220-220.</p> <p>"Completion" means conclusion of construction activities necessary for substantial performance of the contract.</p> <p>"Construction" means the building of a new medical facility or the expansion, remodeling, or alteration of an existing medical care facility.</p> <p>"Construction, initiation of" means that a project shall be considered under construction for the purpose of certificate extension determinations upon the presentation of evidence by the owner of: (i) a signed construction contract; (ii) the completion of short term financing and a commitment for long term (permanent) financing when applicable; (iii) the completion of predevelopment site work; and</p>	<p>generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance. Such expenditure shall also include a series of related expenditures during a 12-month period or a financial obligation or a series of related financial obligations made during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not be made by a medical care facility so long as they are made in behalf of a medical care facility by any person. See definition of "person."</p> <p>"Certificate of public need" means a document that legally authorizes a medical care facility project as defined herein and which is issued by the commissioner to the owner of such project.</p> <p>"Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or palliative procedure as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Commissioner" means the State Health Commissioner who has authority to make a determination respecting the issuance or revocation of a certificate.</p> <p>"Competing applications" means applications for the same or similar services and facilities that are proposed for the same planning district or medical service area and which are in the same review cycle. See 12VAC5-220-220.</p> <p>"Completion" means conclusion of construction activities necessary for substantial performance of the contract.</p> <p>"Construction" means the building of a new medical facility or the expansion, remodeling, or alteration of an existing medical care facility.</p> <p>"Construction, initiation of" means that a project shall be considered under construction for the purpose of certificate extension determinations upon the presentation of evidence by the owner of: (i) a signed construction contract; (ii) the completion of short</p>
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	<p>(iv) the completion of building foundations.</p> <p>"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Designated medically underserved areas" means (i) areas designated as medically underserved areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage Areas (HPSA).</p> <p>"Ex parte" means any meeting that takes place between (i) any person acting in behalf of the applicant or holder of a certificate of public need or any person opposed to the issuance or in favor of the revocation of a certificate of public need and (ii) any person who has authority in the department to make a decision respecting the issuance or revocation of a certificate of public need for which the department has not provided 10 days written notification to opposing parties of the time and place of such meeting. An ex parte contact shall not include a meeting between the persons identified in (i) and staff of the department.</p> <p>"Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction. See definition of "project."</p> <p>"Health planning region" means a contiguous geographical area of the Commonwealth as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Informal fact-finding conference" means a conference held pursuant to § 2.2-4019 of the Code of Virginia.</p> <p>"Inpatient beds" means accommodations within a medical</p>	<p>term financing and a commitment for long term (permanent) financing when applicable; (iii) the completion of predevelopment site work; and (iv) the completion of building foundations.</p> <p>"Date of issuance" means the date of the commissioner's decision awarding a certificate of public need.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Designated medically underserved areas" means (i) areas designated as medically underserved areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage Areas (HPSA).</p> <p>"Ex parte" means any meeting that takes place between (i) any person acting in behalf of the applicant or holder of a certificate of public need or any person opposed to the issuance or in favor of the revocation of a certificate of public need and (ii) any person who has authority in the department to make a decision respecting the issuance or revocation of a certificate of public need for which the department has not provided 10 days written notification to opposing parties of the time and place of such meeting. An ex parte contact shall not include a meeting between the persons identified in (i) and staff of the department.</p> <p>"Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction. See definition of "project."</p> <p>"Health planning region" means a contiguous geographical area of the Commonwealth as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Informal fact-finding conference" means a conference held pursuant</p>
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	<p>care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health-related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations are known by varying nomenclatures including but not limited to: nursing beds, intensive care beds, minimal or self care beds, isolation beds, hospice beds, observation beds equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, substance abuse, medical rehabilitation and pediatric beds, including pediatric bassinets and incubators. Bassinets and incubators in a maternity department and beds located in labor or birthing rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.</p> <p>"Medical care facility" means any institution, place, building, or agency as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Medical service area" means the geographic territory from which at least 75% of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.</p> <p>"Modernization" means the alteration, repair, remodeling, replacement or renovation of an existing medical care facility or any part thereto, including that which is incident to the initial and subsequent installation of equipment in a medical care facility. See definition of "construction."</p> <p>"Operating expenditure" means any expenditure by or in behalf of a medical care facility that, under</p>	<p>to § 2.2-4019 of the Code of Virginia.</p> <p>"Inpatient beds" means accommodations within a medical care facility with continuous support services (such as food, laundry, housekeeping) and staff to provide health or health-related services to patients who generally remain in the medical care facility in excess of 24 hours. Such accommodations are known by varying nomenclatures including but not limited to: nursing beds, intensive care beds, minimal or self care beds, isolation beds, hospice beds, observation beds equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, substance abuse, medical rehabilitation and pediatric beds, including pediatric bassinets and incubators. Bassinets and incubators in a maternity department and beds located in labor or birthing rooms, recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedures rooms, or on-call staff rooms are excluded from this definition.</p> <p>"Medical care facility" means any institution, place, building, or agency as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Medical service area" means the geographic territory from which at least 75% of patients come or are expected to come to existing or proposed medical care facilities, the delineation of which is based on such factors as population characteristics, natural geographic boundaries, and transportation and trade patterns, and all parts of which are reasonably accessible to existing or proposed medical care facilities.</p> <p>"Modernization" means the alteration, repair, remodeling, replacement or renovation of an existing medical care facility or any part thereto, including that which is incident to the initial and subsequent installation of</p>
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		<p>generally accepted accounting principles, is properly chargeable as an expense of operation and maintenance and is not a capital expenditure.</p> <p>"Operator" means any person having designated responsibility and legal authority from the owner to administer and manage a medical care facility. See definition of "owner."</p> <p>"Other plans" means any plan(s) which is formally adopted by an official state agency or regional health planning agency and which provides for the orderly planning and development of medical care facilities and services and which is not otherwise defined in this chapter.</p> <p>"Owner" means any person who has legal responsibility and authority to construct, renovate or equip or otherwise control a medical care facility as defined herein.</p> <p>"Person" means an individual, corporation, partnership, association or any other legal entity, whether governmental or private. Such person may also include the following:</p> <ol style="list-style-type: none"> 1. The applicant for a certificate of public need; 2. The regional health planning agency for the health planning region in which the proposed project is to be located; 3. Any resident of the geographic area served or to be served by the applicant; 4. Any person who regularly uses health care facilities within the geographic area served or to be served by the applicant; 5. Any facility or health maintenance organization (HMO) established under § 38.2-4300 et seq. of the Code of Virginia that is located in the health planning region in which the project is proposed and that provides services similar to the services of the 	<p>equipment in a medical care facility. See definition of "construction."</p> <p>"Operating expenditure" means any expenditure by or in behalf of a medical care facility that, under generally accepted accounting principles, is properly chargeable as an expense of operation and maintenance and is not a capital expenditure.</p> <p>"Operator" means any person having designated responsibility and legal authority from the owner to administer and manage a medical care facility. See definition of "owner."</p> <p>"Other plans" means any plan(s) which is formally adopted by an official state agency or regional health planning agency and which provides for the orderly planning and development of medical care facilities and services and which is not otherwise defined in this chapter.</p> <p>"Owner" means any person who has legal responsibility and authority to construct, renovate or equip or otherwise control a medical care facility as defined herein.</p> <p>"Person" means an individual, corporation, partnership, association or any other legal entity, whether governmental or private. Such person may also include the following:</p> <ol style="list-style-type: none"> 1. The applicant for a certificate of public need; 2. The regional health planning agency for the health planning region in which the proposed project is to be located; 3. Any resident of the geographic area served or to be served by the applicant; 4. Any person who regularly uses health care facilities within the geographic area served or to be served by the applicant; 5. Any facility or health maintenance organization (HMO) established under § 38.2-4300 et seq. of the Code of Virginia that is located in
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		<p>medical care facility project under review;</p> <p>6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or more patients in the health planning region in which the project is proposed to be located; and</p> <p>7. Any agency that reviews or establishes rates for health care facilities.</p> <p>"Physician's office" means a place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, which is designed and equipped solely for the provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive or palliative to ambulatory patients and which does not participate in cost-based or facility reimbursement from third party health insurance programs or prepaid medical service plans excluding pharmaceuticals and other supplies administered in the office. See definition of "medical care facility."</p> <p>"Planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two planning districts: Planning District 20, consisting of the counties of Isle of Wight and Southampton and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk and Virginia Beach; and Planning District 21, consisting of the counties of James City and York and the cities of Hampton, Newport News, Poquoson and Williamsburg.</p> <p>"Predevelopment site work" means any preliminary activity directed towards preparation of the site prior to the completion of the building foundations. This includes, but is not limited to, soil testing,</p>	<p>the health planning region in which the project is proposed and that provides services similar to the services of the medical care facility project under review;</p> <p>6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or more patients in the health planning region in which the project is proposed to be located; and</p> <p>7. Any agency that reviews or establishes rates for health care facilities.</p> <p>"Physician's office" means a place, owned or operated by a licensed physician or group of physicians practicing in any legal form whatsoever, which is designed and equipped solely for the provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive or palliative to ambulatory patients and which does not participate in cost-based or facility reimbursement from third party health insurance programs or prepaid medical service plans excluding pharmaceuticals and other supplies administered in the office. See definition of "medical care facility."</p> <p>"Planning district" means a contiguous area within the boundaries established by the Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two planning districts: Planning District 20, consisting of the counties of Isle of Wight and Southampton and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk and Virginia Beach; and Planning District 21, consisting of the counties of James City and York and the cities of Hampton, Newport News, Poquoson and Williamsburg.</p> <p>"Predevelopment site work" means any preliminary activity</p>
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	<p>clearing, grading, extension of utilities and power lines to the site.</p> <p>"Primary medical care services" means first-contact, whole-person medical and health services delivered by broadly trained, generalist physicians, nurses and other professionals, intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine and pediatrics.</p> <p>"Progress" means actions that are required in a given period of time to complete a project for which a certificate of public need has been issued. See 12VAC5-220-450, Demonstration of progress.</p> <p>"Project" means any plan or proposal as defined in § 32.1-102.1 of the Code of Virginia that is subject to Certificate of Public Need approval.</p> <p>"Public hearing" means a proceeding conducted by a regional health planning agency at which an applicant for a certificate of public need and members of the public may present oral or written testimony in support or opposition to the application that is the subject of the proceeding and for which a verbatim record is made. See subsection A of 12VAC5-220-230.</p> <p>"Regional health plan" means the regional plan adopted by the regional health planning agency board.</p> <p>"Regional health planning agency" means the regional agency as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economics and Statistics Administration.</p> <p>"Schedule for completion" means the timetable that identifies the major activities required to complete a project as identified by the applicant and set forth on the certificate of public need. The timetable is used by the</p>	<p>directed towards preparation of the site prior to the completion of the building foundations. This includes, but is not limited to, soil testing, clearing, grading, extension of utilities and power lines to the site.</p> <p>"Primary medical care services" means first-contact, whole-person medical and health services delivered by broadly trained, generalist physicians, nurses and other professionals, intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine and pediatrics.</p> <p>"Progress" means actions that are required in a given period of time to complete a project for which a certificate of public need has been issued. See 12VAC5-220-450, Demonstration of progress.</p> <p>"Project" means any plan or proposal as defined in § 32.1-102.1 of the Code of Virginia that is subject to Certificate of Public Need approval.</p> <p>"Public hearing" means a proceeding conducted by a regional health planning agency at which an applicant for a certificate of public need and members of the public may present oral or written testimony in support or opposition to the application that is the subject of the proceeding and for which a verbatim record is made. See subsection A of 12VAC5-220-230.</p> <p>"Regional health plan" means the regional plan adopted by the regional health planning agency board.</p> <p>"Regional health planning agency" means the regional agency as defined in § 32.1-102.1 of the Code of Virginia.</p> <p>"Rural" means territory, population, and housing units that are classified as "rural" by the Bureau of the Census of the United States Department of Commerce, Economics and Statistics Administration.</p> <p>"Schedule for completion" means the timetable that identifies the major activities required to complete</p>
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	<p>commissioner to evaluate the applicant's progress in completing an approved project.</p> <p>"Significant change" means any alteration, modification or adjustment to a reviewable project for which a certificate of public need has been issued or requested following the public hearing which:</p> <ol style="list-style-type: none"> 1. Changes the site; 2. Increases the capital expenditure amount authorized by the commissioner on the certificate of public need issued for the project by 10% or more; 3. Changes the service(s) proposed to be offered; 4. Extends the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater. See 12VAC5-220-440 and 12VAC5-220-450. <p>"Standard review process" means the process utilized in the review of all certificate of public need requests with the exception of:</p> <ol style="list-style-type: none"> 1. Certain bed relocations as specified in 12VAC5-220-280; 2. Certain projects that involve an increase in the number of beds in which nursing facility or extended care services are provided as specified in 12VAC5-220-325. <p>"State Medical Facilities Plan" means the planning document as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, used to make medical care facilities and services needs decisions.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p>	<p>a project as identified by the applicant and set forth on the certificate of public need. The timetable is used by the commissioner to evaluate the applicant's progress in completing an approved project.</p> <p>"Significant change" means any alteration, modification or adjustment to a reviewable project for which a certificate of public need has been issued or requested following the public hearing which:</p> <ol style="list-style-type: none"> 1. Changes the site; 2. Increases the capital expenditure amount authorized by the commissioner on the certificate of public need issued for the project by 10% or more; 3. Changes the service(s) proposed to be offered; 4. Extends the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the commissioner at the date of certificate issuance, whichever is greater. See 12VAC5-220-440 and 12VAC5-220-450. <p>"Standard review process" means the process utilized in the review of all certificate of public need requests with the exception of:</p> <ol style="list-style-type: none"> 1. Certain bed relocations as specified in 12VAC5-220-280; 2. Certain projects that involve an increase in the number of beds in which nursing facility or extended care services are provided as specified in 12VAC5-220-325. <p>"State Medical Facilities Plan" means the planning document as contained in Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, used to make medical care facilities and services needs decisions.</p> <p>Statutory Authority</p>
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			<p>§§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of this change is to remove the definition of application fee and instead create a fee schedule in a separate new regulatory section.</p> <p>RATIONALE: The rationale of this change is that since the application fee is no longer set in statute and is now within the discretion of the Board, it is inappropriate for this requirement to remain in the definition sections as it is a substantive requirement.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee a COPN applicant must pay through the creation of a fee schedule.</p>
<p>N/A</p>	<p>12VAC5-220-95</p>	<p>This is a new section.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p><u>12VAC5-220-95. Fee schedule.</u></p> <p><u>A. Unless otherwise provided, fees established by the board shall not be refundable.</u></p> <p><u>B. The fee for any application that requests a certificate of public need shall be 1.0% of the proposed expenditure for the project, but not less than \$1,000 and no more than \$60,000.</u></p> <p><u>C. The fee for any application that requests registration of certain capital expenditures under 12VAC5-220-110 shall be \$70.</u></p> <p><u>D. The fee for any application that requests registration of the addition of medical equipment and services shall be \$70.</u></p> <p><u>E. The fee for any application that requests registration of replacement of existing medical equipment shall be \$70.</u></p> <p>Statutory Authority <u>§§ 32.1-12 and 32.1-102.2</u> of the Code of Virginia.</p> <p>INTENT: The intent of this change is to create a fee schedule for the</p>

			<p>different types of applications that the COPN program processes.</p> <p>RATIONALE: The rationale of this change is that the fee cap for COPN projects is outdated and that the agency should be collecting fees for the processing of registration applications.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee a COPN applicant or registration applicant must pay through the creation of a fee schedule.</p>
<p>12VAC5-220-105</p>	<p>N/A</p>	<p>12VAC5-220-105. Requirements for registration of the replacement of existing medical equipment.</p> <p>Within 30 days of any person contracting to make, or otherwise legally obligating to make, a capital expenditure for the replacement of medical equipment or otherwise acquiring replacement medical equipment for the provision of services listed in subdivision 7 of the definition of "project" in 12VAC5-220-10, the person shall register in writing such equipment replacement with the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement and shall include documentation that the equipment to be replaced has previously been authorized or exempted as allowed by law.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-105. Requirements for registration of the replacement of existing medical equipment.</p> <p>Within 30 days of any person contracting to make, or otherwise legally obligating to make, a capital expenditure for the replacement of medical equipment or otherwise acquiring replacement medical equipment for the provision of services listed in subdivision 7 of the definition of "project" in 12VAC5-220-10, the person shall register in writing such equipment replacement with the commissioner and the appropriate regional health planning agency. Such registration shall be made on forms provided by the department. The registration shall identify the specific unit of equipment to be replaced and the estimated capital cost of the replacement, and shall include documentation that the equipment to be replaced has previously been authorized or exempted as allowed by law, and shall include the fee <u>prescribed by subsection E of 12VAC5-220-95.</u></p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of this change is to specify that the registration must</p>

			<p>be accompanied by the prescribed fee.</p> <p>RATIONALE: The rationale of this change is that the registration provisions should identify where applicants can locate the fee schedule.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee a registration applicant must pay through the creation of a fee schedule.</p>
<p>12VAC5-220-110</p>	<p>N/A</p>	<p>12VAC5-220-110. Requirements for registration of certain capital expenditures.</p> <p>A. At least 30 days before any person contracts to make or is otherwise legally obligated to make a capital expenditure by or on behalf of a medical care facility as defined in this chapter that has not been previously authorized by the commissioner, such expenditure shall be registered in writing with the commissioner. The threshold amount for capital expenditure project registration shall be determined using the formula contained in subsection B of this section.</p> <p>B. The threshold contained in subsection A of this section shall be adjusted annually using the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for the most recent year as follows: $A \times (1 + B)$ where: A = the capital expenditure threshold amount for the previous year and B = the percent increase for the expense category "Medical Care" listed in the most recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.</p> <p>C. The format for registration shall include information concerning the purpose of such expenditure and projected impact that the expenditure will have upon the</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-110. Requirements for registration of certain capital expenditures.</p> <p>A. At least 30 days before any person contracts to make or is otherwise legally obligated to make a capital expenditure by or on behalf of a medical care facility as defined in this chapter that has not been previously authorized by the commissioner, such expenditure shall be registered in writing with the commissioner. The threshold amount for capital expenditure project registration shall be determined using the formula contained in subsection B of this section.</p> <p>B. The threshold contained in subsection A of this section shall be adjusted annually using the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for the most recent year as follows: $A \times (1 + B)$ where: A = the capital expenditure threshold amount for the previous year and B = the percent increase for the expense category "Medical Care" listed in the most recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.</p> <p>C. The format for registration shall include information concerning</p>

		<p>charges for services. For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."</p> <p>D. Annually, the department shall (i) publish the threshold amount in the General Notices section of the Virginia Register of Regulations and (ii) post the threshold amount on its website.</p> <p>Statutory Authority § 32.1-102.2 of the Code of Virginia.</p>	<p>the purpose of such expenditure, and <u>the</u> projected impact that the expenditure will have upon the charges for services, <u>and shall include the fee prescribed by subsection C of 12VAC5-220-95</u> .</p> <p>For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."</p> <p>D. Annually, the department shall (i) publish the threshold amount in the General Notices section of the Virginia Register of Regulations and (ii) post the threshold amount on its website.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of this change is to specify that the COPN applicants are obligated to pay the prescribed fee.</p> <p>RATIONALE: The rationale of this change is that the COPN provisions should identify where applicants can locate the fee schedule.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee an COPN applicant must pay through the creation of a fee schedule.</p>
<p>12VAC5-220-180</p>	<p>N/A</p>	<p>12VAC5-220-180. Application forms.</p> <p>A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities which are proposed for the same planning district or medical service area. The letter shall identify the</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-180. Application forms.</p> <p>A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency, by the later of (i) 30 days prior to the submission of an application for a project included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities</p>

		<p>owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12VAC5-220-310 C.)</p> <p>B. Application fees. The department shall collect application fees for applications that request a certificate of public need. The fee required for an application shall be 1.0% of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000. No application will be deemed to be complete for review until the required application fee is paid. (See 12VAC5-220-310 C.)</p> <p>C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, or prepare in triplicate two copies to be submitted to the department and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12VAC5-220-200.)</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p>	<p>which are proposed for the same planning district or medical service area. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void one year after the date of receipt of such letter. (See 12VAC5-220-310 C.)</p> <p>B. Application fees. The department shall collect application fees for applications that request a certificate of public need. <u>The applicant shall pay the fee required prescribed by subsection B of 12VAC5-220-95 for an any application that requests a certificate of public need shall be 1.0% of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000.</u> No application will be deemed to be complete for review until the required application fee is paid. (See 12VAC5-220-310 C.)</p> <p>C. Filing application forms. Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. In order to verify the date of the department's and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, or prepare in triplicate two copies to be submitted to the department and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency. (See 12VAC5-220-200.)</p>
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			<p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of this change is to specify that the COPN applicants are obligated to pay the prescribed fee.</p> <p>RATIONALE: The rationale of this change is that the COPN provisions should identify where applicants can locate the fee schedule.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee an COPN applicant must pay through the creation of a fee schedule.</p>
<p>12VAC-220-355</p>	<p>N/A</p>	<p>12VAC5-220-355. RFA project application forms. A. Letter of intent. A RFA project applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA. B. Application fees. The department shall collect application fees for RFA applications that request a certificate of public need. The fee required for an application is 1.0% of the proposed capital expenditure for the project but no less than \$1,000 and no more than \$20,000. No application will be deemed to be complete for review until the required application fee is paid.</p>	<p>CHANGE: The Board is proposing the following change:</p> <p>12VAC5-220-355. RFA project application forms. A. Letter of intent. A RFA project applicant shall file a letter of intent with the commissioner to request appropriate application forms, and submit a copy of that letter to the appropriate regional health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify the owner, the type of project for which an application is requested, and the proposed scope (size) and location of the proposed project. The department shall transmit application forms to the applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the department shall be considered void if an application is not filed for the project by the application deadline specified in the RFA. B. Application fees. The department shall collect application fees for RFA applications that request a certificate of public need. The <u>applicant shall pay the fee required prescribed by subsection B of 12VAC5-220-95 for an application is 1.0% of the proposed capital expenditure for the project but no</u></p>

		<p>C. Filing application forms. Applications must be submitted to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, or prepare in triplicate two copies to be submitted to the department and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p>	<p>less than \$1,000 and no more than \$20,000. No application will be deemed to be complete for review until the required application fee is paid.</p> <p>C. Filing application forms. Applications must be submitted to the department and the appropriate regional health planning agency by the application filing deadline specified in the RFA. In order to verify the department and the appropriate regional health planning agency's receipt of the application, the applicant shall transmit the document electronically, or prepare in triplicate two copies to be submitted to the department and one copy to be submitted to the appropriate regional health planning agency and sent by certified mail or a delivery service, return receipt requested, or by hand, with a signed receipt to be provided. No application shall be deemed to have been submitted until required copies have been received by the department and the appropriate regional health planning agency.</p> <p>Statutory Authority §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.</p> <p>INTENT: The intent of this change is to specify that the RFA applicants are obligated to pay the prescribed fee.</p> <p>RATIONALE: The rationale of this change is that the RFA provisions should identify where applicants can locate the fee schedule.</p> <p>LIKELY IMPACT: The likely impact of this change is clarity regarding which fee an RFA applicant must pay through the creation of a fee schedule.</p>
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1 **Project 6433 - Fast-Track**

2 **Department Of Health**

3 **Promulgation of Fee Schedule**

4 **12VAC5-220-10. Definitions.**

5 The following words and terms when used in this chapter shall have the following meanings
6 unless the context clearly indicates otherwise:

7 "Acquisition" means an expenditure of \$600,000 or more that changes the ownership of a
8 medical care facility. It shall also include the donation or lease of a medical care facility. An
9 acquisition of a medical care facility shall not include a capital expenditure involving the purchase
10 of stock. See 12VAC5-220-120.

11 "Amendment" means any modification to an application that is made following the public
12 hearing and prior to the issuance of a certificate and includes those factors that constitute a
13 significant change as defined in this chapter. An amendment shall not include a modification to
14 an application that serves to reduce the scope of a project.

15 "Applicant" means the owner of an existing medical care facility or the sponsor of a proposed
16 medical care facility project submitting an application for a certificate of public need.

17 "Application" means a prescribed format for the presentation of data and information deemed
18 necessary by the board to determine a public need for a medical care facility project.

19 ~~"Application fees" means fees required for a project application and application for a significant
20 change. Fees shall not exceed the lesser of 1.0% of the proposed capital expenditure or cost
21 increase for the project or \$20,000.~~

22 "Board" means the State Board of Health.

23 "Capital expenditure" means any expenditure by or in behalf of a medical care facility that,
24 under generally accepted accounting principles, is not properly chargeable as an expense of
25 operation and maintenance. Such expenditure shall also include a series of related expenditures
26 during a 12-month period or a financial obligation or a series of related financial obligations made
27 during a 12-month period by or in behalf of a medical care facility. Capital expenditures need not
28 be made by a medical care facility so long as they are made in behalf of a medical care facility by
29 any person. See definition of "person."

30 "Certificate of public need" means a document that legally authorizes a medical care facility
31 project as defined herein and which is issued by the commissioner to the owner of such project.

32 "Clinical health service" means a single diagnostic, therapeutic, rehabilitative, preventive or
33 palliative procedure as defined in § 32.1-102.1 of the Code of Virginia.

34 "Commissioner" means the State Health Commissioner who has authority to make a
35 determination respecting the issuance or revocation of a certificate.

36 "Competing applications" means applications for the same or similar services and facilities
37 that are proposed for the same planning district or medical service area and which are in the same
38 review cycle. See 12VAC5-220-220.

39 "Completion" means conclusion of construction activities necessary for substantial
40 performance of the contract.

41 "Construction" means the building of a new medical facility or the expansion, remodeling, or
42 alteration of an existing medical care facility.

43 "Construction, initiation of" means that a project shall be considered under construction for
44 the purpose of certificate extension determinations upon the presentation of evidence by the

45 owner of: (i) a signed construction contract; (ii) the completion of short term financing and a
46 commitment for long term (permanent) financing when applicable; (iii) the completion of
47 predevelopment site work; and (iv) the completion of building foundations.

48 "Date of issuance" means the date of the commissioner's decision awarding a certificate of
49 public need.

50 "Department" means the Virginia Department of Health.

51 "Designated medically underserved areas" means (i) areas designated as medically
52 underserved areas pursuant to § 32.1-122.5 of the Code of Virginia; (ii) federally designated
53 Medically Underserved Areas (MUA); or (iii) federally designated Health Professional Shortage
54 Areas (HPSA).

55 "Ex parte" means any meeting that takes place between (i) any person acting in behalf of the
56 applicant or holder of a certificate of public need or any person opposed to the issuance or in
57 favor of the revocation of a certificate of public need and (ii) any person who has authority in the
58 department to make a decision respecting the issuance or revocation of a certificate of public
59 need for which the department has not provided 10 days written notification to opposing parties
60 of the time and place of such meeting. An ex parte contact shall not include a meeting between
61 the persons identified in (i) and staff of the department.

62 "Gamma knife surgery" means stereotactic radiosurgery, where stereotactic radiosurgery is
63 the noninvasive therapeutic procedure performed by directing radiant energy beams from any
64 source at a treatment target in the head to produce tissue destruction. See definition of "project."

65 "Health planning region" means a contiguous geographical area of the Commonwealth as
66 defined in § 32.1-102.1 of the Code of Virginia.

67 "Informal fact-finding conference" means a conference held pursuant to § 2.2-4019 of the
68 Code of Virginia.

69 "Inpatient beds" means accommodations within a medical care facility with continuous support
70 services (such as food, laundry, housekeeping) and staff to provide health or health-related
71 services to patients who generally remain in the medical care facility in excess of 24 hours. Such
72 accommodations are known by varying nomenclatures including but not limited to: nursing beds,
73 intensive care beds, minimal or self care beds, isolation beds, hospice beds, observation beds
74 equipped and staffed for overnight use, and obstetric, medical, surgical, psychiatric, substance
75 abuse, medical rehabilitation and pediatric beds, including pediatric bassinets and incubators.
76 Bassinets and incubators in a maternity department and beds located in labor or birthing rooms,
77 recovery rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or
78 treatment procedures rooms, or on-call staff rooms are excluded from this definition.

79 "Medical care facility" means any institution, place, building, or agency as defined in § 32.1-
80 102.1 of the Code of Virginia.

81 "Medical service area" means the geographic territory from which at least 75% of patients
82 come or are expected to come to existing or proposed medical care facilities, the delineation of
83 which is based on such factors as population characteristics, natural geographic boundaries, and
84 transportation and trade patterns, and all parts of which are reasonably accessible to existing or
85 proposed medical care facilities.

86 "Modernization" means the alteration, repair, remodeling, replacement or renovation of an
87 existing medical care facility or any part thereto, including that which is incident to the initial and
88 subsequent installation of equipment in a medical care facility. See definition of "construction."

89 "Operating expenditure" means any expenditure by or in behalf of a medical care facility that,
90 under generally accepted accounting principles, is properly chargeable as an expense of
91 operation and maintenance and is not a capital expenditure.

92 "Operator" means any person having designated responsibility and legal authority from the
93 owner to administer and manage a medical care facility. See definition of "owner."

94 "Other plans" means any plan(s) which is formally adopted by an official state agency or
95 regional health planning agency and which provides for the orderly planning and development of
96 medical care facilities and services and which is not otherwise defined in this chapter.

97 "Owner" means any person who has legal responsibility and authority to construct, renovate
98 or equip or otherwise control a medical care facility as defined herein.

99 "Person" means an individual, corporation, partnership, association or any other legal entity,
100 whether governmental or private. Such person may also include the following:

- 101 1. The applicant for a certificate of public need;
- 102 2. The regional health planning agency for the health planning region in which the
103 proposed project is to be located;
- 104 3. Any resident of the geographic area served or to be served by the applicant;
- 105 4. Any person who regularly uses health care facilities within the geographic area served
106 or to be served by the applicant;
- 107 5. Any facility or health maintenance organization (HMO) established under § 38.2-4300
108 et seq. of the Code of Virginia that is located in the health planning region in which the
109 project is proposed and that provides services similar to the services of the medical care
110 facility project under review;
- 111 6. Third party payors who provide health care insurance or prepaid coverage to 5.0% or
112 more patients in the health planning region in which the project is proposed to be located;
113 and
- 114 7. Any agency that reviews or establishes rates for health care facilities.

115 "Physician's office" means a place, owned or operated by a licensed physician or group of
116 physicians practicing in any legal form whatsoever, which is designed and equipped solely for the
117 provision of fundamental medical care whether diagnostic, therapeutic, rehabilitative, preventive
118 or palliative to ambulatory patients and which does not participate in cost-based or facility
119 reimbursement from third party health insurance programs or prepaid medical service plans
120 excluding pharmaceuticals and other supplies administered in the office. See definition of
121 "medical care facility."

122 "Planning district" means a contiguous area within the boundaries established by the
123 Department of Housing and Community Development as set forth in § 15.2-4202 of the Code of
124 Virginia, except that for purposes of this chapter, Planning District 23 shall be divided into two
125 planning districts: Planning District 20, consisting of the counties of Isle of Wight and Southampton
126 and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk and Virginia Beach; and
127 Planning District 21, consisting of the counties of James City and York and the cities of Hampton,
128 Newport News, Poquoson and Williamsburg.

129 "Predevelopment site work" means any preliminary activity directed towards preparation of
130 the site prior to the completion of the building foundations. This includes, but is not limited to, soil
131 testing, clearing, grading, extension of utilities and power lines to the site.

132 "Primary medical care services" means first-contact, whole-person medical and health
133 services delivered by broadly trained, generalist physicians, nurses and other professionals,
134 intended to include, without limitation, obstetrics/gynecology, family practice, internal medicine
135 and pediatrics.

136 "Progress" means actions that are required in a given period of time to complete a project for
137 which a certificate of public need has been issued. See 12VAC5-220-450, Demonstration of
138 progress.

139 "Project" means any plan or proposal as defined in § 32.1-102.1 of the Code of Virginia that
140 is subject to Certificate of Public Need approval.

141 "Public hearing" means a proceeding conducted by a regional health planning agency at which
142 an applicant for a certificate of public need and members of the public may present oral or written
143 testimony in support or opposition to the application that is the subject of the proceeding and for
144 which a verbatim record is made. See subsection A of 12VAC5-220-230.

145 "Regional health plan" means the regional plan adopted by the regional health planning
146 agency board.

147 "Regional health planning agency" means the regional agency as defined in § 32.1-102.1 of
148 the Code of Virginia.

149 "Rural" means territory, population, and housing units that are classified as "rural" by the
150 Bureau of the Census of the United States Department of Commerce, Economics and Statistics
151 Administration.

152 "Schedule for completion" means the timetable that identifies the major activities required to
153 complete a project as identified by the applicant and set forth on the certificate of public need.
154 The timetable is used by the commissioner to evaluate the applicant's progress in completing an
155 approved project.

156 "Significant change" means any alteration, modification or adjustment to a reviewable project
157 for which a certificate of public need has been issued or requested following the public hearing
158 which:

- 159 1. Changes the site;
- 160 2. Increases the capital expenditure amount authorized by the commissioner on the
161 certificate of public need issued for the project by 10% or more;
- 162 3. Changes the service(s) proposed to be offered;
- 163 4. Extends the schedule for completion of the project beyond three years (36 months) from
164 the date of certificate issuance or beyond the time period approved by the commissioner
165 at the date of certificate issuance, whichever is greater. See 12VAC5-220-440 and
166 12VAC5-220-450.

167 "Standard review process" means the process utilized in the review of all certificate of public
168 need requests with the exception of:

- 169 1. Certain bed relocations as specified in 12VAC5-220-280;
- 170 2. Certain projects that involve an increase in the number of beds in which nursing facility
171 or extended care services are provided as specified in 12VAC5-220-325.

172 "State Medical Facilities Plan" means the planning document as contained in Article 1.1 (§
173 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia, used to make medical care
174 facilities and services needs decisions.

175 **Statutory Authority**

176 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

177 **Historical Notes**

178 Derived from VR355-30-000 § 1.1, eff. June 30, 1993; amended, Volume 10, Issue 17, eff. June
179 15, 1994; amended, Virginia Register Volume 13, Issue 07, eff. January 24, 1997; Volume 14,
180 Issue 12, eff. April 2, 1998; Volume 19, Issue 08, eff. February 3, 2003; Volume 20, Issue 26, eff.
181 September 27, 2004; Volume 24, Issue 11, eff. March 5, 2008.

182 **12VAC5-220-95. Fee schedule.**

183 A. Unless otherwise provided, fees established by the board shall not be refundable.

184 B. The fee for any application that requests a certificate of public need shall be 1.0% of the
185 proposed expenditure for the project, but not less than \$1,000 and no more than \$60,000.

186 C. The fee for any application that requests registration of certain capital expenditures under
187 12VAC5-220-110 shall be \$70.

188 D. The fee for any application that requests registration of the addition of medical equipment
189 and services shall be \$70.

190 E. The fee for any application that requests registration of replacement of existing medical
191 equipment shall be \$70.

192 **Statutory Authority**

193 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

194 **12VAC5-220-105. Requirements for registration of the replacement of existing medical**
195 **equipment.**

196 Within 30 days of any person contracting to make, or otherwise legally obligating to make, a
197 capital expenditure for the replacement of medical equipment or otherwise acquiring replacement
198 medical equipment for the provision of services listed in subdivision 7 of the definition of "project"
199 in 12VAC5-220-10, the person shall register in writing such equipment replacement with the
200 commissioner and the appropriate regional health planning agency. Such registration shall be
201 made on forms provided by the department. The registration shall identify the specific unit of
202 equipment to be replaced and the estimated capital cost of the replacement, and shall include
203 documentation that the equipment to be replaced has previously been authorized or exempted
204 as allowed by law, and shall include the fee prescribed by subsection E of 12VAC5-220-95.

205 **Statutory Authority**

206 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

207 **Historical Notes**

208 Derived from Virginia Register Volume 14, Issue 12, eff. April 2, 1998; amended, Virginia Register
209 Volume 19, Issue 8, eff. February 3, 2003; Volume 26, Issue 2, eff. November 1, 2009.

210 **12VAC5-220-110. Requirements for registration of certain capital expenditures.**

211 A. At least 30 days before any person contracts to make or is otherwise legally obligated to
212 make a capital expenditure by or on behalf of a medical care facility as defined in this chapter that
213 has not been previously authorized by the commissioner, such expenditure shall be registered in
214 writing with the commissioner. The threshold amount for capital expenditure project registration
215 shall be determined using the formula contained in subsection B of this section.

216 B. The threshold contained in subsection A of this section shall be adjusted annually using
217 the percentage increase listed in the Consumer Price Index for All Urban Consumers (CPI-U) for
218 the most recent year as follows:

219
$$A \times (1 + B)$$

220 where:

221 A = the capital expenditure threshold amount for the previous year

222 and

223 B = the percent increase for the expense category "Medical Care" listed in the most
224 recent year available of the CPI-U of the U.S. Bureau of Labor Statistics.

225 C. The format for registration shall include information concerning the purpose of such
226 expenditure, and the projected impact that the expenditure will have upon the charges for
227 services, and shall include the fee prescribed by subsection C of 12VAC5-220-95. For purposes
228 of registration, the owner shall include any person making the affected capital expenditure. See
229 definition of "project."

230 D. Annually, the department shall (i) publish the threshold amount in the General Notices
231 section of the Virginia Register of Regulations and (ii) post the threshold amount on its website.

232 **Statutory Authority**

233 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

234 **Historical Notes**

235 Derived from VR355-30-000 § 3.2, eff. June 30, 1993; amended, Virginia Register Volume 10,
236 Issue 17, eff. June 15, 1994; Volume 13, Issue 7, eff. January 24, 1997; Volume 24, Issue 11, eff.
237 March 5, 2008; Volume 25, Issue 1, eff. October 15, 2008; Volume 26, Issue 2, eff. November 1,
238 2009; Volume 26, Issue 26, eff. September 30, 2010; Volume 27, Issue 24, eff. September 1,
239 2011; Volume 30, Issue 8, eff. February 3, 2014.

240 **12VAC5-220-180. Application forms.**

241 A. Letter of intent. An applicant shall file a letter of intent with the commissioner to request
242 appropriate application forms, and submit a copy of that letter to the appropriate regional health
243 planning agency, by the later of (i) 30 days prior to the submission of an application for a project
244 included within a particular batch group or (ii) 10 days after the first letter of intent is filed for a
245 project within a particular batch group for the same or similar services and facilities which are
246 proposed for the same planning district or medical service area. The letter shall identify the owner,
247 the type of project for which an application is requested, and the proposed scope (size) and
248 location of the proposed project. The department shall transmit application forms to the applicant
249 within seven days of the receipt of the letter of intent. A letter of intent filed with the department
250 shall be considered void one year after the date of receipt of such letter. (See 12VAC5-220-310
251 C.)

252 B. Application fees. The department shall collect application fees for applications that request
253 a certificate of public need. The applicant shall pay the fee required prescribed by subsection B
254 of 12VAC5-220-95 for an any application that requests a certificate of public need shall be 4.0%
255 of the proposed expenditure for the project, but not less than \$1,000 and no more than \$20,000.

256 No application will be deemed to be complete for review until the required application fee is
257 paid. (See 12VAC5-220-310 C.)

258 C. Filing application forms. Applications must be submitted at least 40 days prior to the first
259 day of a scheduled review cycle to be considered for review in the same cycle. In order to verify
260 the date of the department's and the appropriate regional health planning agency's receipt of the
261 application, the applicant shall transmit the document electronically, or prepare in triplicate two
262 copies to be submitted to the department and one copy to be submitted to the appropriate regional
263 health planning agency and sent by certified mail or a delivery service, return receipt requested,
264 or by hand, with a signed receipt to be provided. No application shall be deemed to have been
265 submitted until required copies have been received by the department and the appropriate
266 regional health planning agency. (See 12VAC5-220-200.)

267 **Statutory Authority**

268 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

269 **Historical Notes**

270 Derived from VR355-30-000 § 5.2, eff. June 30, 1993; amended, Volume 10, Issue 17, eff. June
271 15, 1994; amended, Virginia Register Volume 14, Issue 12, eff. April 2, 1998; Volume 19, Issue
272 08, eff. February 3, 2003; Volume 26, Issue 02, eff. November 1, 2009.

273 **12VAC5-220-355. RFA project application forms.**

274 A. Letter of intent. A RFA project applicant shall file a letter of intent with the commissioner to
275 request appropriate application forms, and submit a copy of that letter to the appropriate regional
276 health planning agency by the letter of intent deadline specified in the RFA. The letter shall identify

277 the owner, the type of project for which an application is requested, and the proposed scope (size)
278 and location of the proposed project. The department shall transmit application forms to the
279 applicant within seven days of the receipt of the letter of intent. A letter of intent filed with the
280 department shall be considered void if an application is not filed for the project by the application
281 deadline specified in the RFA.

282 B. Application fees. The department shall collect application fees for RFA applications that
283 request a certificate of public need. The applicant shall pay the fee required prescribed by
284 subsection B of 12VAC5-220-95 for an application is 1.0% of the proposed capital expenditure
285 for the project but no less than \$1,000 and no more than \$20,000. No application will be deemed
286 to be complete for review until the required application fee is paid.

287 C. Filing application forms. Applications must be submitted to the department and the
288 appropriate regional health planning agency by the application filing deadline specified in the RFA.
289 In order to verify the department and the appropriate regional health planning agency's receipt of
290 the application, the applicant shall transmit the document electronically, or prepare in triplicate
291 two copies to be submitted to the department and one copy to be submitted to the appropriate
292 regional health planning agency and sent by certified mail or a delivery service, return receipt
293 requested, or by hand, with a signed receipt to be provided. No application shall be deemed to
294 have been submitted until required copies have been received by the department and the
295 appropriate regional health planning agency.

296 **Statutory Authority**

297 §§ 32.1-12 and 32.1-102.2 of the Code of Virginia.

298 **Historical Notes**

299 Derived from Volume 13, Issue 07, eff. January 24, 1997; amended, Virginia Register Volume 19,
300 Issue 08, eff. February 3, 2003; Volume 26, Issue 02, eff. November 1, 2009.