

**State of Board of Health
Agenda
December 14, 2012 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Mr. Edwards
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of September 14, 2012 Minutes	Mr. Edwards
Commissioner’s Report	Maureen Dempsey, MD, FAAP Acting State Health Commissioner
Abortion Facility Licensure Status Report	Marissa Levine, MD, MPH Acting Chief Deputy Commissioner for Public Health
Sexual Violence Prevention Activities - Overview	David Trump, MD, MPH, MPA Acting Director, Office of Family Health Services
Break	
Strategic Plan Overview	Joan Martin Deputy Commissioner for Administration
Performance Improvement Overview	Josh Czarda Performance Improvement Manager
Freedom of Information Act/Electronic Meeting Provisions - Update	Mr. Hilbert
Lunch	
Luncheon Speaker	John Agola, MD Co-Chair, Virginia Stroke Systems Task Force
Overview of Pending Regulatory Actions	Mr. Hilbert
Public Comment	

Regulatory Action Items

Certificate of Public Need Regulations
12VAC5-220
(Final Amendments – Fast Track Action)

Peter Boswell, Director
Division of Certificate of Public Need

State Medical Facilities Plan
12VAC5-230
(Final Amendments – Fast Track Action)

Peter Boswell

Proposed Revisions to 2013 Board
Meeting Schedule

Joseph Hilbert

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Department of Health

Maureen E. Dempsey, MD, FAAP
Acting State Health Commissioner

Office of Licensure and Certification

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

9960 Mayland Drive, Suite 401
Henrico, Virginia 23233-1485
Fax: (804) 527-4502

November 29, 2012

MEMORANDUM

TO: The Board of Health

FROM: Erik O. Bodin *EB*
Director

SUBJ: Fast-Track Regulatory Action for the:
Virginia Medical Care Facilities Certificate of Public Need (COPN) Rules and
Regulations and the State Medical Facilities Plan (SMFP)

These amendments to the COPN Rules and Regulations and the SMFP Rules and Regulations are classified as "fast track" as the amendments are necessary to conform to Virginia law. Since they are non-controversial, they are suitable for using the expedited promulgation process known as fast track.

These actions affect the cost threshold amounts for miscellaneous capital expenditure projects requiring a COPN in two ways: i) raises the threshold for registration for projects costing more than \$5,859,565 and ii) raises the threshold for projects requiring a COPN application to more than \$17,608,697.

After BOH approval, this amendment will be published in the Virginia Registrar and will become effective 60-days after publication.

Thank you.

DIRECTOR
(804) 367-2102

ACUTE CARE
(804) 367-2104

COPN
(804) 367-2126

VDH VIRGINIA
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Regulatory
Town Hall

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Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-220-110 and 220
Regulation title	Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations
Action title	To amend specific sections related to miscellaneous capital expenditures pursuant to § 321.1-102.1
Date this document prepared	November 13, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Section 32.1-102.1 of the Code of Virginia pertains to the certificate of public need (COPN) program by requiring an annual increase in the threshold for capital expenditure projects to "reflect inflation using appropriate measures incorporating construction costs and medical inflation." Therefore, 12VAC5-220-110 and 200 must be amended annually to conform to the statute. Using the Consumer Price Index published by the U.S. Department of Labor, the capital expenditure threshold for projects requiring registration increased from \$5,698,607 to \$5,869,565 and those projects requiring the filing of an application increased from \$17,095,823 to \$17,608,697.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulation is promulgated under the authority of § 32.1-102.2 of the Code of Virginia, which grants the Board of Health the legal authority to "promulgate regulations that are consistent with" Article 1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia. Therefore, this authority is mandated. Section 32.1-102.1 of the Code of Virginia requires that sections 110 and 220 of 12VAC5-220 be updated annually.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The COPN program is the mechanism used in Virginia to restrain specified health care facilities and services from unnecessary duplication as a cost control measure. Section 32.1-102.1 of the Code of Virginia requires an annual adjustment to the project cost threshold by which health care entities subject to COPN can make necessary capital improvements such as parking decks and computer systems without having to register or obtain a certificate. Raising the cost threshold for capital expenditures projects benefits health care entities by reducing the costs of those projects.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Because § 32.102.1 of the Code of Virginia does not specify which nationally recognized consumer price index to use in adjusting the capital expenditure threshold, the department chose to use the Consumer Price Index published by the U.S. Department of Labor (USDL). The discretionary decision prohibits use of the exempt regulatory action process for updating the project threshold each year. The department, however, has not received negative response from affected constituents in using the USDL index in prior

years. Therefore, the department believes this action will remain noncontroversial and is appropriate for the fast track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

This action affects the cost threshold amounts for miscellaneous capital expenditure projects requiring a COPN in two ways: 1) raises the threshold for registration for projects costing more than \$5,859,565 and ii) raises the threshold for projects requiring a COPN application to more than \$17,608,697.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

Section 32.1-102.1 of the Code of Virginia addresses the issue of rising construction costs for health care facilities and services projects that require a COPN. The statute mandates that the cost threshold amount for miscellaneous capital expenditures such as parking decks, computer systems, and heating and air conditioning systems be adjusted annually. The department chose to use the Consumer Price Index published by the U.S. Department of Labor, which is a nationally accepted inflation index.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are not federal requirements pertaining to the approval of certain medical care facilities and services

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is disproportionately affected by this required action.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The regulation is clearly mandated by law; there are no other available alternatives to comply with the law.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	Cost to the department to implement and enforce this action is considered the routine cost to promulgate regulations (i.e., \$5,000). Program 40608, fund 0220, cost code 552
Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.	There is no impact on localities as a result of this action.
Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.	Medical care facilities and service entities (large and small) subject to COPN and their legal representatives are affected by this action.
Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	Unless a medical care facilities and services entity plans to make capital improvements, there is no impact on the entity.
All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential	None, in fact this action would save entities dollars towards to costs of certain planned capital improvements.

<p>purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Providers subject to the COPN law have save the cost of filing a COPN application for miscellaneous capital expenditures each year since 2007,</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no alternatives that meet the intent of the law.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no direct impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

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

<p>Current section number</p>	<p>Proposed new section number, if applicable</p>	<p>Current requirement</p>	<p>Proposed change, intent, rationale, and likely impact of proposed requirements</p>
<p>110</p>		<p>Registration of certain capital</p>	<p>Raises the threshold for registration of</p>

		expenditures	capital improvement projects to only those costing more than \$5,869,565. Capital projects costing less are not required to register.
220		On hundred ninety-day review cycle	Amends the threshold amount in each batch cycle listed to more than \$17,608,697 for projects that are required to obtain a COPN before construction begins.

DRAFT

Project 3191 - Final

DEPARTMENT OF HEALTH

Amend Regulations related to Miscellaneous Capital Expenditures Pursuant to HB2546 of 2007

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

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 that is ~~\$5,698,607~~ \$5,869,565 or more but is less than ~~\$17,095,823~~ \$17,608,697 and has not been previously authorized by the commissioner, the owner of any medical care facility as defined in this chapter shall register in writing such expenditure with the commissioner. The format for registration shall include information concerning the purpose of such expenditure and projected impact that the expenditure will have upon the charges for services. For purposes of registration, the owner shall include any person making the affected capital expenditure. See definition of "project."

12VAC5-220-200. One hundred ninety-day review cycle.

The department shall review the following groups of completed applications in accordance with the following 190-day scheduled review cycles and the following descriptions of projects within each group, except as provided for in 12VAC5-220-220.

BATCH GROUP	GENERAL DESCRIPTION	REVIEW CYCLE	
		Begins	Ends
A	General Hospitals/Obstetrical Services/Neonatal Special Care Services	Feb. 10 Aug. 10	Aug. 18 Feb. 16
B	Open Heart Surgery/Cardiac Catheterization/Ambulatory Surgery Centers/Operating Room Additions/Transplant Services	Mar. 10 Sep. 10	Sep. 16 Mar. 19
C	Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities	Apr. 10 Oct. 10	Oct. 17 Apr. 18
D/F	Diagnostic Imaging Facilities/Services Selected Therapeutic Facilities/Services	May 10 Nov. 10	Nov. 16 May 19
E	Medical Rehabilitation Beds/Services	June 10 Dec. 10	Dec. 17 Jun. 18
D/F	Selected Therapeutic Facilities/Services Diagnostic Imaging Facilities/Services	July 10 Jan. 10	Jan. 16 Jul. 18
G	Nursing Home Beds at Retirement Communities/Bed Relocations/Miscellaneous Expenditures by Nursing Homes	Jan. 10 Mar. 10 May 10 July 10 Sep. 10 Nov. 10	Jul. 18 Sep. 16 Nov. 16 Jan. 16 Mar. 19 May 19

Batch Group A includes:

1. The establishment of a general hospital.

2. An increase in the total number of general acute care beds in an existing or authorized general hospital.
3. The relocation at the same site of 10 general hospital beds or 10% of the general hospital beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period if such relocation involves a capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more (see 12VAC5-220-280).
4. The introduction into an existing medical care facility of any new neonatal special care or obstetrical services that the facility has not provided in the previous 12 months.
5. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category included in Batch Groups B through G, by or in behalf of a general hospital.

Batch Group B includes:

1. The establishment of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
2. An increase in the total number of operating rooms in an existing medical care facility or establishment of operating rooms in a new facility.
3. The introduction into an existing medical care facility of any new cardiac catheterization, open heart surgery, or organ or tissue transplant services that the facility has not provided in the previous 12 months.
4. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization.
5. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a specialized center, clinic, or portion of a physician's office developed for the provision of outpatient or ambulatory surgery or cardiac catheterization services.
6. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Group A or Batch Groups C through G, by or in behalf of a medical care facility, that is primarily related to the provision of surgery, cardiac catheterization, open heart surgery, or organ or tissue transplant services.

Batch Group C includes:

1. The establishment of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
2. An increase in the total number of beds in an existing or authorized mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
3. An increase in the total number of mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds in an existing or authorized medical care facility which is not a dedicated mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facility.
4. The relocation at the same site of 10 mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds or 10% of the mental hospital, psychiatric hospital, substance abuse treatment and rehabilitation, or mental retardation beds of a medical care facility, whichever is less, from one existing physical

facility to another in any two-year period if such relocation involves a capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more (see 12VAC5-220-280).

5. The introduction into an existing medical care facility of any new psychiatric or substance abuse treatment service that the facility has not provided in the previous 12 months.

6. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A and B or Batch Groups D/F through G, by or in behalf of a mental hospital, psychiatric hospital, intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts, or mental retardation facilities.

7. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A through B or Batch Groups D/F through G, by or in behalf of a medical care facility, which is primarily related to the provision of mental health, psychiatric, substance abuse treatment or rehabilitation, or mental retardation services.

Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.

2. The introduction into an existing medical care facility of any new computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging services, except for the purpose of nuclear cardiac imaging that the facility has not provided in the previous 12 months.

3. The addition by an existing medical care facility of any equipment for the provision of computed tomography (CT), magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning.

4. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A B, C, E, and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except that portion of a physician's office dedicated to providing nuclear cardiac imaging.

5. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of computed tomographic (CT) scanning, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, or nuclear medicine imaging, except for the purpose of nuclear cardiac imaging.

Batch Group E includes:

1. The establishment of a medical rehabilitation hospital.

2. An increase in the total number of beds in an existing or authorized medical rehabilitation hospital.

3. An increase in the total number of medical rehabilitation beds in an existing or authorized medical care facility that is not a dedicated medical rehabilitation hospital.

4. The relocation at the same site of 10 medical rehabilitation beds or 10% of the medical rehabilitation beds of a medical care facility, whichever is less, from one existing physical facility to another in any two-year period, if such relocation involves a capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more (see 12VAC220-280).
5. The introduction into an existing medical care facility of any new medical rehabilitation service that the facility has not provided in the previous 12 months.
6. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A B, C, D/F, and G, by or in behalf of a medical rehabilitation hospital.
7. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A B, C, D/F, and G, by or in behalf of a medical care facility, that is primarily related to the provision of medical rehabilitation services.

Batch Group D/F includes:

1. The establishment of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
2. Introduction into an existing medical care facility of any new gamma knife surgery, lithotripsy, or radiation therapy services that the facility has not provided in the previous 12 months.
3. The addition by an existing medical care facility of any medical equipment for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
4. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project in Batch Groups A B, C, E, and G, by or in behalf of a specialized center, clinic, or that portion of a physician's office developed for the provision of gamma knife surgery, lithotripsy, or radiation therapy.
5. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project in Batch Groups A B, C, E, and G, by or in behalf of a medical care facility, which is primarily related to the provision of gamma knife surgery, lithotripsy, or radiation therapy.

Batch Group G includes:

1. The establishment of a nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
2. The establishment of a nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
3. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility of a continuing care retirement community by a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 of the Code of Virginia.
4. An increase in the total number of beds in an existing or authorized nursing home, intermediate care facility, or extended care facility that does not involve an increase in the number of nursing home facility beds within a planning district.
5. The relocation at the same site of 10 nursing home, intermediate care facility, or extended care facility beds or 10% of the nursing home, intermediate care facility, or extended care facility beds of a medical care facility, whichever is less, from one

physical facility to another in any two-year period, if such relocation involves a capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more (see 12VAC5-220-280).

6. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A through D/F, by or in behalf of a nursing home, intermediate care facility, or extended care facility, which does not increase the total number of beds of the facility.

7. Any capital expenditure of ~~\$17,095,823~~ \$17,608,697 or more, not defined as a project category in Batch Groups A through D/F, by or in behalf of a medical care facility, that is primarily related to the provision of nursing home, intermediate care, or extended care services, and does not increase the number of beds of the facility.



Fast Track Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-230-530 and 760
Regulation title	State Medical Facilities Plan (SMFP)
Action title	To amend specific sections related to miscellaneous capital expenditures pursuant to § 32.1-102.1
Date this document prepared	November 13, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Section 32.1-102.1 of the Code of Virginia pertains to the certificate of public need (COPN) program and requires an annual increase in the threshold for capital expenditure projects to "reflect inflation using appropriate measures incorporating construction costs and medical inflation." Therefore, 12VAC5-230-530 and 760 must be amended annually to conform to the statute. Using the Consumer Price Index published by the U.S. Department of Labor, the capital expenditure threshold for projects requiring the filing of an application has increased to \$17,608,697.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulation is promulgated under the authority of § 32.1-102.2 of the Code of Virginia, which grants the Board of Health the legal authority to "promulgate regulations that are consistent with" Article 1 (§ 32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia. Therefore, this authority is mandated. Section 32.1-102.1 of the Code of Virginia requires that section 760 of 12VAC5-230 be updated annually.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The SMFP is the tool used by the COPN program to restrain specified health care facilities and services from unnecessary duplication as a cost control measure. Section 32.1-102.1 of the Code of Virginia requires an annual adjustment to the project cost threshold by which health care entities subject to COPN can make necessary capital improvements such as parking decks and computer systems without having to obtain a certificate. Raising the cost threshold for capital expenditure projects benefits health care entities by reducing the costs of those projects.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Because § 32.1-102.1 of the Code of Virginia does not specify which nationally recognized consumer price index to use in adjusting the capital expenditure threshold, the department chose to use the Consumer Price Index published by the U.S. Department of Labor (USDL). The discretionary decision prohibits use of the exempt regulatory action process for updating the miscellaneous capital expenditure project thresholds listed in Chapters 220 and 230 each year. The department, however, has not received negative response from affected constituents in using the USDL index in prior years. Therefore, the department believes this action will remain noncontroversial and is appropriate for the fast track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

This action affects the cost threshold amounts for miscellaneous capital expenditure projects requiring a COPN by raising the threshold for projects requiring a COPN application to more than \$17,694,176.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If there are no disadvantages to the public or the Commonwealth, please indicate.

Section 32.1-102.1 of the Code of Virginia addresses the issue of rising construction costs for health care facilities and services projects that require a COPN. The statute mandates that the cost threshold amount for miscellaneous capital expenditures such as parking decks, computer systems, and heating and air conditioning systems be adjusted annually. The department chose to use the Consumer Price Index published by the U.S. Department of Labor, which is a nationally accepted inflation index.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are not federal requirements pertaining to the approval of certain medical care facilities and services

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality is disproportionately affected by this required action.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The regulation is clearly mandated by law; there are no other available alternatives to comply with the law.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>Cost to the department to implement and enforce this action considered the routine cost to promulgate regulations (i.e., \$5,000). Program 40608, fund 0220, cost code 552</p>
<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>There is no impact on localities as a result of this action.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</p>	<p>Medical care facilities and service entities (large and small) subject to COPN and their legal representatives are affected by this action.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Unless a medical care facilities and services entity plans to make capital improvements, there is no impact on the entity.</p>
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>None, in fact this action would save entities dollars towards to costs of certain planned capital improvements.</p>

Beneficial impact the regulation is designed to produce.	Providers subject to the COPN law have save the cost of filing a COPN application for miscellaneous capital expenditures each year since 2007,
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Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no alternatives that meet the intent of the law.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no direct impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
530		Need for new service	Raises the threshold for capital improvement projects to more than \$17,608,697 for projects that are required to obtain a COPN before construction begins.

760		Project need	Raises the threshold for capital improvement projects to more than \$17,608,697 for projects that are required to obtain a COPN before construction begins.
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DRAFT

DEPARTMENT OF HEALTH

Amend Regulations related to Miscellaneous Capital Expenditures Pursuant to HB2546 of 2007

12VAC5-230-530. Need for new service.

A. No new inpatient beds should be approved in any health planning district unless:

1. The resulting number of beds for each bed category contained in this article does not exceed the number of beds projected to be needed for that health planning district for the fifth planning horizon year; and
2. The average annual occupancy based on the number of beds in the health planning district for the relevant reporting period is:
 - a. 80% at midnight census for medical/surgical or pediatric beds;
 - b. 65% at midnight census for intensive care beds.

B. For proposals to convert under-utilized beds that require a capital expenditure of \$15 million ~~\$17,608,697~~ or more, consideration may be given to such proposal if:

1. There is a projected need in the applicable category of inpatient beds; and
2. The applicant can demonstrate that the average annual occupancy of the converted beds would meet the utilization standard for the applicable bed category by the first year of operation.

For the purposes of this part, "underutilized" means less than 80% average annual occupancy for medical/surgical or pediatric beds, when the relocation involves such beds and less than 65% average annual occupancy for intensive care beds when relocation involves such beds.

12VAC5-230-760. Project need.

All applications involving the expenditure of ~~\$15 million~~ \$17,608,697 or more by a medical care facility should include documentation that the expenditure is necessary in order for the facility to meet the identified medical care needs of the public it serves. Such documentation should clearly identify that the expenditure:

1. Represents the most cost-effective approach to meeting the identified need; and
2. The ongoing operational costs will not result in unreasonable increases in the cost of delivering the services provided.

Virginia State Board of Health Public Participation Policy

The Board of Health (~~the~~ Board) encourages public participation in the performance of its duties and responsibilities. To assure that public comment submitted to the Board is properly processed and to assure that all Board actions are made in compliance with the Administrative Process Act, the Board hereby adopts this Public Participation Policy.

A. Public Comments at Board of Health Meetings

These procedures establish the times for the public to provide appropriate comment to the Board for its consideration. In light of these established procedures, the Board accepts public comment on regulatory actions, as well as general comments, at Board meetings in accordance with the following:

1. REGULATORY ACTIONS (adoption, amendment or repeal of regulations): Public participation for regulatory actions is governed by the Administrative Process Act and the Department of Health's Public Participation Guidelines. ~~12-VAC-5-10-10-12VAC5-11~~ *et seq.* Public comment is accepted during the Notice of Intended Regulatory Action phase (which is a minimum of 30 days and may include a public hearing when required under the Department of Health's Public Participation Guidelines) and during the Notice of Public Comment Period on Proposed Regulatory Action (which is a minimum of 60 days and may include a public hearing if required by the NOIRA). Notice of these comment periods is announced in the Virginia Register. The comments received during the announced public comments periods are summarized for the Board and considered by the Board when making a decision on regulatory action.

2. PUBLIC COMMENT PERIOD

The Board schedules a public comment period at the beginning of each regular meeting to provide an opportunity for citizens to address the Board. Anyone wishing to speak to the Board during this time should, at the beginning of the Board meeting, indicate his or her desire on the sign-in sheet. Presentations during the Public Forum shall not exceed two minutes per person. The public comment period shall be no more than twenty minutes.

The Board reserves the right to alter the time limitations set forth above without notice and to ensure that comments presented at the meeting conform to this policy.

B. Public Comment submitted to Board Members outside of Board of Health meetings

Whenever a Board member receives written or verbal comment pertaining to the Department of Health's programs or personnel he or she should decline to make a substantive response and should proceed as follows.

1. Comment that appears to address specific pending regulatory action should be immediately referred to the [Commissioner/or agency other designee]. If the subject of a verbal or written comment received by a Board member pertains to specific proposed regulatory action that will be subject to Board approval, the member should immediately forward it to the Commissioner for inclusion in the agency record with other public comment in accordance with the Administrative Process Act. If the comment is a verbal communication, the Board member should immediately report the substance of the comment to the Commissioner who will place a summary of it in the agency record.
2. Comment that is not the subject of specific pending regulatory action: such as comments or complaints about the implementation of specific health programs, or actions of agency staff also should be referred to the [Commissioner/ or other agency designee] for appropriate review and handling. A Board member may, in the alternative, inform the author of the public comment that it should be directed to the appropriate agency staff.
3. When a Board member receives public comments outside Board meetings he or she should acknowledge receipt of the comment and, when appropriate, notify the sender that his comment has been forwarded to the Commissioner for appropriate review and handling.

Adopted October 23, 2003

Abortion Facility Survey and Licensure - Status Report

Marissa Levine, MD MPH
Acting Chief Deputy Commissioner
December 14, 2012

Abortion Facility Survey Progress

20 Abortion Facilities applied for a license

- All 20 were surveyed, submitted an acceptable plan of correction when requested and received a license
- All abortion facility licenses expire April 30, 2013
- Applications for license renewal are expected by March 2, 2013

Abortion Facility License Process

Applications

20 expected / 20 received

Form available 12/29/11
Due by 3/28/12
Received between 2/13 - 3/28

Letter of Readiness for Survey

20 eligible / 20 received

Due by 3/28/12
Received between 3/19 - 3/28

All surveys conducted
between 5/1 - 8/15

Initial License Surveys

20 eligible / 20 surveyed

Requests for a PoC sent between 5/23 - 9/6
First PoC received 6/4

Request Plan of Correction

20 requested / 20 Accepted

First license issued 7/23, the last on 10/24
Application for License Renewal due 3/2/13
All initial licenses expire 4/30/13

20 Licenses Issued

Abortion Facility Initial License Survey

The most common deficiencies cited on survey have been related to (not in order of frequency):

- **Patient Care** (e.g., multiple use of single dose medication vial)
- **Infection Prevention** (e.g., inadequate safeguards to prevent contamination)
- **Functional Safety & Maintenance** (e.g., absence of preventive maintenance policies and procedures for equipment)
- **Design and Construction** (e.g., no verification of adequate air flow)
- **Personnel & Administrative** (e.g., staff criminal background check not conducted in accordance with regulation)
- **Medical Records** (e.g., medical record incomplete)

5 Most Common Building Related Deficiencies

- Sterile/clean storage with proper air flow/temp/humidity control not available and/or not separate from soiled utility,
- Inadequate hand wash and service sinks,
- No documentation of air filter (particle size) efficiency,
- Entrance not handicap accessible or covered from elements,
- Corridor and/or doorway width too narrow

Abortion Facility Plans to Correct Building Deficiencies

Of the 20 plans of correction accepted to date:

- 1 had no deficiencies concerning compliance with building Code / Standards
- 11 identified they will renovate within 2 years to be compliant with building Code / Standards
- 2 noted they plan to relocate within 2 years to be compliant with building Code / Standards
- 6 identified they plan to seek waiver vs renovation vs relocation, and will decide and complete the selected process within 2 years to be compliant.
- None indicated an intention to close.

Abortion Facility Complaints

20 individual complaints have been received for 6 separate abortion facilities

- 18 complaints have been investigated at 5 facilities
 - 1 complaint was substantiated
- 3 complaints were received in November 2012 and 1 has been investigated 12/3/2012 through 12/7/2012. The complaint outcome is not available as of 12/10/2012.