REPORT OF THE
DEPARTMENT OF HEALTH

ANNUAL REPORT ON THE STATUS OF VIRGINIA'S MEDICAL CARE FACILITIES CERTIFICATE OF PUBLIC NEED PROGRAM

TO THE GOVERNOR AND THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2007

Table of Contents

Table of Contents ……i
Executive Summary iii
Preface 1
SUMMARY OF THE STATE HEALTH COMMISSIONER'S ACTIONS AND OTHER COPN PROGRAM ACTIVITY DURING FISCAL YEAR 2007 1
Project Review 1
Decisions 1
Adjudication 3
Judicial Review 3
Certificate Surrenders 4
Significant Changes 4
Competitive Nursing Home Review 5
Timeliness Of COPN Application Review 5
Legislation 5
Regulation 7
FIVE-YEAR SCHEDULE FOR ANNUAL PROJECT CATEGORY ANALYSIS 8
Overview 8
PROJECT CATEGORY ANALYSES 9
General Hospitals 10
General Surgery 14
Specialized Cardiac Services 17
Organ and Tissue Transplantation 22
Effectiveness of the COPN Application Review Procedures for FY 2007 Project Categories 25
Other Data Relevant to the Efficient Operation of COPN Program 26
Accessibility of Regulated Health Care Services by the Indigent 26
Relevance of COPN to Quality of Care Rendered by Regulated Facilities 28
Equipment Registration 28
Appendix A 30
Appendix B 31
Appendix C 33
Appendix D 35
Appendix E 36
Appendix F 37
Appendix G 38
Appendix H 41
Appendix I 50
Appendix J 53

Executive Summary

This annual report to the Governor and the General Assembly of Virginia on the status of Virginia's Certificate of Public Need (COPN) program has been developed pursuant to § 32.1-102.12 of the *Code of Virginia*. The report is required to address the activities of the program in the previous fiscal year; review the appropriateness of continued regulation of at least three specific project categories; and to discuss the issues of access to care by the indigent, quality of care within the context of the program, and health care market reform. A copy of the enabling *Code* section is reproduced at Appendix A. This report includes data for the most recent fiscal year (FY 2007).

Program activity for the period covered in this report includes the issuance of 96 decisions. The State Health Commissioner authorized 79 projects with a total expenditure of $1,171,485,980 and denied 17 projects with proposed capital expenditures of $137,671,697. Appendix D summarizes the authorization decisions. Additional program activities are described in the "Summary of the State Health Commissioner's Actions" beginning on page 1.

The following project categories are analyzed in this report: general hospitals, general surgery, specialized cardiac services and organ and tissue transplantation. The section on project analysis addresses the history of COPN regulation for these project categories, the nature of the specific services, the current state of the service in the Commonwealth and three potential options for the future of each of the categories with a recommended action. The Virginia Department of Health (VDH) recommends maintaining the current COPN review process for the review of these project types.

Applicants that have not demonstrated a historical commitment to charity care, consistent with other providers in their health service area, may have a "condition" to provide some level of indigent care placed upon any COPNs they are awarded. Compliance with the conditions to provide indigent care remains relatively poor but has improved considerably. Historically, many conditioned COPN holders have either not reported their compliance with conditions or have reported that they have been unable, for various reasons, to reach the required level of indigent care. Language for the "conditioning" of COPNs is now being augmented to include the second type of condition allowed in the *Code*, namely that the applicant facilitate access through the development and operation of primary health care services for special populations. A guidance document was issued to clarify the conditioning process and provide definition to the elements of a condition. These initiatives helped remove the barriers to compliance most often cited by facility managers as their reason for failing to satisfy indigent care conditions.

During FY 2007 the application review process was completed as directed by the *Code*. There were no delays in receiving recommendations from regional health planning agencies that adversely affected timely decision-making.

Preface

This 2007 annual report to the Governor and the General Assembly of Virginia on the status of Virginia's Certificate of Public Need (COPN) program has been developed pursuant to § 32.1-102.12 of the *Code of Virginia*. It includes data for the most recent fiscal year (2007). A copy of the enabling *Code* section is provided in Appendix A.

The COPN program is a regulatory program administered by the Virginia Department of Health (VDH). The program was established in 1973. The historical objectives of the program are: (i) promoting comprehensive health planning to meet the needs of the public; (ii) promoting the highest quality of care at the lowest possible cost; (iii) avoiding unnecessary duplication of medical care facilities; and (iv) providing an orderly procedure for resolving questions concerning the need to construct or modify medical care facilities. In essence, the program seeks to contain health care costs while ensuring financial and geographic access to quality health care for Virginia citizens at a reasonable cost. The current regulatory scope of the COPN program is shown in Appendix B.

The statute establishing Virginia's COPN program is found in Article 1 of Chapter 5 of Title 32.1 of the *Code* (§ 32.1-102.1 et seq.). The State Health Commissioner (Commissioner) authorizes capital projects regulated within the COPN program prior to implementation. The Commissioner must be satisfied that the proposed project meets public need criteria. The *Code* specifies 20 factors (Appendix C) that must be considered in the determination of public need.

SUMMARY OF THE STATE HEALTH COMMISSIONER'S ACTIONS AND OTHER COPN PROGRAM ACTIVITY DURING FISCAL YEAR 2007

Project Review

Decisions

During FY 2007, the Division of Certificate of Public Need (DCOPN), which assists the Commissioner in administering the COPN program, received 87 letters of intent to submit COPN requests and 77 applications for COPNs. There were seven applications withdrawn by applicants during the year and one that was not accepted for review. The balance of letters of intent and applications are those for which the appropriate review cycles have crossed fiscal years. Letters of intent are required of all persons intending to become applicants for COPNs. These letters describe the proposed project in enough detail to enable DCOPN to batch the project in an appropriate review cycle and provide the applicant with the appropriate COPN application package for the proposed project. A letter of intent will lapse if a COPN application is not submitted within a year of the time the letter of intent was submitted.

Table 1 summarizes COPN review activity for FY 2007. Graph 1 puts this activity in historical context. The Commissioner issued 96 decisions on applications to establish new medical care facilities or modify existing medical care facilities. Seventy-nine of these decisions were to approve or conditionally approve, for a total authorized capital expenditure of $1,171,485,980. Seventeen requests were denied. These seventeen denied projects had proposed

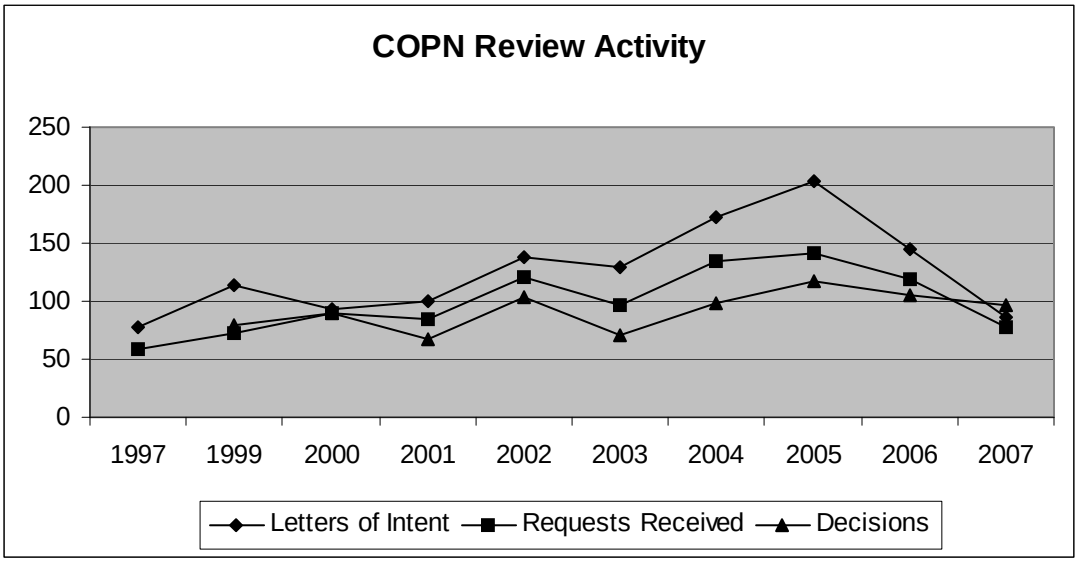
total capital expenditures of $137,671,697. COPN decisions in FY 2007 are profiled in Appendix D.

Table 1. COPN Activity Summary

Fiscal Year	Total Letters of Intent Received	Total COPN Applications Received	Applications Withdrawn	Approvals	Denials	Appeals to Circuit Court	Determined to be Not Reviewable
2007	87	77	7	79	17	5	0

The number of decisions does not equal the number of requests due to review cycles overlapping the fiscal year.
Source: DCOPN

Graph 1



Source: DCOPN

In addition to assisting the Commissioner in the administration of the COPN program, DCOPN provides written recommendations addressing the merits of approval or denial of COPN applications. The DCOPN provides advisory reports on all completed applications that are not subsequently withdrawn.

COPN reports and recommendations are also provided to the Commissioner by the regional health planning agencies. The regional health planning agencies are not-for-profit corporations that receive state funding to conduct regional health planning and to provide an independent recommendation to assist the Commissioner in the COPN decision process. The regional health planning agencies conduct public hearings and make recommendations to the Commissioner concerning the public's need for proposed projects in their respective regions. The five health planning regions in Virginia are shown on the map in Appendix E.

Adjudication

If the DCOPN or one of the regional health planning agencies recommends denial of a COPN project, or if requested by any person seeking to demonstrate good cause, an informal fact-finding conference (IFFC) is held. The IFFC is the central feature of an informal adjudication process that serves as an administrative appeal prior to final decisions on projects by the Commissioner. These conferences, conducted in accordance with the Administrative Process Act, are held to provide the applicant an opportunity to submit information and testimony in support of a project application. An IFFC is also held when two or more requests are competing to provide the same or similar services in the same jurisdiction and one or more of the requests are recommended for denial. Another purpose for IFFCs is to permit persons opposed to a project, who have shown good cause, to voice their concerns.

There were 43 COPN applications heard before a VDH Adjudication Officer at 24 individual IFFC's in FY 2007. An additional two applications were exempted from participation in IFFC's with competing applicants due to an agreed upon stipulation agreement. Twenty-five of the COPN requests warranting an IFFC were approved in FY 2007. Fourteen requests were denied after the IFFC. Four projects heard in an IFFC in FY 2007 still have decisions pending and will be resolved in the Fall of 2007.

Table 2 illustrates the types of projects that were forwarded to an IFFC in FY 2007.

Table 2 Projects at IFFC in FY 2007

Project Type	Approved	Denied	Pending	Total
Establish/Relocate/Replace Hospital	2	1	0	3
Add Hospital Beds	2	1	0	3
Medical Rehabilitation Services	0	0	0	0
Magnetic Resonance Imaging	3	3	2	8
Computed Tomography Services	6	5	0	11
Positron Emission Tomography Services	0	0	0	0
Radiation Therapy / Establish Comprehensive Cancer Care Center	2	0	0	2
Establish Outpatient Surgery Hospital	4	2	2	8
Add Operating Rooms	3	1	0	4
Organ Transplant Program	0	0	0	0
Cardiac Catheterization	0	1	0	1
Neonatal Special Care	2	0	0	2
Nursing Home	1	0	0	1
TOTAL	25	14	4	43

Source: DCOPN

Judicial Review

COPN decision challenges are not limited to administrative appeals. Once an applicant has exhausted his administrative remedies, he can take his claim to state court for judicial review. Notice of appeal was filed for three decisions in FY 2007. None of the appeals were perfected with a filed appeal.

Reston Hospital Center, an HCA The Hospital Company facility, filed a notice of appeal of the State Health Commissioner's denial of a request to introduce stereotactic radiosurgery and radiation therapy services at the hospital. The Commissioner also denied similar competing requests by the Inova Health System and the Virginia Hospital Center. No appeal was filed.

In September 2006 the Commissioner denied a request from Riverside Health System to establish an outpatient surgical hospital in Planning District 20. The applicant filed a notice of appeal of that decision, but again, the appeal was not perfected.

In January 2007 Carilion Medical Center submitted a letter of intent to add operating rooms in a competitive review cycle with another applicant seeking to establish an outpatient surgical hospital. The Virginia Department of Health's Division of Certificate of Public Need refused to accept the letter as a valid letter of intend citing Carilion Medical Center's failure to construct the letter in accordance with the requirements of the regulations that govern the certificate of public need process in Virginia. Carilion Medical Center filed notice of appeal for the rejection of their letter of intent. The appeal was not perfected.

Certificate Surrenders

Infrequently, an applicant awarded a COPN may have reasons to surrender it. A typical reason is the applicant's inability to proceed with the project. In FY 2007 no certificates were surrendered.

Significant Changes

A significant change results when there has been any alteration, modification, or adjustment to a reviewable project for which a COPN approval has been issued. To be considered a significant change, the alteration, modification, or adjustment must change the site, increase the authorized capital expenditure by 10% or more, change the service proposed to be offered, or extend 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.

The Commissioner received fifteen requests for significant changes in FY 2007. Five requests were for extension of the schedule beyond the three-year generic time limit or the time authorized on the certificate, one of which also included a request to increase the authorized capital cost. Two requests were to increase the authorized capital cost by more than 10% but less than 20%, one request was to change the scope of services authorized and seven requests were to change the authorized site for the project. Fourteen of the fifteen reviewed requests were authorized. A request by Louise Obici Memorial Hospital to change the site of an authorized diagnostic imaging center within Planning District 20 was denied.

Competitive Nursing Home Review

Beginning in 1988, a general prohibition on the issuance of COPNs that would increase the supply of nursing home beds in the Commonwealth, commonly known as the "nursing home bed moratorium," was imposed. Effective July 1, 1996 the moratorium was replaced with an amended process governing COPN regulation of increases in nursing home bed supply (*Code of Virginia* §32.1-102.3:2). The new process requires the Commissioner to issue, at least annually in collaboration with Virginia's Department of Medical Assistance Services, a Request for Applications (RFA) that will target geographic areas for consideration of increased bed supply and establish competitive review cycles for the submission of applications.

The 2006 RFA was issued for the addition of 60 Medicaid-certified nursing facility beds in Planning District 12. A single applicant presented a request to develop the 60 nursing facility beds as a new nursing home in Chatham, Pittsylvania County. A decision on this request is expected in the Fall of 2007.

The 2007 RFA is expected to be issued in the Fall of 2007.

Timeliness Of COPN Application Review

As a result of legislative changes in 1999 and 2000, all COPN recommendations by DCOPN must be completed by the 70th day of the review cycle. Review cycles begin on the 10th day of each month. Only the applicant has the authority to extend the review schedule. In FY 2007 all COPN applications were reviewed within the statutory or applicant extended time limit. A flow chart illustrating COPN timelines as a result of these and other bills can be found at Appendix F. The flow chart identifies the time periods within which VDH is to perform certain COPN functions.

The *Code* also specifies that the Commissioner has up to 70 days from the close of the record to render a decision unless the schedule is extended by the applicant. Failure to do so results in a deemed approval of the request. In FY 2007, all of the Commissioner's decisions were rendered within the statutory or applicant extended time limit.

Legislation

In the 2007 session of the General Assembly, there were eight House bills and one Senate bill that addressed some aspect of the COPN program. There was no central theme to the types of bills considered during the session.

Table 3 COPN Bills in the 2007 Session of the Virginia General Assembly

Bill	Patron	Topic in Relation to COPN	Status
HB 1630	Del. Poisson	This bill continued, for a third extended period, a special exemption for the Falcon's Landing nursing home in Sterling, Virginia. The bill allows Falcon's Landing to admit patients with private payment sources that are not continuing care contract holders of the real estate cooperative until the continuing care contract holders constitute 85% of the occupancy of the nursing home, or July 1, 2013, whichever occurs first.	Passed
HB 1691	Del. Landes	The bill repealed §32.1-102.13 of the Code of Virginia, the section of the Code of Virginia added in 2000 that required the development of a transition for the elimination of the requirements for determination of need under the certificate of public need program. The transition was to have been made between July 1, 2001 and July 1, 2004.	Passed
HB 1992	Del. Wittman	The bill allows a specific nursing home to increase the number of beds in a planning district, irrespective of the results of a needs assessment determination that no additional beds were needed, evidenced by Requests for Applications issued by the Board of Health, by relocating the beds from a nursing home meeting certain criteria in another planning district.	Passed
HB 2155	Del. O'Bannon	The bill proposed to adopt, with some modification, most of the recommendations the Virginia Department of Health (VDH) made to the Certificate of Public Need Task Force of the House of Delegates' Health, Welfare, and Institutions Committee. The effect of HB 2155, if passed, would have been that the number of projects requiring a certificate of public need (COPN) would be reduced, providers not now subject to utilization reporting would be required to report to the Department, COPN applications would be required to be complete upon submission, informal fact-finding conferences would be based on the COPN requests as originally presented and the Regional Health Planning Agencies role in COPN review would be eliminated.	Stricken at the Request of the Patron
HB 2274	Del. Purkey	This bill would have amended §2.2-1504 to make it the policy of the Commonwealth to fund the cost of indigent care at Virginia Commonwealth University Health System, the University of Virginia Medical Center and the Eastern Virginia Medical School. It would have required a three-phase deregulation of Certificate of Public Need and required all facilities currently subject to COPN to be licensed by the department with a supporting requirement to report utilization and financial data to the Department. The bill provided for the monitoring of the impact deregulation has in Virginia.	Stricken at the Request of the Patron
HB 2276	Del. Purkey	The bill would have reduced the total timeframe available for the review of COPN requests to between 30 and 60 days (down from 190 days) and have reduced the COPN application fees to less than half their current level. COPN requests would have been categorized as either contested or uncontested, with the review schedule and fees based on the category assigned.	Failed to Report

HB 2277	Del. Purkey	This bill would have eliminated the role of the Regional Health Planning Agencies (RHPA) in the review of medical care facilities and services that require a Certificate of Public Need (COPN). The bill retained the provision that the State Health Commissioner and the appropriate RHPA be notified 30-calendar days in advance of any acquisition of existing medical facilities costing $600,000 or more. The bill would have also reduced the current allowed project review time from 190 days to 120 days.	Stricken at the Request of the Patron
HB 2546	Del. Hogan	The bill raised the requirement thresholds for miscellaneous capital projects by increasing the project costs as follows: (i) those requiring a COPN from $5 million to $15 million and (ii) those requiring registration from $1 million to $5 million. The bill also tied the thresholds to an inflation index. In addition, the bill clarified that the Commissioner can authorize cost overruns of more than 20% when the applicant can demonstrate that the cost increases are reasonable and necessary and do not result from any material expansion of the project as approved.	Passed
SB 740	Sen. Herring	The bill continued, for a third extended period, a special exemption for the Falcon's Landing nursing home in Sterling, Virginia. The bill allows Falcon's Landing to admit patients with private payment sources that are not continuing care contract holders of the real estate cooperative until the continuing care contract holders constitute 85% of the occupancy of the nursing home or July 1, 2013, whichever occurs first. This is a companion bill to HB1630.	Passed

Source: Virginia Legislative Information System

Regulation

The State Medical Facilities Plan (SMFP) is being reviewed and revised with the assistance of an advisory committee consisting of industry representatives from the Virginia Health Care Association, Virginia Hospital and Healthcare Association, the Medical Society of Virginia, and the Virginia Association of Regional Health Planning Agencies. The revised SMFP has been approved by the Department of Planning and Budget and the Governor's Office and was open to public comment in early FY 2005. In the Fall of 2005 the State Board of Health asked the Department revisit the draft SMFP to address some concerns voiced by the regulated community. Additional public comments were accepted and in April 2006 an advisory committee was reconvened to provide input to the revised SMFP. The reconvened advisory committee met through December 2006 to develop a consensus draft SMFP. The proposed SMFP was presented to the Board of Health at their February 2007 meeting. The Department was instructed to seek an additional comment period. Currently, the draft is proceeding through the necessary Executive Branch reviews in preparation for that re-proposal comment period.

FIVE-YEAR SCHEDULE FOR ANNUAL PROJECT CATEGORY ANALYSIS

Overview

For purposes of understanding the pattern of change in supply of many types of medical care facilities and services in Virginia since 1973, the year of the COPN program's inception, it is useful to understand that the program's 34 years can be segmented into three distinct periods. These periods can be characterized as regulatory, non-regulatory, and return to regulation. Those periods are: 1) 1973 to 1986, a period of relatively consistent regulation; 2) 1986 to 1992, a period of dramatic deregulation; and 3) 1992 to the present, a period in which Virginia not only revived COPN regulation but also began, in 1996, a process of review and consideration of the scope of the new regulatory environment.

Between 1973 and the mid-1980s, there was an effort, with mixed results, to ground COPN decision-making in established plans and standards of community need, based on an assumption that controlling the supply of medical care facilities and equipment is a viable strategy for aiding in the containment of medical care costs. Increases in the supply of medical care facilities in Virginia during this period were, in most cases, gradual and tended to be in balance with population growth, aging of the population, and increases in the population's use of emerging technological advances in medical diagnosis and treatment.

Beginning around 1986 and through 1992, there was a period of "de facto" (1986 to mid-1989) and formal (mid-1989 to mid-1992) deregulation. Few proposed non-nursing home projects were denied during this period, followed by the actual deregulation of most non-nursing home project categories. There was a growth of most specialized diagnostic and treatment facilities and services that were deregulated.

On July 1, 1992, Virginia "re-regulated" in response to the perceived excesses of the preceding years of deregulation, however no process had been set up to evaluate whether there were actually any service capacity excesses. Re-regulation brought the scope of COPN regulation on non-nursing home facilities and services to a level similar to that in place prior to 1989. Project review standards were updated and tightened and a more rigorous approach was taken to controlling growth in the supply of new medical care facilities and the proliferation of specialized services.

In recent years, VDH has taken an incremental approach to reviewing COPN regulation in response to legislative initiatives, by de-emphasizing regulation of replacement and smaller, non-clinically related expenditures, and focusing COPN regulation on new facilities development, new services development, and expansion of service capacity.

As a result of legislation passed during the 2000 session of the General Assembly, the Joint Commission on Health Care (JCHC) developed a plan for the phased deregulation of COPN in a manner that preserved the perceived positive aspects of the program. Due to the high cost of implementing the plan, it failed to gain General Assembly support in the 2001 session and was not enacted. The Act that required the development of the phased deregulation was repealed by the 2007 session of the General Assembly.

In accordance with section 32.1-102.12 of the *Code*, VDH has established a five-year schedule for analysis of all project categories within the current scope of COPN regulation that provides for analysis of at least three project categories per year. The five-year schedule is shown in Appendix G.

PROJECT CATEGORY ANALYSES

Section 32.1-102.12 of the *Code* provides guidance concerning the content of the project analysis. It requires the report to consider the appropriateness of continuing the certificate of public need program for each of the project categories. It also mandates that, in reviewing the project categories, the report address:

- The review time required during the past year for various project categories;
- The number of contested or opposed applications and the categories of these proposed projects;
- The number of applications upon which the health systems agencies (regional health planning agencies) have failed to act in accordance with the timelines of Section 32.1-102.B of the *Code*, and the number of deemed approvals from the Department because of their failure to comply with the timelines required by statute; and
- Any other data determined by the Commissioner to be relevant to the efficient operations of the program.

Section 32.1-102.12 of the *Code* requires this report to consider at least three COPN project categories. For FY 2007, the project categories are:

> General hospitals, general surgery, specialized cardiac services and organ and tissue transplantation.

The following list is the specific project definitions for the categories considered in this report:

- Establishment of a general hospital,
- An increase in the total number of beds in an existing medical care facility,
- Establishment of an outpatient surgical hospital or specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery,
- An increase in the number of operating rooms in an existing medical care facility,
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of cardiac catheterization,
- Introduction into an existing medical care facility of any new cardiac catheterization service,
- Addition or replacement by an existing medical care facility of equipment for the provision of cardiac catheterization, and
- Introduction into an existing medical care facility of any new organ or tissue transplantation service.

Prior to the 2007 General Assembly session, at the request of the Certificate of Public Need Task Force of the House Health, Welfare and Institutions (HWI) Committee, the Virginia Department of Health presented a new option for the modification of the program. This option, which would require legislative approval, included, among other changes, expansion of the current concept of a request for applications (RFA) by applying a prospective need analysis to the regulated service and accepting COPN applications for only those services proposed in locations identified in the RFA. These targeted RFAs would limit COPN review to just those services and areas in which a public need, as identified by the Department, exists, potentially stimulating development in some areas and limiting submission of more speculative applications elsewhere. Many elements of this option were included in several of the bills presented at the 2007 session of the Virginia General Assembly. The complete text of the recommendation to HWI is contained in Appendix H.

As the following discussions will note, the majority of COPN requests are approved. This does not imply that the COPN process is ineffective at limiting the number of new services or capital expenditures. Indications are that, for the most part, applicants are only submitting requests for projects that meet the criteria for approval and that the number of speculative requests has declined. While impossible to quantify, the presence of the deterrent effect of COPN on the development of duplicative, speculative or un-necessary services is generally accepted.

General Hospitals

The Code of Virginia, at §32.1-102.1, establishes the types of projects that require COPN authorization. They include the establishment of a medical care facility, which includes general hospitals, and an increase in the total number of beds in an existing medical care facility. A general hospital can be established as a new medical care facility requiring COPN authorization in one of two ways, either by replacement, in whole or part, of an existing general hospital at a new site or by the development of a new hospital.

The Code of Virginia defines hospital, at *Va Code* §32.1-123, "as any facility licensed pursuant to this article in which the primary function is the provision of diagnosis, of treatment, and of medical and nursing services, surgical or nonsurgical, for two or more nonrelated individuals, including hospitals known by varying nomenclature or designation such as sanatoriums, sanitariums and general, acute, rehabilitation, chronic disease, short-term, long-term, outpatient surgical, and inpatient or outpatient maternity hospitals." The Rules and Regulations for the Licensure of Hospitals in Virginia define general hospitals, at 12VAC 5-410-10, as "institutions as defined by §32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity."

Hospital inpatient beds are defined in the State Medical Facilities Plan, 12VAC 5-240-10, as "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 various nomenclatures including but not limited to; nursing facility 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 the maternity department and beds located in labor and birthing rooms, emergency rooms, preparation or anesthesia inductor rooms, diagnostic or treatment procedure rooms, or on-call staff rooms are excluded from this definition."

In the last five years there have been sixteen COPN requests for the establishment of a general hospital. Five of the requests were approved, four were denied, the applicant withdrew one application, and six are still pending a decision. An additional three letters of intent for projects involving the establishment of a general hospital were received but expired without an application being submitted.

In the same five years there were ten applications to add inpatient beds at existing medical care facilities, six of these were approved and four were denied. A total of 183 new beds were authorized as additions while 84 beds were denied.

Between the addition of new beds through the authorization of new hospitals and the addition of beds at existing hospitals there have been 413 new beds authorized. COPN authorization was given for the replacement of 894 beds in replacement hospitals. Three of the replacement hospitals elected to reduce their bed inventory by a total of 224 beds. This has resulted in a net increase of 189 inpatient beds in the Commonwealth.

Table 4 summarizes the types of projects requested and the disposition of those requests.

Table 4 General Hospital COPN Requests FY 2003 – FY 2007

	Total Requests	Approved	Denied	Withdrawn	Pending
General Hospitals					
Establish a general hospital by replacement and relocation	12	3	3	0	6
Establish a new general hospital	4	2	1	1	0
Total	16	5	4	1	6
Add new inpatient beds to an existing general hospital	10	6	4	0	0

Source: Division of Certificate of Public Need

Table 5 General Hospital Bed Requests FY 2003 – FY 2007

Beds		Approved	Denied	Reduced as Part of the Project	Pending
Beds in replacement hospitals		894	274	224	447
New beds in new hospitals		230	33	0	0
New beds added to existing hospitals		183	84	0	0
Total New Beds		413	117	0	0
Total Project Beds		**1,307**	**391**	**224**	**447**
Net Increase in Beds Approved new less reduced existing	**189**				

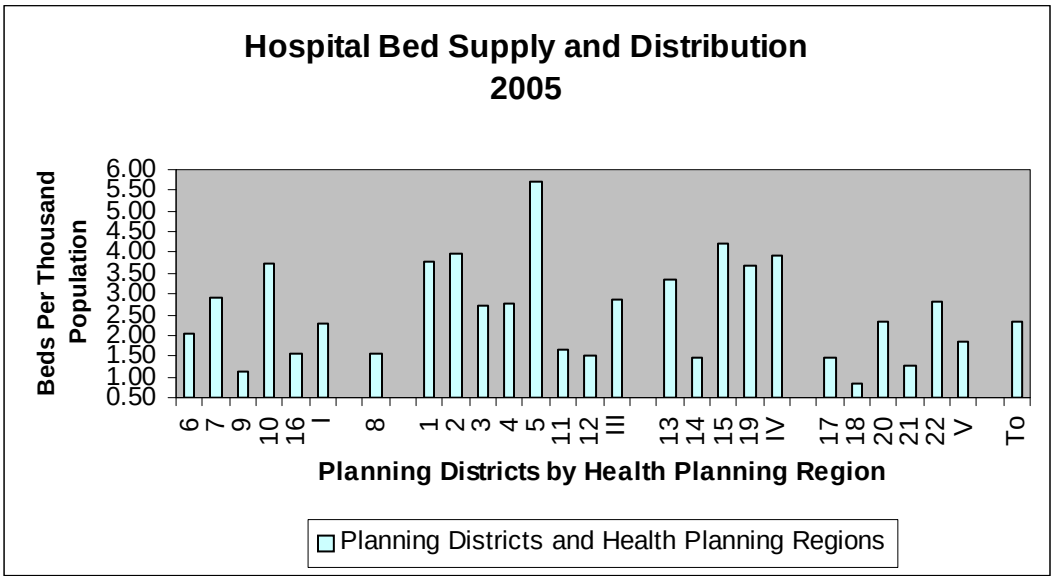
Source: Division of Certificate of Public Need

These eleven approved hospital and bed requests represent a five-year authorized capital outlay of $1.07 billion.

Except for four Planning Districts (14 - Piedmont, 16 - Rappahannock/Rapidan, 17 - Northern Neck, and 22 - Eastern Shore) every planning district in Virginia has at least two acute care hospitals. The density of acute care hospital beds ranges from 0.83 beds per thousand population in Planning District 18 (Middle Peninsula) to 5.7 beds per thousand population in Planning District 5 (Roanoke Valley). The average density in Virginia is 2.35 beds per thousand population.

Planning District 17, Rappahannock/Rapidan, which currently has a single hospital (Mary Washington Hospital) with 429 beds and a bed density of 1.27 beds per thousand population (ranked 15th of 22 planning districts) will be adding two new acute care hospitals which received COPN authorization this year. The addition of the 280 new acute care inpatient beds associated with these two new hospitals will increase the bed density to 2.55 beds per thousand population (based on 2005 population) in Planning District 16.

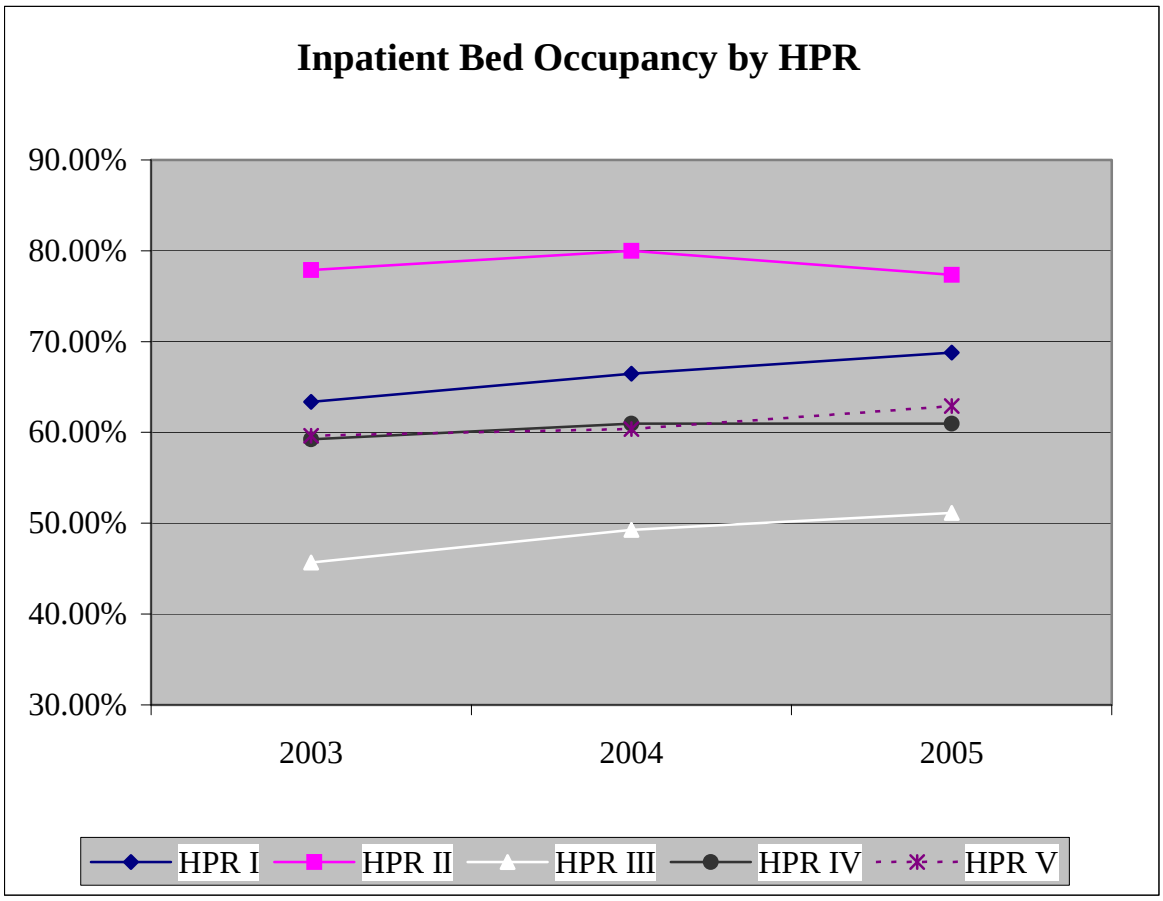
Chart I



In 2005, the most recent year for which data is available, average occupancy of acute care inpatient hospital beds in Virginia ranged from 16.2% of Smyth County Community Hospital's 154 licensed beds to 93.1% of Inova Fair Oaks Hospital's 196 licensed beds in 2005. Average occupancy of the Commonwealth's 18,835 acute care inpatient beds was 62.7% in 2005. Only 16,047 (85.2%) of the licensed acute care inpatient beds were staffed and open.

Over the three-year period 2003 to 2005 occupancy generally rose, at least slightly, in every Health Planning Region except Health Planning Region II, where occupancy essentially remained flat.

Chart 2



The State Health Commissioner has set aside most of the quantitative criteria found in the State Medical Facilities Plan for establishing need for additional acute care inpatient beds. The remaining numeric criterion is the requirement that no additional beds should be added in a planning district unless the average occupancy of all licensed beds in the planning was at least 85% in the relevant reporting period. The most recent period for which data is available, the relevant reporting period, is 2005. In 2005 no planning district met the 85% average occupancy standard.

The SMFP methodology and the twenty required considerations for determining need allow for factors beyond simple occupancy such that new beds can be authorized where need is found or reasonably projected for the near future, such as occurred in Planning District 16 with the authorization of two new hospitals. It appears that bed inventory is fairly well matched to meet or exceed the need for these beds throughout the Commonwealth.

Appropriateness of Continuing COPN for General Hospital Services

The COPN experience concerning general hospital services supports a contention that the program is appropriate for these services. The presence of a COPN program is thought to serve as a deterrent to speculative requests and facilitates a planning process for individual providers. The number of denied hospital and bed requests, in proportion to the total number of requests, tends to support this idea. However, there are alternatives to consider.

Options:
No Change: Continue applying the COPN program to the establishment of new and replacement hospitals and the addition of beds at existing hospitals as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. All key stakeholders would likely support this option. This option is consistent with the recommendation VDH made to the HWI COPN Task Force.

Minimal Change: In collaboration with the hospital industry, physicians, and consumers VDH could produce a comprehensive assessment of the State's needs for the various facilities and service capacity subject to COPN regulation, and by way of a targeted RFA, publicize the locations where a demonstrated need for new or additional facilities/capacity exists as a means of stimulating interest in requesting authorization for development of the service. Most providers, except some providers seeking competitive advantage despite actual public need, would likely support this option.

Deregulation: Support efforts to deregulate general hospital services. It is doubtful key stakeholders would support this option.

RECOMMENDATION: Consistent with the recommendation to the HWI COPN Task Force make no change outside the efforts to update the State Medical Facilities Plan.

General Surgery

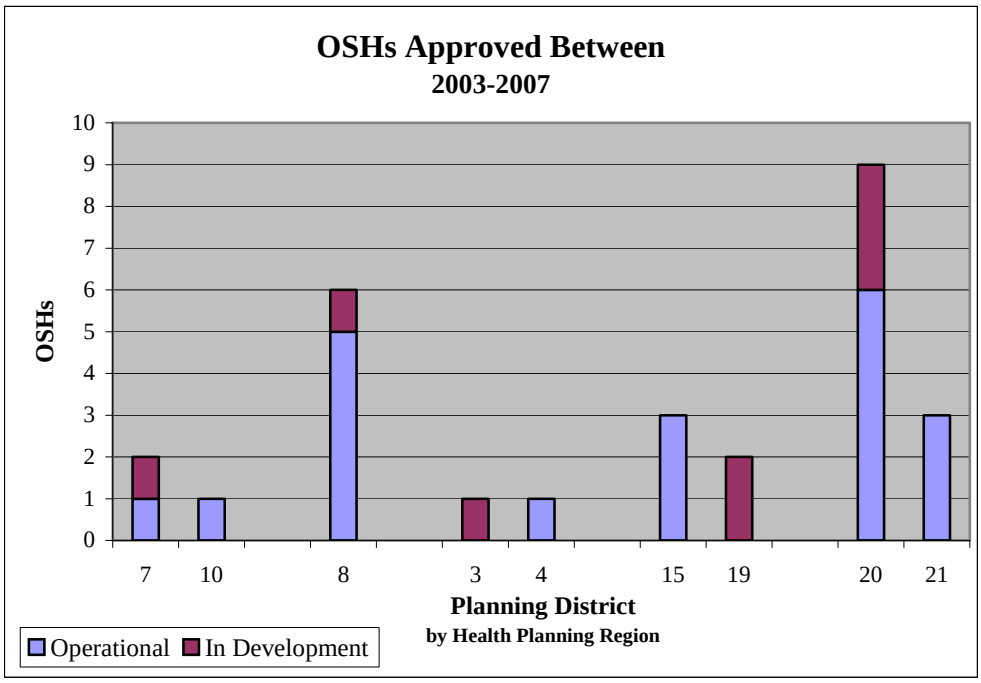
The Code of Virginia defines a project requiring COPN authorization, in part, as "Establishment of a medical care facility" and "an increase in the total number of … operating rooms in an existing medical care facility." A medical care facility is defined to include outpatient surgical hospitals, frequently referred to as ambulatory surgery centers.

In the last five years there have been 50 requests for general surgery services. Fourteen requests for additional operating rooms (ORs) were approved for the addition of 26 ORs with a

cumulative capital authorization of $23,047,453. Three requests for a total of seven ORs, with a cumulative capital cost of $7,376,818 were denied.

Requests for 28 new outpatient surgical hospitals were approved for a total of 53 new ORs and a capital cost of $123,023,258. Five requests for new outpatient surgical hospitals, with eight ORs, were denied at a capital cost avoidance of $30,344,078.

Twenty of the twenty-eight outpatient surgical hospitals approved in the last five years have been completed and are operational. Five of the eight OSHs still in development are being added in the Health Planning Regions (IV and V) that already have the highest number of OSHs.

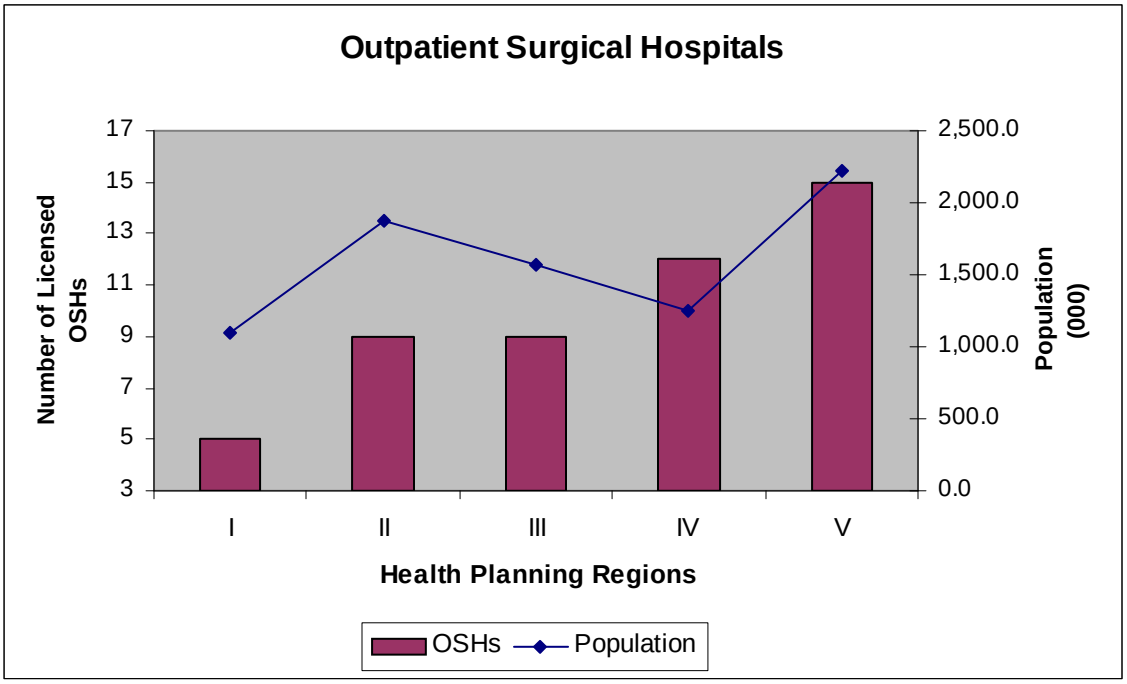


There are fifty OSHs operational throughout the Commonwealth, with eight more still in the development stages. Forty-one are general OSHs, five are eye surgery specialty centers, three are urology surgery specialty centers and one is a skin cancer specialty center. One of the OSHs still in development is an eye specialty center and the remaining seven are general surgery OSHs.

Except for Health Planning Regions III and IV, the number of OSHs generally follow population, e.g., regions with higher population have more OSHs. OSHs are distributed throughout Health Planning Region III except for Planning Districts 1 and 2. These two westernmost planning districts in Virginia account for 13.7% of the population of the region. Sparse population over a wide area and mountainous terrain in these planning districts would make the operation of an OSH difficult.

All of Health Planning Region IV's OSHs are in Planning District 15, specifically the 12 OSHs in Health Planning Region IV are in the Richmond / Mechanicsville / Midlothian area. Two additional OSHs have been approved for the region in Colonial Heights (Planning District 19).

Chart 3



The average capital expenditure per request to establish an OSH was $4.4 million, or $2.3 million per operating room. The average cost to add operating rooms to existing hospitals was $2.2 million per project, or $1.1 million per operating room.

The lack of denied requests should not detract from the usefulness of requiring COPN review of this type of request. The COPN process requires a close review by both internal and external parties. Such a review can only lead to well thought out requests and the abandonment of less feasible projects.

Appropriateness of Continuing COPN for General Surgery Services

The COPN experience concerning general surgery services supports a contention that the program is appropriate for these services. The presence of a COPN program is thought to serve as a deterrent to speculative requests and facilitates a planning process for individual providers. However, there are alternatives to consider.

Options:
No Change: Continue applying the COPN program to the establishment of new outpatient surgical hospitals and the addition of operating rooms at existing hospitals as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. All key stakeholders would likely support this option. This option is consistent with the recommendation VDH made to the HWI COPN Task Force.

Minimal Change: In collaboration with the hospital industry, physicians, and consumers VDH could produce a comprehensive assessment of the State's needs for the various facilities and service capacity subject to COPN regulation, and by way of a targeted RFA, publicize the locations where a demonstrated need for new or additional facilities/capacity exists as a means of stimulating interest in requesting authorization for development of the service. Most providers, except some providers seeking competitive advantage despite actual public need, would likely support this option.

Deregulation: Support efforts to deregulate general surgery services. It is doubtful key stakeholders would support this option.

RECOMMENDATION: Consistent with the recommendation to the HWI COPN Task Force make no change outside the efforts to update the State Medical Facilities Plan.

Specialized Cardiac Services

The SMFP defines cardiac catheterization as "a procedure performed in a cardiac catheterization room or laboratory whereby a flexible tube is inserted into the patient's body, usually through an extremity blood vessel, and advanced under fluoroscopic guidance into the heart chambers to perform a hemodynamic, electrophysiologic or angiographic examination of the left or right heart chamber, or coronary arteries. Therapeutic intervention in a coronary artery may also be performed using cardiac catheterization."

The *Code of Virginia*, at §32.1-102.1, defines a project requiring COPN authorization, in part, as "Introduction into an existing medical care facility of any new cardiac catheterization . . . which the facility has never provided or has not provided in the previous 12 months" and "The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization . . ."

In addition to the COPN requests that were approved and listed in the following tables, there were also three requests filed in FY 2003 that were withdrawn prior to responding to completeness questions. In FY 2006 one request was delayed by the applicant and has not been reactivated as scheduled and the State Health Commissioner denied the only request filed in FY 2007.

Table 6 Authorizations to Introduce or Add Cardiac Catheterization Laboratories in FY 2003 - 2007

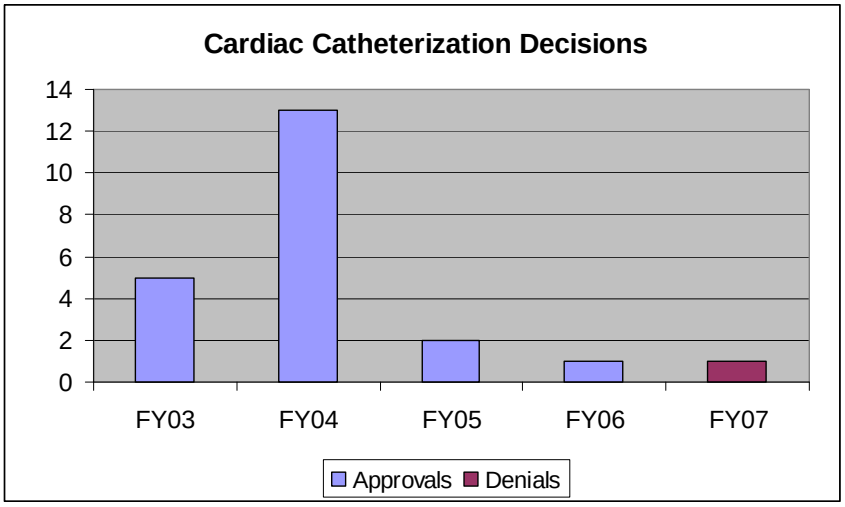
Applicant	Project	Requested Capital Expenditure	Date COPN Issued
Sentara Norfolk General Hospital	Addition of Open Heart OR and Cardiac Catheterization Lab	$2,692,900	3/19/2003
Maryview Medical Center	Add Second Cardiac Catheterization Lab	$2,052,669	3/19/2003
Chesapeake General Hospital	Add Second Cardiac Catheterization Lab	$1,416,000	3/19/2003
Lewis-Gale Medical Center	Add Cardiac Catheterization Equipment	$1,596,648	6/15/2003
Bon Secours Memorial Regional Medical Center	Add 3rd Cardiac Catheterization Lab	$2,570,899	6/16/2003
Lee Regional Medical Center	Introduce Cardiac Catheterization Services	$549,500	12/15/2003
Community Memorial Healthcenter	Introduce Mobile Cardiac Catheterization Services	$25,000	12/15/2003
Bon Secours St. Mary's Hospital	Add 4th Cardiac Catheterization Lab	$3,805,537	2/27/2004
Henrico Doctors' Hospital-Forrest	Add 4th Cardiac Catheterization Lab	$1,481,090	2/27/2004
Chippenham & Johnston-Willis Hospitals, Inc.	Add 6th Cardiac Catheterization Lab	$782,456	3/19/2004
Bon Secours St. Francis Medical Center	Introduction of Cardiac Catheterization Services	$1,753,224	3/19/2004
Norton Community Hospital	Introduce Cardiac Catheterization Services, Mobile Site	$89,000	6/15/2004
Winchester Medical Center	Add a Cardiac Catheterization Lab	$2,940,100	6/21/2004
Rockingham Memorial Hospital	Add a Cardiac Catheterization Lab	$2,633,380	6/21/2004
Martha Jefferson Hospital	Add a Cardiac Catheterization Lab	$0	7/30/2004
Sentara Bayside Hospital	Introduce Cardiac Catheterization Services	$2,143,700	7/30/2004
Sentara CarePlex Hospital	Add a Cardiac Catheterization Lab	$0	12/13/2004
Loudoun Hospital Center	Introduce Cardiac Catheterization Services	$2,991,250	1/11/2005
Memorial Hospital of Martinsville and Henry County	Add One Cardiac Catheterization Lab	$2,692,000	6/15/2005
Mary Washington Hospital, Inc.	Add One Cardiac Catheterization Lab	$2,434,500	6/15/2005
Carilion New River Valley Medical Center	Add One Cardiac Catheterization Lab	$1,592,836	12/15/2005

In FY 2003 eight certificate of public need applications were filed for cardiac catheterization services. Of these, five were approved and three were withdrawn. Three of the approved projects were issued with indigent care conditions. In FY 2004 13 certificates of public need applications were filed for cardiac catheterization services. All were approved and only two were issued without indigent care conditions. In FY 2005 two certificate of public need applications were filed for cardiac catheterization services. Both were approved with indigent care conditions. In FY 2006 two certificate of public need applications were filed for cardiac catheterization services.

One was approved with no indigent care condition and the other application was delayed and has not been reviewed. In FY 2007 one certificate of public need application was filed for cardiac catheterization services and was denied.

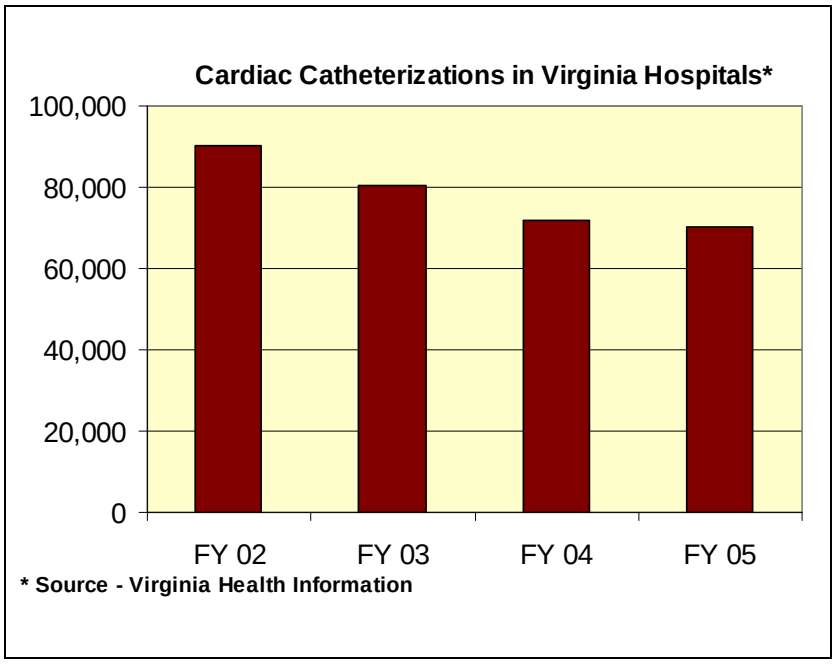
Chart 4 shows the decisions involving cardiac catheterization services for the last five fiscal years. With a marked decline in requests, the vast majority of the decisions have been approvals prior to FY 2007.

Chart 4



Virginia has experienced a steady decline on overall cardiac catheterizations performed.

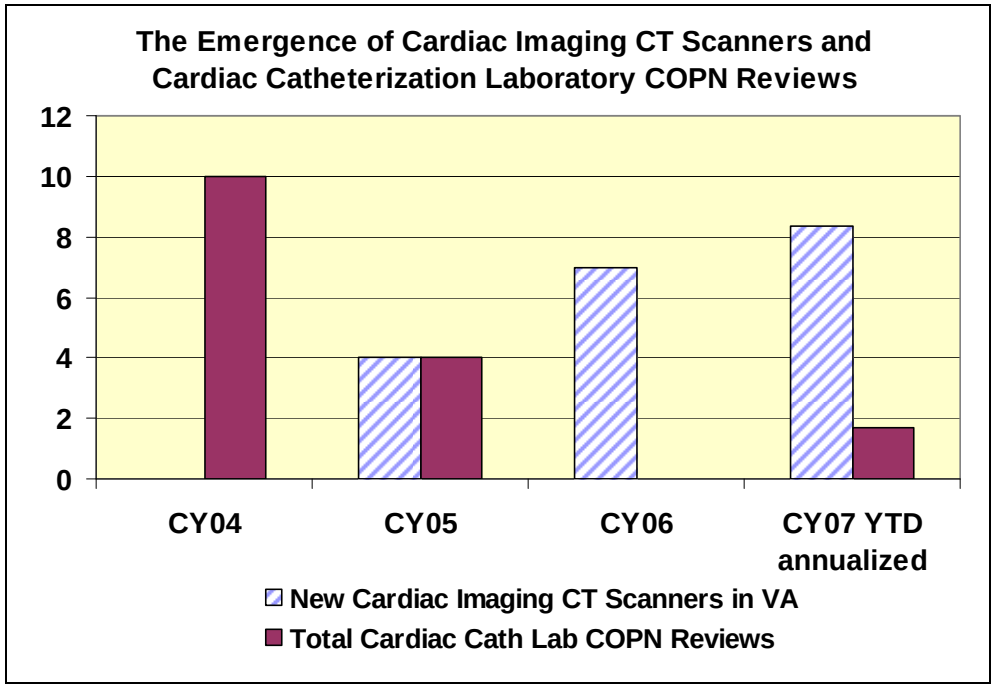
Chart 5



According to information recently published by the American Heart Association (AHA), the decline in cardiac catheterizations should not lead to the assumption that there is a decrease in the incidence or prevalence of coronary heart disease. The AHA points out that the aging of the population, the explosive increase in the prevalence of obesity and type 2 diabetes, the unattended risk factors in the younger generations all continue to contribute to the 30% increase in cardiovascular disease over the last 30 years.

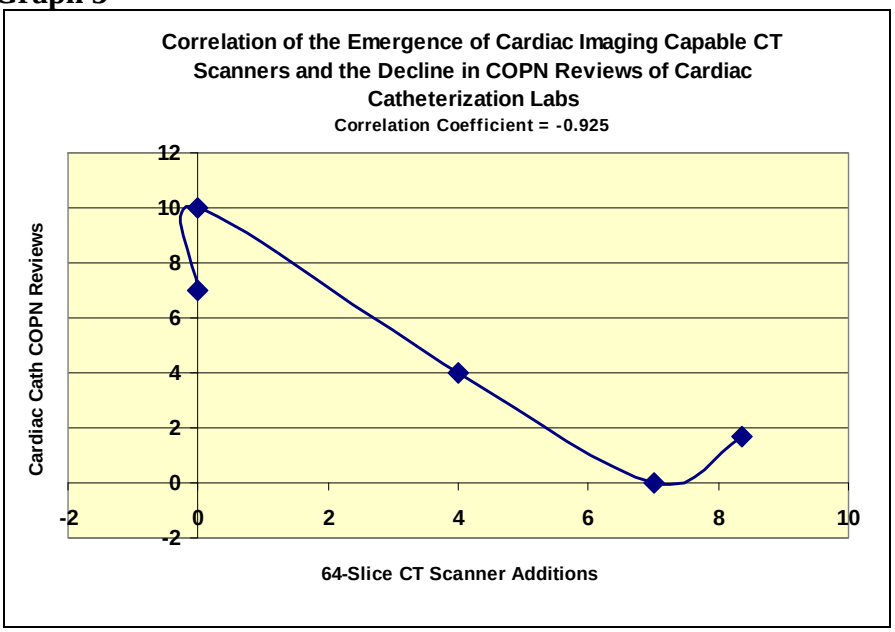
Within the last few years in Virginia COPN reviews and major medical equipment replacement registrations have shown the emergence of, and rapid increase in, the number of computed tomography (CT) scanners capable of detailed cardiac imaging. These ultrafast CT scanners use their imaging speed, timed to individual heartbeats, and advanced imaging software to non-invasively create detailed three dimensional pictures of the heart and the coronary arteries.

Chart 6



There is a strong statistical relationship between the emergence of 64-slice CT scanners and the decline in COPN cardiac catheterization laboratory projects. However, in some cases, a correlation may only imply causation meaning that there can be a strong correlation between two events that are both caused by a third event. As no actual data is yet available showing the number of cardiac CT scans performed in Virginia, the effect of the availability of 64-slice CT scanners on the use of cardiac catheterization laboratories will have to be revisited in the future.

Graph 3



Appropriateness of Continuing COPN for Cardiac Catheterization Services

Even though there has been a decline in the utilization of cardiac catheterization laboratories, if caused by the emergence of 64-slice CT scanners the decline would only be in the use of catheterization for diagnostic procedures. The cardiac catheterization laboratories will still be needed for all therapeutic procedures and still for many diagnostic procedures and the technology remains very capital intensive. The cardiology community has been careful in the scientific literature to note that coronary CT imaging is not (yet) considered a replacement for traditional cardiac catheterization.

The recent COPN experience concerning cardiac catheterization services should not be used to support a contention that the program is not appropriate for these services. Therapeutic cardiac catheterization procedures will continue to be needed and many diagnostic catheterizations will continue if indicated by the patient's condition. Also the CT technology is so new, its true usefulness is not completely known.

The presence of a COPN program is thought to serve as a deterrent to speculative requests. With the declining utilization of cardiac catheterization laboratories, there is growing excess capacity in existing service sites and, absent the tempering effect of a COPN program, these otherwise un-requested speculative projects would be carried forth, resulting in, potentially, gross duplication of services. One of the goals of the COPN program is the promotion of comprehensive health planning to meet the needs of the public. Planning that results in the decision to not pursue the development of a service is the successful meeting of that goal. However, there are alternatives to consider.

Options:

No Change: Continue applying the COPN program to the establishment of new cardiac catheterization service and the addition of cardiac catheterization services at existing programs as

currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. This option would likely be supported by everyone except some hospitals or freestanding facilities seeking to introduce cardiac catheterization services. This option is consistent with the recommendation VDH made to the HWI COPN Task Force.

Minimal Change: In collaboration with the hospital industry, physicians, consumers and advocates, VDH could produce a comprehensive assessment of the State's needs for the various facilities and service capacity subject to COPN regulation and by way of a targeted RFA, publicize the locations where a demonstrated need for new or additional facilities/capacity exists as a means of stimulating interest in requesting authorization for development of the service. This option would likely be supported by everyone except some hospitals or freestanding facilities seeking to introduce cardiac catheterization services irrespective of actual need.

Deregulation: Support efforts to deregulate cardiac catheterization services. Hospitals with authorization to provide cardiac catheterization services and other existing providers of the service will likely oppose deregulation. Facilities seeking to introduce the service would be likely to support deregulation.

RECOMMENDATION: Consistent with the recommendation to the HWI COPN Task Force make no change outside the efforts to update the State Medical Facilities Plan.

Organ and Tissue Transplantation

At Va Code §32.1-102.1 a project requiring COPN authorization is defined to include the introduction into an existing medical care facility any new organ or tissue transplant program. The State Medical Facilities Plan defines organ and organ system as "any number of clinically distinct components of the human body containing tissues performing a function for which it is especially adapted. Distinct organ/organ systems include, but are not limited to, kidney, heart, heart/lung, liver, and pancreas." A project for kidney/pancreas has also been reviewed in Virginia.

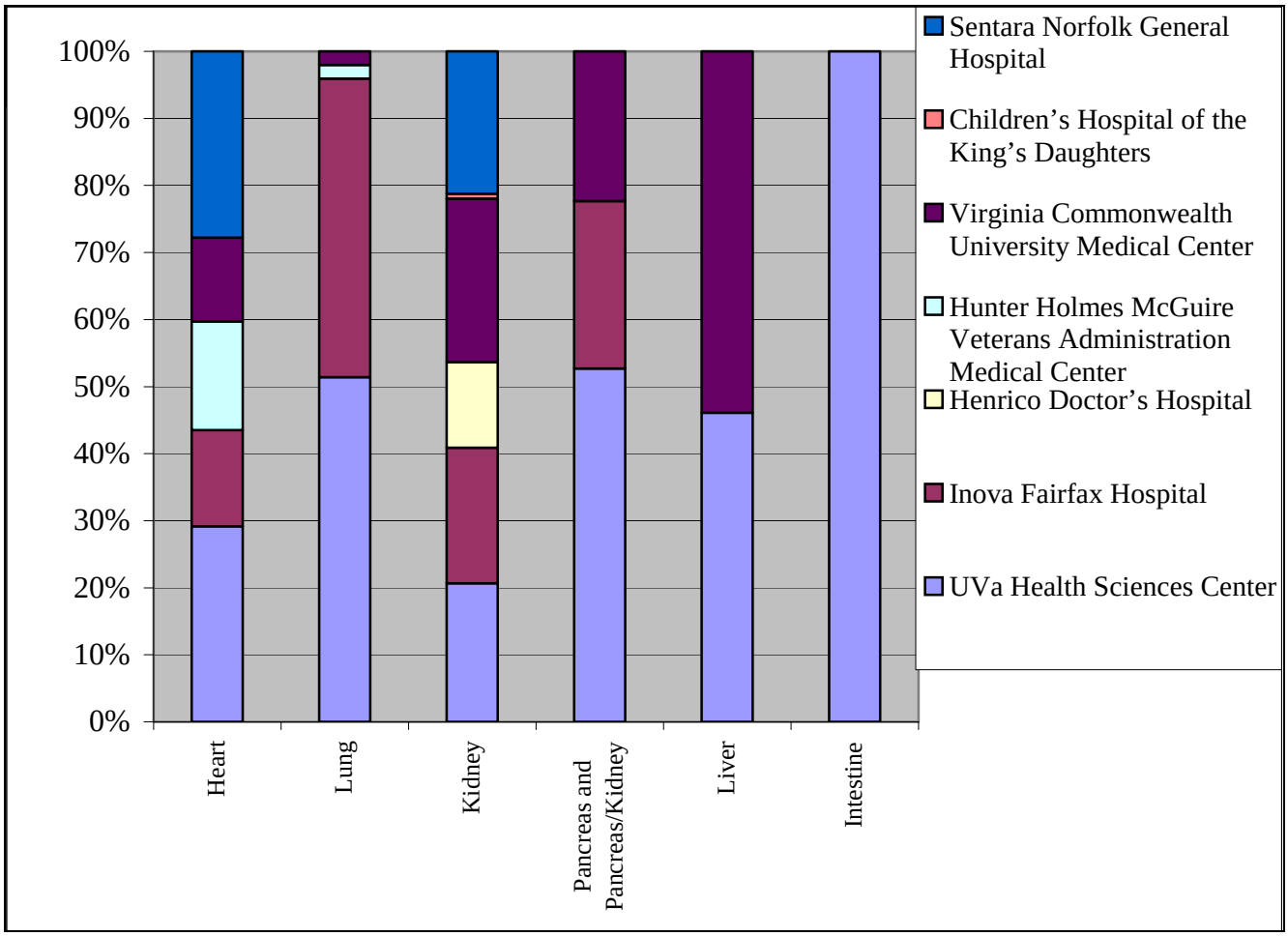
According to the United Network for Organ Sharing (UNOS), under federal contract as the Organ Procurement and Transplantation Network (OPTN), there are seven recognized transplant centers in Virginia. Health Planning Region III is the only region in Virginia that does not have a transplant center. Three of the seven centers offer transplant of a single organ, Henrico Doctor's Hospital and Children's Hospital of the King's Daughters offer only kidney transplant and the Hunter Holmes McGuire Veteran's Administration Hospital offers only heart transplant. Three of the seven centers are located in Planning District 15 of Health Planning Region IV, two of the single organ centers, Henrico Doctor's Hospital and Hunter Holmes McGuire Veterans Administration Hospital, and a comprehensive center, the Virginia Commonwealth University Medical Center, which performs transplant of four organs/systems.

Table 7

	UVa Health Sciences Center	Inova Fairfax Hospital	Henrico Doctor's Hospital	Hunter Holmes McGuire Veterans Administration Medical Center	Virginia Commonwealth University Medical Center	Children's Hospital of the King's Daughters	Sentara Norfolk General Hospital
Health Planning Region	I	II	IV	IV	IV	V	V
Planning District	10	8	15	15	15	20	20
Organ/Organ Systems Transplanted							
Heart	X	X		X	X		X
Heart / Lung		X					
Lung	X	X					
Kidney	X	X	X		X	X	X
Pancreas	X	X			X		X
Liver	X				X		
Intestine	X						

Source: UNOS

Chart 7



Source: UNOS

Chart 7 shows the relative transplant case volume for each of Virginia's transplant centers, by organ/system. As would be expected the more comprehensive centers provide a higher proportion of the transplants for each of the organ/systems types. The University of Virginia Health Sciences Center is the most comprehensive transplant center in Virginia, offering all six of the organ/systems for transplant. They are the only center in Virginia offering intestine transplant and, over the last five years, have performed more than half the pancreas or kidney/pancreas, and lung transplants in Virginia.

Over the past fourteen years several centers have either stopped performing transplant altogether or have not transplanted specific organs/systems for at least a year. These Centers are listed in Table 8.

Table 8 Dropped Transplant Programs

Provider	Organ or System	Last Year Performed
Children's Hospital of the King's Daughters	Heart	1997
Henrico Doctor's Hospital	Heart	2006
Virginia Commonwealth University Medical Center	Heart/Lung	1993
Hunter Holmes McGuire VA Medical Center	Heart/Lung	1994
Sentara Norfolk General Hospital	Heart/Lung	1996
University of Virginia Medical Center	Heart/Lung	1997
Carilion Roanoke Memorial Hospital	Kidney	1997
Henrico Doctor's Hospital	Liver	1991
Inova Fairfax Hospital	Liver	2006
Sentara Norfolk General Hospital	Lung	2003
Hunter Holmes McGuire VA Medical Center	Lung	2003
Virginia Commonwealth University Medical Center	Lung	2006

Source: UNOS

The performance of Virginia transplant centers, as reported by UNOS and measured as patient survival at one-year post transplant, is as predicted by UNOS, which is at the acceptable level.

In the last five years there have been two requests for COPN authorization for transplant services. Both requests were authorized. The first was a request by Children's Hospital of the King's Daughters to offer kidney transplant. This request was to essentially take the pediatric kidney transplant cases from the adjacent Sentara Norfolk General Hospital and perform them in the specialized pediatric hospital. The transplant staff remained the same, but the patients were treated in an age appropriate facility.

The second request was by Sentara Norfolk General Hospital, an established transplant center, to introduce pancreas transplant services. The applicant expected the program to be operational by March 2005. As yet, Sentara Norfolk General Hospital has not requested an indefinite extension to their COPN, indicating completion of the project, nor have they performed any pancreas or kidney/pancreas transplants, although UNOS reports three pancreas transplant candidates on the waiting list at Sentara Norfolk General Hospital.

Appropriateness of Continuing COPN for Transplant Services

The availability of transplant services is not driven so much by the availability of centers capable of performing the transplant but by the availability of organs to transplant. In Virginia 40% of patients wait more than two years for a kidney, pancreas or kidney/pancreas transplant, 50% of patients wait more than three years for a liver or heart transplant and 40% of patients wait more than five years for a lung transplant. Virginia's experience with wait times is a little better than the national average for pancreas and lung transplant waiting lists and a little worse than the national average for heart transplant waiting lists.

The concentration of transplant cases in a few centers is viewed as a means of also concentrating the expertise of not only the transplant surgeon but also of the entire transplant care team. It also serves to make the management of the wait lists more controllable, thereby decreasing wait list mortality. Employment of the COPN program to limit the number of transplant centers remains an appropriate use of the program.

Options:
No Change: Continue applying the COPN program to the establishment of new transplant services as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. This option would likely be supported by everyone except some hospitals seeking to introduce transplant services. This option is consistent with the recommendation VDH made to the HWI COPN Task Force.

Minimal Change: In collaboration with the hospital industry, physicians, consumers and advocates, VDH could produce a comprehensive assessment of the State's needs for the various facilities and service capacity subject to COPN regulation and by way of a targeted RFA, publicize the locations where a demonstrated need for new or additional facilities/capacity exists as a means of stimulating interest in requesting authorization for development of the service. This option would likely be supported by everyone except some hospitals seeking to introduce transplant services.

Deregulation: Support efforts to deregulate transplant services. Hospitals with authorization to provide transplant services will likely oppose deregulation. Facilities seeking to introduce the service would be likely to support deregulation.

RECOMMENDATION: Consistent with the recommendation to the HWI COPN Task Force make no change outside the efforts to update the State Medical Facilities Plan.

Effectiveness of the COPN Application Review Procedures for FY 2007 Project Categories

The statute defining the contents of this report requires an analysis of the effectiveness of the application review procedures used by the regional health planning agencies and VDH. An analysis of effectiveness must detail the review time required during the past year for various project categories. To ensure consistency, the project categories, for purposes of this document, are the same project categories that were selected for review during FY 2007. The statute also

dictates that this report address the number of contested or opposed applications and the project categories of these contested or opposed projects. Information concerning all contested or opposed COPNs for FY 2007 can be found under the section entitled "Judicial Review" as well as the section labeled "Adjudication." Finally, the statute requires the report to identify the number of projects automatically approved from the regional health planning agencies because of their failure to comply with the statutory timelines.

The application review process was completed in a timely manner as mandated by the *Code*. In FY 2007 there were no requests recommended for approval from a regional health planning agency due to their failure to act in accordance with statutory timelines. At no time did delays occur in receipt of a recommendation from a regional health planning agency such that there was an impact in DCOPN's ability to make a recommendation or in the Commissioner's ability to make a decision. Where appropriate, projects were authorized, but more importantly, projects were denied and prevented from proceeding when there was no need for the project demonstrated. This avoided duplication of services and costs without adversely impacting access to care.

Other Data Relevant to the Efficient Operation of COPN Program

The final consideration in the analysis of project categories is that the Commissioner include any other data he determines to be relevant to the efficient operation of the COPN program. Nationally, the debate continues as to the usefulness of COPN, with no clear conclusions drawn. Like Virginia other states are adjusting their certificate of public need programs. In their 2006 session Connecticut increased their capital expenditure threshold for projects that require certificate of public need authorization to $3 million and Florida extended their moratorium on nursing home beds. In their 2007 sessions Alaska is considering limiting certificate of public need to just jurisdictions with small populations or critical access hospitals and a bill to repeal certificate of public need for all except specialty hospitals failed Mississippi.

Some local governments, without the benefit of, or with only a weak, state certificate of need program are taking or considering actions to limit health care growth in their jurisdictions, e.g., several counties in Indiana attempted to enact local level certificate of need programs but failed due to conflict with State laws.

Accessibility of Regulated Health Care Services by the Indigent

One of the 20 factors considered in the COPN process is whether the indigent have access to health care services. Applicants that have not demonstrated a historical commitment to charity care, consistent with other providers in their health service area, may have a "condition" to provide some level of charity care placed upon any COPNs they are awarded.

Prior to 2002 most conditioned COPNs included a requirement to report compliance with the condition for three years. The language used for most conditions on COPNs since 2002 has dropped the three-year reporting requirement in favor of an annual reporting requirement over the life of the service.

Beginning in June 2002, the DCOPN began recommending that the certificate language for the "conditioning" of COPNs be augmented to include the second type of condition allowed in the *Code*, namely that the applicant facilitate the development and operation of primary care for special populations. This added condition requirement allows an applicant a further opportunity for meeting the conditions placed on a COPN. Facilities that are unable to meet the conditioned requirement to provide service directly as charity care to the indigent can meet the obligation by supporting, including by direct monetary support, the development and operation of primary care through safety net providers such as the free clinics or community health centers. COPN holders opting to meet their condition obligation in this manner do so by making their contribution to the Virginia Association of Free Clinics, the Virginia Health Care Foundation, and/or the Virginia Primary Care Association, Inc., each of which has a memorandum of understanding with the Virginia Department of Health to distribute all such funds received.

In March 2004 a Guidance Document was issued to provide direction for compliance with indigent care and primary care conditions on COPNs. This Guidance Document established a definition of indigent that includes individuals whose household income is at or below 200% of the Federal non-farm poverty level (prior practice had defined indigent as 100% of the Federal non-farm poverty level). It also provided a simplified mechanism for COPN holders to report compliance with conditions.

In FY 2007 46 COPNs were issued with a condition for the performance of a certain level of charity, indigent and/or primary care. This represents 58.2% of all COPNs issued in FY 2007. The table presented in Appendix I lists all COPNs issued in FY 2007 with a condition that the applicant provide free or reduced cost care for the indigent and facilitate the development and operation of primary care for special populations.

Failure to comply with obligations accepted as conditions on the receipt of a COPN can have negative consequences for providers. There are provisions for fines, revocation of the COPN, and conditioning the issuance or renewal of a facility license for failure to meet the obligations of the condition. The Guidance Document already discussed was developed, at least in part, to help providers meet their agreed upon conditions when, for a host of legitimate reasons, they could not meet the condition through the provision of the conditioned service.

There are 128 active COPN authorized and conditioned projects, (i.e., those that are operational and have annual reporting requirements). This number is up from 89 in FY 2006. The increase reflects the number of conditioned projects that have been completed less the number of projects that no longer are required to report. For FY 2007 only 35 active COPN projects (27.3%), reported compliance with conditions. While lower than FY 2006, it is still an improvement over the 14% that were in compliance in FY 2004. Non-reporting facilities are being contacted with reminders and those failing to meet their conditioned obligation are being reminded of the options in the Guidance Document.

Attachment J is a list of organizations holding COPNs that were issued conditioned on the performance of a certain level of charity, indigent and/or primary care. The list also shows the number of conditioned COPN projects that each organization has reported compliance on the

condition and the number of COPN projects for which a report of compliance on the condition was due in FY 2007 and was not received. There are a total of 66 organizations with conditioned projects that are expected to report compliance.

Relevance of COPN to Quality of Care Rendered by Regulated Facilities

One of the features attributed to the COPN program is its goal of assuring quality by instituting volume thresholds. One study from the University of California at San Francisco concluded that there is scientific evidence supporting the contention that, for some procedures or diagnoses, higher hospital volume is associated with lower patient mortality. Other studies refute any correlation between COPN programs and quality of services rendered. However, there is little dispute about the relationship between quality and patient volume in open-heart surgery, cardiac catheterization and organ transplant services. By using COPN to limit the number of service providers, patient care is concentrated in centers where the service volume is maintained at a high level, which statistically allows for better patient outcomes. There is an intuitive logic to the idea that the more of a certain kind of care that is delivered the more successful the provider would be in providing it, and hence, the better the outcome for the patient.

Equipment Registration

The legislation defining the scope of this report requires an analysis of equipment registrations, including the type of equipment, whether the equipment is an addition or a replacement, and the equipment costs.

In FY 2007, there were thirty-one equipment replacement registrations (Table 9) and nineteen to register capital expenditures in excess of $1 million (Table 10). All registered expenditures appeared to be appropriate to the mission of the facility and to the life cycle of the equipment being replaced.

Table 9 Equipment Registrations

Project Type	Number of Registrations	Capital Expenditure
Replace cardiac catheterization equipment	4	$4,029,484
Replace lithotripsy equipment	1	$451,156
Replace MRI Equipment	5	$10,650,867
Replace computed tomography equipment	14	$18,146,906
Replace linear accelerator	7	$22,558,046
TOTAL	31	$55,836,459

Table 10 Capital Expense Registrations

Project Type	Number of Registrations	Capital Expenditure
Hospital renovations, clinical departments	10	$23,481,581
Hospital renovations, support departments	2	$7,414,784
Facility infrastructure	3	$4,632,650
Major software/computer upgrades	3	$8,893,824
Miscellaneous	1	$2,650,000
TOTAL	19	$47,072,839

Appendix A

§ 32.1-102.12. Report required.

The Commissioner shall annually report to the Governor and the General Assembly on the status of Virginia's certificate of public need program. The report shall be issued by October 1 of each year and shall include, but need not be limited to:

1. A summary of the Commissioner's actions during the previous fiscal year pursuant to this article;

2. A five-year schedule for analysis of all project categories, which provides for analysis of at least three project categories per year;

3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;

4. An analysis of the effectiveness of the application review procedures used by the health systems agencies and the Department required by § 32.1-102.6 which details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the health systems agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, and the number of deemed approvals from the Department because of their failure to comply with the timelines required by § 32.1-102.6 E, and any other data determined by the Commissioner to be relevant to the efficient operation of the program;

5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;

6. An analysis of the accessibility by the indigent to care provided by the medical care facilities regulated pursuant to this article and the relevance of this article to such access;

7. An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article; and

8. An analysis of equipment registrations required pursuant to § 32.1-102.1:1, including the type of equipment, whether an addition or replacement, and the equipment costs.

(1997, c. 462; 1999, cc. 899, 922.)

Appendix B

12VAC5-220-10. Definitions.

"Medical care facility" means any institution, place, building, or agency, at a single site, whether or not licensed or required to be licensed by the board or the State Mental Health, Mental Retardation and Substance Abuse Services Board, whether operated for profit or nonprofit and whether privately owned or operated or owned or operated by a local governmental unit, (i) by or in which facilities are maintained, furnished, conducted, operated, or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical, of two or more nonrelated mentally or physically sick or injured persons, or for the care of two or more nonrelated persons requiring or receiving medical, surgical, or nursing attention or services as acute, chronic, convalescent, aged, physically disabled, or crippled or (ii) which is the recipient of reimbursements from third party health insurance programs or prepaid medical service plans. For purposes of this chapter, only the following medical care facility classifications shall be subject to review:

1. General hospitals.

2. Sanitariums.

3. Nursing homes.

4. Intermediate care facilities, except those intermediate care facilities established for the mentally retarded that have no more than 12 beds and are in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

5. Extended care facilities.

6. Mental hospitals.

7. Mental retardation facilities.

8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts.

9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

The term “medical Care facility” shall not include any facility of (i) the Department of Mental Health, Mental Retardation and Substance Abuse Services; (ii) any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community

services board under the Department of Mental Health, Mental Retardation and Substance Abuse Services Comprehensive Plan; (iii) an intermediate care facility for the mentally retarded that has no more than 12 beds and is in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Mental Health, Mental Retardation and Substance Abuse Services; (iv) a physician's office, except that portion of the physician's office described above in subdivision 9 of the definition of "medical care facility"; or (v) the Woodrow Wilson Rehabilitation Center of the Virginia Department of Rehabilitative Services. " Medical care facility shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging.

"Project" means:

1. The establishment of a medical care facility.

2. An increase in the total number of beds or operating rooms in an existing or authorized medical care facility.

3. Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any two-year period; however, a hospital shall not be required to obtain a certificate for the use of 10% of its beds as nursing home beds as provided in §32.1-132;

4. The introduction into any existing medical care facility of any new nursing home service, such as intermediate care facility services, extended care facility services or skilled nursing facility services, regardless of the type of medical care facility in which those services are provided;

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomography (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care services, obstetrical services, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, substance abuse treatment, or such other specialty clinical services as may be designated by the Board by regulation, which the facility has never provided or has not provided in the previous 12 months;

6. The conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds;

7. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomography (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the board by regulation. Replacement of existing medical equipment shall not require a certificate of public need; or

8. Any capital expenditure of $5 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between $1 million and $5 million shall be registered with the commissioner pursuant to regulations developed by the Board.

Appendix C

§ 32.1-102.3. Certificate required; criteria for determining need.

B. In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The recommendation and the reasons therefor of the appropriate health planning agency.
2. The relationship of the project to the applicable health plans of the Board and the health planning agency.
3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.
4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.
5. The extent to which the project will be accessible to all residents of the area proposed to be served and the effects on accessibility of any proposed relocation of an existing services or facility.
6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.
7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.
8. The immediate and long-term financial feasibility of the project.
9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.
10. The availability of resources for the project.
11. The organizational relationship of the project to necessary ancillary and support services.
12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.
13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

14. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

15. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

16. In the case of a construction project, the costs and benefits of the proposed construction.

17. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

18. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

19. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

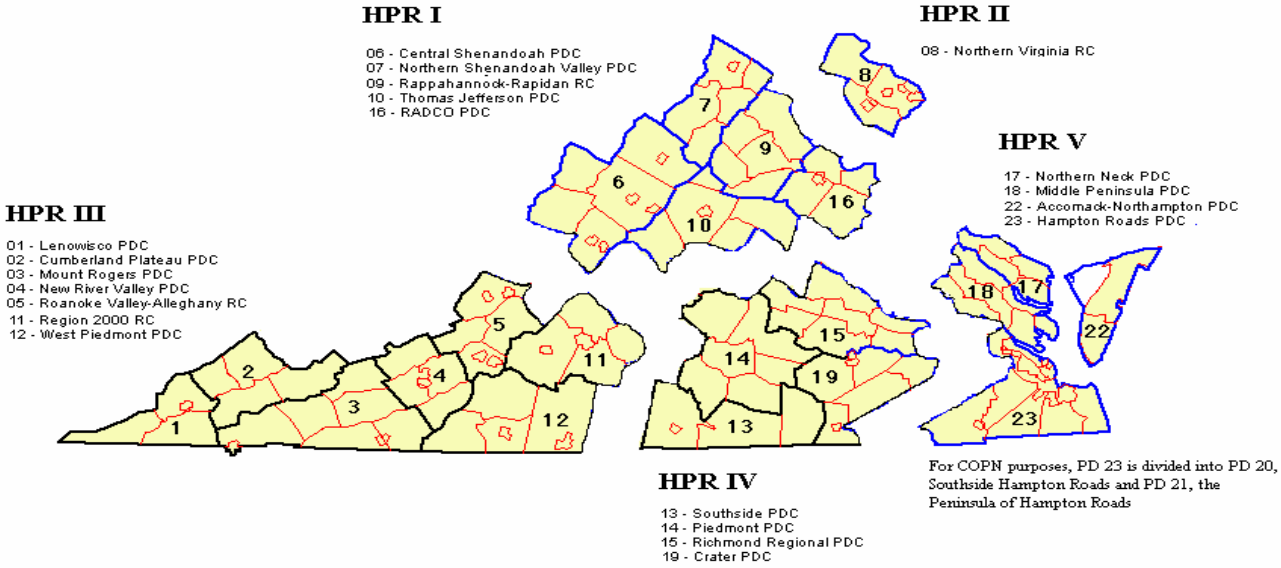
20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

Appendix D

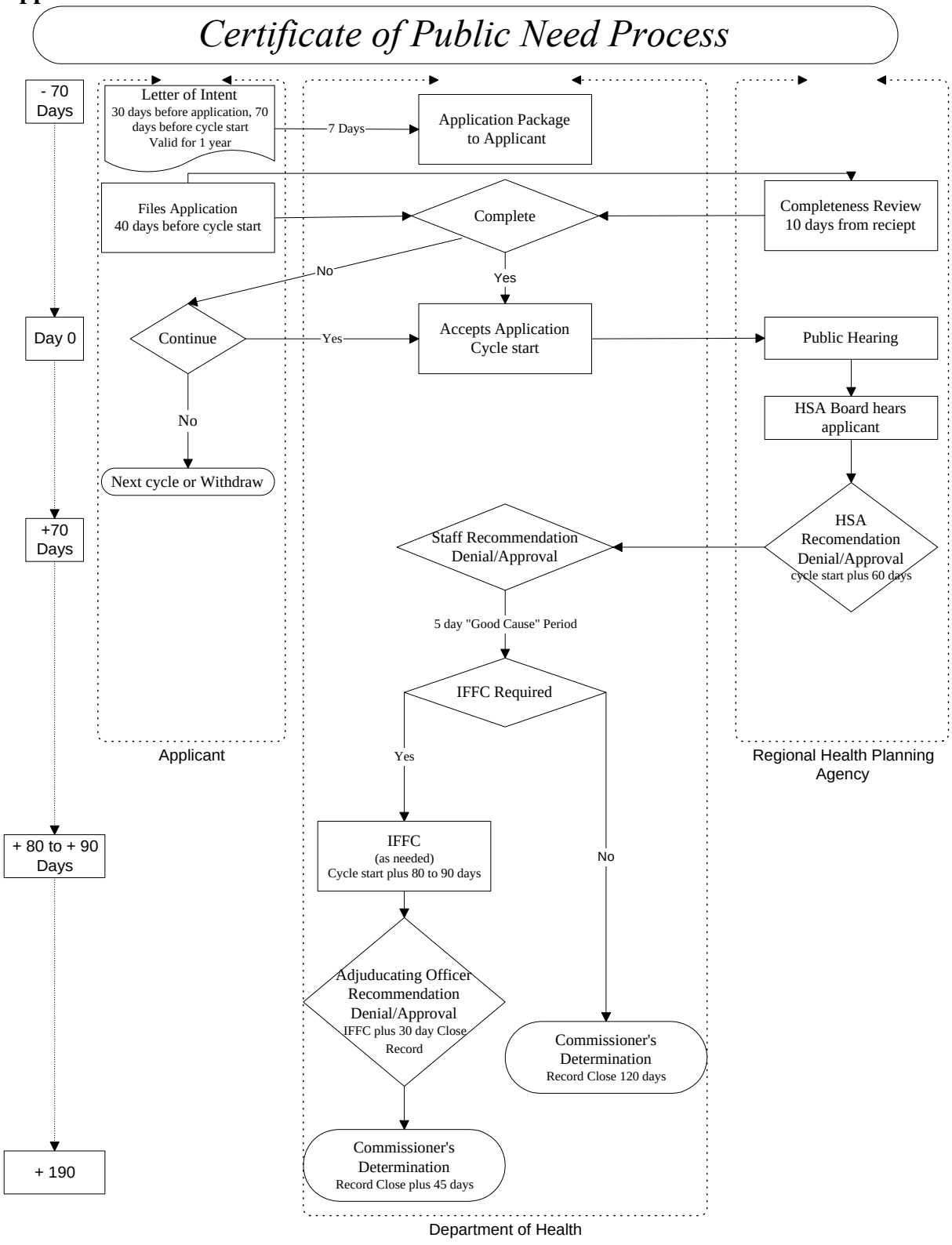
Authorized COPN Requests in Fiscal Year 2007

Project Categories	Number of Projects	Capital Costs
Batch Group A General hospitals, obstetrical services, neonatal special care services	24	
Subtotal		**$910,152,471**
Batch Group B Open heart surgery, cardiac catheterization, ambulatory surgery centers, operating room additions, transplant services	8	
Subtotal		**$46,547,835**
Batch Group C Psychiatric facilities, substance abuse treatment, mental retardation facilities	0	
Subtotal		**$0**
Batch Group D Diagnostic imaging	31	
Subtotal		**$67,880,378**
Batch Group E Medical rehabilitation	2	
Subtotal		**$1,507,593**
Batch Group F Gamma knife surgery, lithotripsy, radiation therapy, comprehensive cancer care centers	9	
Subtotal		**$96,722,846**
Batch Group G Nursing home beds, capital expenditures	5	
Subtotal		**$48,674,857**
COPN Program Total	**79**	**$1,171,485,980**

Virginia's Health Planning Regions
Virginia's Planning Districts



Appendix F


Certificate of Public Need Process
- 70 Days
Day 0
+70 Days
+ 80 to + 90 Days
+ 190
Letter of Intent
30 days before application, 70 days before cycle start
Valid for 1 year
7 Days
Application Package to Applicant
Files Application
40 days before cycle start
Complete
Completeness Review
10 days from reciept
No
Yes
Continue
Yes
Accepts Application
Cycle start
Public Hearing
No
Next cycle or Withdraw
HSA Board hears applicant
HSA Recomendation Denial/Approval
cycle start plus 60 days
Staff Recommendation Denial/Approval
5 day "Good Cause" Period
IFFC Required
Yes
No
IFFC
(as needed)
Cycle start plus 80 to 90 days
Adjuducating Officer Recommendation Denial/Approval
IFFC plus 30 day Close Record
Commissioner's Determination
Record Close 120 days
Commissioner's Determination
Record Close plus 45 days
Applicant
Regional Health Planning Agency
Department of Health

Appendix G

FIVE YEAR PROJECT CATEGORY GROUPING FOR ANNUAL REPORTS ON THE STATUS OF CERTIFICATE OF PUBLIC NEED

Twelfth Annual Report – 2008

Group 2 Diagnostic Imaging

- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of computed tomography (CT)
- Introduction by an existing medical care facility of any new CT service
- Addition by an existing medical care facility of CT equipment
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of magnetic resonance imaging (MRI)
- Introduction by an existing medical care facility of any new MRI service
- Addition by an existing medical care facility of MRI equipment
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of magnetic source imaging (MSI)
- Introduction by an existing medical care facility of any new MSI service
- Addition by an existing medical care facility of MSI equipment
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of nuclear medicine imaging
- Introduction by an existing medical care facility of any new nuclear medicine imaging service
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of positron emission tomography (PET)
- Introduction by an existing medical care facility of any new PET service
- Addition by an existing medical care facility of PET equipment

Thirteenth Annual Report – 2009

Group 3 Medical Rehabilitation, long-term care hospital services, nursing home services and mental retardation facilities

- Establishment of a medical rehabilitation hospital
- Introduction by an existing medical care facility of any new medical rehabilitation service
- Conversion of beds in an existing medical care facility to medical rehabilitation beds
- Establishment of a long-term care hospital
- Establishment of a nursing home
- Establishment of an extended care facility
- Introduction by an existing medical care facility of any new nursing home service, such as intermediate care facility services, extended care facility services, or skilled nursing facility services, regardless of the type of medical care facility in which those services are provided

Fourteenth Annual Report – 2010

Group 4 Radiation therapy, lithotripsy, obstetrical services and neonatal special care

- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of radiation therapy, including gamma knife surgery
- Introduction into an existing medical care facility of any new radiation therapy, including gamma knife surgery, service
- Addition by an existing medical care facility of equipment for the provision of radiation therapy, including gamma knife surgery
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of lithotripsy
- Introduction into an existing medical care facility of any new lithotripsy service
- Addition by an existing medical care facility of equipment for the provision of lithotripsy
- Establishment of an outpatient maternity hospital (non-general hospital birthing center)
- Introduction into an existing medical care facility of any new obstetrical service
- Introduction into an existing medical care facility of any new neonatal special care service

Fifteenth Annual Report – 2011

Group 5 Psychiatric services, substance abuse treatment services and miscellaneous capital expenditures

- Establishment of a sanitarium
- Establishment of a mental hospital
- Establishment of a psychiatric hospital
- Establishment of an intermediate care facility established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts
- Introduction by an existing medical care facility of any new psychiatric service
- Introduction by an existing medical care facility of any new substance abuse treatment service
- Conversion of beds in an existing medical care facility to psychiatric beds
- Any capital expenditure of five million dollars or more, not defined as reviewable in subdivisions 1 through 7 of the definition of "project," by or in behalf of a medical care facility

Sixteenth Annual Report - 2012

Group 1 General hospitals, general surgery, specialized cardiac services and organ and tissue transplantation

- Establishment of a general hospital
- Establishment of an outpatient surgical hospital or specialized center or clinic or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery
- An increase in the number of operating rooms in an existing medical care facility
- Establishment of a specialized center or clinic or that portion of a physician's office developed for the provision of cardiac catheterization
- Introduction into an existing medical care facility of any new cardiac catheterization service
- Addition or replacement by an existing medical care facility of equipment for the provision of cardiac catheterization
- Introduction into an existing medical care facility of any new open heart surgery service
- Addition by an existing medical care facility of equipment for the provision of open heart surgery
- Introduction into an existing medical care facility of any new organ or tissue transplantation service

Project Categories Presented in the First Ten Years of Annual Reports (1997 – 2006)

First Annual Report – 1997

Group 1 General Hospitals, general surgery, specialized cardiac services and organ and tissue transplantation

Second Annual Report – 1998

Group 2 Diagnostic Imaging

Third Annual Report – 1999

Group 3 Medical Rehabilitation, long-term care hospital services, nursing home services and mental retardation facilities

Fourth Annual Report – 2000

Group 4 Radiation therapy, lithotripsy, obstetrical services and neonatal special care

Fifth Annual Report - 2001

Group 5 Psychiatric services, substance abuse treatment services and miscellaneous capital expenditures

Sixth Annual Report - 2002

Group 1 General hospitals, general surgery, specialized cardiac services and organ and tissue transplantation

Seventh Annual Report - 2003

Group 2 Diagnostic Imaging

Eighth Annual Report - 2004

Group 3 Medical rehabilitation; long-term care hospital services, nursing home services and mental retardation facilities

Ninth Annual Report - 2005

Group 4 Radiation therapy, lithotripsy, obstetrical services and neonatal special care

Tenth Annual Report - 2006

Group 5 Psychiatric services, substance abuse treatment services and miscellaneous capital expenditures

Appendix H

Proposed Changes to the COPN section of the Code of Virginia Presented by the Virginia Department of Health to the COPN Task Force of the House Health, Welfare and Institutions Committee in the Fall of 2006

Explanation of Specific Proposed Changes and Their Impact

New language is underlined, language to be deleted is in strikethrough. Explanation and comments is in italics.

§ 32.1-102.1. Definitions

"*Medical care facility*," as used in this title, means…

9. Specialized centers or clinics or that portion of a physician's office developed for the provision of outpatient or ambulatory surgery, cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~ stereotactic radiosurgery, ~~lithotripsy,~~ magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, ~~nuclear medicine imaging, except for the purpose of nuclear cardiac imaging~~, or such other specialty services as may be designated by the Board by regulation.

These changes to the definition of "Medical Care Facility" support the deregulation of lithotripsy and nuclear medicine imaging from COPN. Gamma knife is a trademarked term for a particular manufacturer of a device that performs cranial stereotactic radiosurgery. Changing the term here and throughout the Code removes the use of a trademarked name and inserts the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

1. Establishment of a medical care facility;

2. An increase in the total number of beds or operating rooms in an existing medical care facility;

~~3. Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any two-year period; however, a hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing home beds as provided in § 32.1-132;~~

There appears to be little, if any, public benefit to regulating the movement of beds within a facility but between buildings on a campus. If to move the beds would result in a capital expenditure meeting the threshold requiring review, then a certificate of public need (COPN) would be required, but this is addressed later in the definition of "Project".

In the last three years there have been no requests for projects meeting this definition of "Project".

§ 32.1-102.1. Definitions

"*Project*" means:

5. Introduction into an existing medical care facility of any new cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy~~, magnetic resonance imaging (MRI), magnetic source imaging (MSI), medical rehabilitation, neonatal special care, obstetrical, open heart surgery, positron emission tomographic (PET) scanning, psychiatric, organ or tissue transplant service, radiation therapy, ~~nuclear medicine~~

~~imaging, except for the purpose of nuclear cardiac imaging,~~ substance abuse treatment, or such other specialty clinical services as may be designated by the Board by regulation, which the facility has never provided or has not provided in the previous 12 months;

The technology of lithotripsy has changed dramatically since first regulated under COPN. The equipment has evolved from large apparatuses that required large rooms to accommodate full body immersion tubs to small, portable units. Lithotripsy, or external shock wave lithotripsy (ESWL) has expanded beyond use to smash renal, or kidney, stones to the treatment of orthopedic issues such as chronic plantar fasciitis and chronic lateral epicondylitis. It also is being tested for calcific tendonitis, shoulder calcifications, stress fractures and delayed union and nonunion, as well as other musculoskeletal problems. The FDA, to date, has not approved any lithotripsy device for treatment of these conditions. The use of lithotripsy to treat biliary, or gall, stones has not gained much clinical favor, at least not in Virginia. In past three years there have been nine requests for lithotripsy services, all were approved at a total capital authorization of $89,000. There seems to be little or no public good to be gained by regulating the supply of lithotripsy capacity. Deregulation of lithotripsy from COPN was recommended in the 2005 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

Nuclear medicine imaging has already been partially de-regulated such that use of the technology for one of its primary indications no longer requires a COPN. Nuclear medicine imaging has become a basic element in any hospital's clinical inventory and no longer represents a significant capital expenditure. In past three years there have been three requests for non-cardiac nuclear medicine imaging. Two of the requests were part of requests for new hospitals. One of the hospitals was authorized and therefore so was the non-cardiac nuclear medicine imaging and one of the hospitals was denied and therefore so was the non-cardiac nuclear medicine imaging. The third request, the only on received in the last three years purely for the service, was authorized for a capital expenditure of $6,540. Deregulation of nuclear medicine imaging from COPN was recommended in the 2003 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

The change also supports the removal of the trademarked term gamma knife and substitutes the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

7. The addition by an existing medical care facility of any medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, ~~gamma knife surgery~~stereotactic radiosurgery, ~~lithotripsy,~~ magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation. Replacement of existing equipment shall not require a certificate of public need; or

This change to the Code would complete the deregulation of lithotripsy from COPN. The change also supports the removal of the trademarked term gamma knife and substitutes the term used to describe the clinical procedure that was regulated.

§ 32.1-102.1. Definitions

"*Project*" means:

8. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between ~~$1~~ 5 and $15 million not defined as reviewable in subdivisions 1 through 7

of this definition, by or in behalf of a medical care facility shall be registered with the Commissioner pursuant to regulations developed by the Board.

It has been 10 years since the threshold for defining a capital expenditure needing COPN authorization (when not otherwise defined as a project) was increased from $1 million to $5 million. Inflation, especially in the medical environment, has resulted in little value in reviewing a miscellaneous capital project of $5 million. In the last 3 years 7 requests ($70,677,513) were received and approved for projects with estimated capital costs between $5 million and $15 million ($6,544,500 - $14,213,796). No requests for miscellaneous capital expenditures within this cost range were denied. These projects were generally physical plant renovations, infrastructure upgrades and minor expansions. During the same period 13 miscellaneous capital expenditure projects ranging from $17 million to $242 million were reviewed and approved. No requests for miscellaneous capital expenditures within this cost range were denied. These projects were generally major new construction, including parking structures, major information system replacements, major physical plant renovations, and infrastructure upgrades.

In the last five years the average capital expenditure per request was just under $47 million and none were denied. The lack of denied requests should not detract from the usefulness of requiring COPN review of this type of request. The COPN process requires a close review by both internal and external parties. Such a review can only lead to well thought out requests and the abandonment of less feasible projects. The lack of progress, either by withdrawal or allowing the request to expire, on 14% of all requests in this category in the last five years illustrates the success of this planning aspect of review.

§ 32.1-102.1. Definitions

~~"*Virginia Health Planning Board*" means the statewide health planning body established pursuant to § 32.1-122.02 which serves as the analytical and technical resource to the Secretary of Health and Human Resources in matters requiring health analysis and planning.~~

The Code of Virginia section establishing the Virginia Health Planning Board was repealed by Acts 2002, c. 83. Removing the term from this section is simply housekeeping.

§ 32.1-102.1:1. Equipment registration required.

Within thirty calendar days of becoming contractually obligated to acquire any replacement medical equipment for the provision of cardiac catheterization, computed tomographic (CT) scanning, gamma knife surgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart surgery, positron emission tomographic (PET) scanning, radiation therapy, or other specialized service designated by the Board by regulation, any person shall register such purchase with the Commissioner and the appropriate health planning agency.

Adding "replacement" makes it clear that registration of equipment is only required when equipment is replaced. Otherwise it appears that registration is required within thirty calendar days of becoming contractually obligated to acquire equipment, including that equipment already authorized with a COPN.

§ 32.1-102.2. Regulations. - A. The Board shall promulgate regulations which are consistent with this article and:

1. Shall establish concise procedures for the prompt review of applications for certificates consistent with the provisions of this article which may include a structured batching process which incorporates, but is not limited to, authorization for the Commissioner to request proposals for certain projects. In any structured batching process established by the Board, applications, combined or separate, for computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, ~~radiation therapy~~ or nuclear imaging and radiation therapy shall be considered in the radiation therapy batch. A single application may be filed for a combination of (i) radiation therapy and (ii) any or

all of the computed tomographic (CT) scanning, magnetic resonance imaging (MRI), positron emission tomographic (PET) scanning, and nuclear medicine imaging;

Placing “radiation therapy” after “and” clarifies that the diagnostic imaging modalities listed may be reviewed in the radiation therapy batch only when combined with a request for radiation therapy. The original intent of this language was to allow the concurrent review of all the elements to make a comprehensive cancer care center, which included the diagnostic imaging and radiation therapy equipment. Prior to inclusion of the language beginning “In any structured batching process…” an applicant seeking to provide comprehensive cancer care at a single facility was required to apply for a COPN for the imaging equipment in the diagnostic imaging batch and the radiation therapy equipment in the radiation therapy batch, which may have been separated by as much as much as four months.

§ 32.1-102.3:2. Certificates of public need; applications ~~for increases in nursing home bed supplies~~ to be filed in response to Requests For Applications (RFAs). - A. Except for applications for continuing care retirement community nursing home bed projects filed by continuing care providers registered with the State Corporation Commission pursuant to Chapter 49 (§ 38.2-4900 et seq.) of Title 38.2 which comply with the requirements established in this section, the Commissioner of Health shall only approve, authorize or accept applications for the issuance of any certificate of public need pursuant to this article for any project which would result in an increase in the number of beds in which nursing facility or extended care services are provided in a planning district ~~in which nursing facility or extended care services are provided~~, establish a new radiation therapy service and/or stereotactic radiosurgery service or increase the number of radiation therapy or stereotactic radiosurgery machines at an existing medical care facility, establish a new neonatal special care service, establish a new obstetrical service, establish a new medical rehabilitation service, establish a new psychiatric service or increase the number of psychiatric care beds or establish a new long term-acute care hospital when such applications are filed in response to Requests For Applications (RFAs).

B. The Board of Health shall adopt regulations establishing standards for the approval and issuance of Requests for Applications by the Commissioner of Health. The standards shall include, but shall not be limited to, a requirement that determinations of need take into account any limitations on access to existing ~~nursing home beds~~services in the planning districts. The RFAs, which shall be published at least annually, shall be jointly developed by the Department of Health and the Department of Medical Assistance Services and based on analyses of the need, or lack thereof, for increases in the ~~nursing home bed~~relevant service supply in each of the Commonwealth's planning districts in accordance with standards adopted by the Board of Health by regulation. The Commissioner shall only accept for review applications in response to such RFAs which conform with the geographic and ~~bed~~ need determinations of the specific RFA.

C. Sixty days prior to the Commissioner's approval and issuance of any Request For Applications, the Board of Health shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district ~~bed~~ needs set forth in the RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within fourteen days of the publication, the Board and the Commissioner of his objection and the objection's regulatory basis. The Commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the Commissioner's response in writing within five days of receiving the Commissioner's response. If objections are received, the Board may, after considering the provisions of the RFA, any objections, the Commissioner's responses, and if filed, any written rebuttals of the Commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the Request for Applications, the Commissioner shall consider any recommendations made by the Board.

Use a Request for Applications (RFA) process to proactively conduct a statewide assessment and establish the existence of a public need for a service in advance and solicit applications for COPN authorization to fulfill that identified need has been used successfully to manage the inventory of nursing home beds for some years now. The changes to this section of the Code would expand the services subject to the RFA process to include radiation therapy, stereotactic radiosurgery, neonatal special care, medical rehabilitation and long term acute care hospitals in addition to nursing homes. Applications for the services subject to the RFA process would only be accepted in response to an RFA. Adoption of the RFA process for these services was recommended in the 2004 and 2005 Annual Report On The Status Of Virginia's Medical Care Facilities Certificate Of Public Need Program.

In past three years there have been; 15 radiation therapy requests approved ($82,577,676) and 10 denied ($57,772,318), 3 gamma knife/stereotactic radiosurgery requests approved ($149,764,976) and 4 denied ($21,156,316), 2 neonatal special care requests approved, one as part of an entire facility request, one to introduce the service at an existing hospital ($996,000), both were approved, 6 medical rehabilitation service requests approved ($10,533,167) and 1 denied ($13,064,757), and 3 long term acute care hospitals approved ($19,425,034) and 2 denied ($1,415,706).

Virginia does not have a problem with limiting the over supply of obstetric services but rather with assuring the availability of the service. Since 2001 seven Virginia hospitals have closed their obstetric programs. Each of the closed programs had delivered less than 255 babies in their last year of operation and each closed program was located at a hospital in an area designated as rural. Since 2000 there have been four COPN requests for new or expanded obstetric services. Two of the requests were to include obstetrics in relocated replacement hospitals, one was to add obstetric beds to an existing service, and one was to re-introduce obstetric services at a hospital that had previously had to discontinue the service. All four requests were approved.

Use of the RFA process would be expected to reduce the number of speculative COPN requests, since applications would only be accepted in response to a process that predetermined that a public need exists for the service. Use of the RFA process may attract applicants to areas of the State with an identified need since the potential applicants would know that a State determination of need had already been made and therefore the likelihood of successfully obtaining a COPN is increased.

§ 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates. **- A.** A certificate shall be issued with a schedule for the completion of the project and a maximum capital expenditure amount for the project. The schedule may not be extended and the maximum capital expenditure may not be exceeded without the approval of the Commissioner in accordance with the regulations of the Board.

1. All facilities, whether licensed or not and whether or not required to be licensed, holding, or seeking, certificate of public need authorization for one or more projects will report their patient volume, gross patient revenue, net patient revenue and charity care for all certificate of public need regulated services annually to Virginia Health Information.
2. Failure of a facility holding a certificate of public need to provide the report required by this section will;
    a. render the facility, the facility's parent organization and the facility's owners ineligible to apply for additional certificates of public need until such time as all reporting is current to the later of the start of the service or January 1, 2007
    b. cause capacity at non-reporting services to not be counted in the calculations to determine need.

In order to fairly access a reasonable and equitable level of performance for indigent care conditions placed on COPNs the amount of indigent care being provided must be known. Currently the conditioned

level is selected based on the average provided by all hospitals in the health planning region. No consideration is given to the charity care provided to the indigent by non-hospital providers. This is because non-hospital providers are not required to report their financial data, including charity care. Without their data they cannot be included in the calculation to determine a reasonable level for the condition.

A determination that additional resources are needed in a planning district or health planning region is based in part on how well utilized existing resources are as compared to the standard established in the State Medical Facilities Plan. Utilization data are reported by hospitals and nursing homes, the licensed providers, to Virginia Health Information. No such reports are required of non-licensed providers; the freestanding diagnostic imaging facilities, the cancer care centers, the physician's offices with COPN regulated services. As such, decisions are made with at best a partial view of the utilization, and therefore the need for, resources.

This change to the Code provides the data needed for the Commissioner to make decisions based on a complete picture, to assign conditions in the most fair and equitable manner, and to provide consequences for failure to comply.

§ 32.1-102.4. Conditions of certificates; monitoring; revocation of certificates

F. The Commissioner may condition, pursuant to the regulations of the Board, the approval of a certificate (i) upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area.

Any person willfully refusing, failing, or neglecting to honor such agreement shall be subject to a civil penalty of up to $100 per violation per day until the date of compliance. Failure to report compliance with any condition of a certificate of public need by the established deadline shall be grounds for denial of additional certificate of public need requests until full compliance is demonstrated and reported.

The current formal consequences of failure to report or failure to meet conditions include the $100 fine per day per violation. At most that is $36,500 per year per conditioned COPN, significantly less than the six and seven figure sums required to be provided as free care to indigents. The fines would not contribute to care for the indigent, thereby missing an opportunity on behalf of the indigent, and, establishing that any such failure to meet the condition is willful is extremely difficult such that to the best of my knowledge this provision has never been used.

The Code also states at § 32.1-102.2. Regulations, C., in relevant part;

> *"In addition, the Board's licensure regulations shall direct the Commissioner to condition the issuing or renewing of any license for any applicant whose certificate was approved upon such condition on whether such applicant has complied with any agreement to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care."*

This provision only has meaning for licensed facilities. Non-licensed providers such as freestanding diagnostic imaging facilities, cancer care centers, and physician's offices with COPN regulated services have no threat to their ability to operate if they fail to report or comply with a condition placed on a COPN. Compliance with reporting is currently less than 60%.

This change to the Code would provide additional incentive, applicable to all providers, for compliance with conditions.

§ 32.1-102.6. Administrative procedures. - A. To obtain a certificate for a project, the applicant shall file a completed application for a certificate with the Department and the appropriate health planning agency. In order to verify the date of the Department's and the appropriate health planning agency's receipt of the application, the applicant shall transmit the document electronically, by certified mail or a delivery service, return receipt requested, or shall deliver the document by hand, with signed receipt to be provided.

This allows the electronic transmission of the application. The guidance document currently in development will allow the electronic transmission (email or CD) of all other documents related to a COPN request. This also allows for the ultimate development and adoption of an online web-based application process.

§ 32.1-102.6. Administrative procedures. - A

Within 10 calendar days of the date on which the document is received, the Department and the appropriate health planning agency shall determine whether the application is complete or not and the Department shall notify the applicant, if the application is complete, that the application has been accepted for review and if the application is not complete, of the information needed to complete the application, that the application will not be accepted for the current review cycle and the dates of the next available review cycle.

The Code at § 32.1-102.6. Administrative procedures, B., establishes that a cycle for the review of a COPN request is 190 days. There is, however, a 70-day period prior to the start of the review cycle for the submission of the letter of intent, the application and the review of the application for completeness. At the first meeting of the HWI Task Force this 70-day period was referred to as the Pre-application Phase. The result is effectively that the real time for a review is 260 days (approximately 8¾ months).

This change, with the appropriate adjustment to the Regulations, viewed in the context of the rest of the pre-application phase that would remain intact, establishes that applicants are to submit a complete application on or before the application deadline. Currently the submissions received on the deadline for applications are often incomplete and occasionally are barely shells of a completed form. By requiring that the initial submission be complete the opportunity for completeness review and follow-up submissions is removed and the pre-application phase is shortened from 70 days to 35 days, such that the over all process is shortened from 270 days to 235 days (7¾ months). Other states, including North Carolina, utilize this "complete upon submission" approach.

§ 32.1-102.6. Administrative procedures. - B

The health planning agency shall submit its recommendations on each application and its reasons therefor to the Department within ~~10~~ 5 calendar days after the completion of its 60-calendar-day review or such other period in accordance with the applicant's request for extension.

If the health planning agency has not completed its review within the specified 60 calendar days or such other period in accordance with the applicant's request for extension and submitted its recommendations on the application and the reasons therefor within ~~10~~ 5 calendar days after the completion of its review, the Department shall, on the ~~eleventh~~ sixth calendar day after the expiration of the health planning agency's review period, proceed as though the health planning agency has recommended project approval without conditions or revision.

As written the Regional Health Planning Agency does not need to send their recommendation to the Department until the day the DCOPN staff report and recommendation is due. This housekeeping change allows the DCOPN five days to review and address, or incorporate, the Regional Health Planning Agency's recommendation into it's own analysis, as required by consideration number 1, B. - "In

determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The recommendation and the reasons therefor of the appropriate health planning agency."

§ 32.1-102.6. Administrative procedures. - D

If the application is not determined to be complete ~~within 40 calendar days from~~upon submission, the application shall be refiled in the next batch for like projects.

Additional change necessary to require an application to be complete upon submission, cutting 35 days from the pre-application phase.

§ 32.1-102.6. Administrative procedures.

E. Upon entry of each completed application or applications into the appropriate batch review cycle:

1. The Department shall establish, for every application, a date between the eightieth and ninetieth calendar days within the 190-calendar-day review period for holding an informal fact-finding conference, if such conference is necessary. Once scheduled by the department the informal fact-finding conference will be held on the scheduled date unless changed by the presiding Adjudication Officer in response to special, unavoidable circumstances and with the concurrence of all parties.

Frequently delays in reaching a final decision for a request that is to be heard before an informal fact-finding conference occur, at least in part, because the applicant delays the date of the informal fact-finding conference, which delays all other subsequent deadlines. The conference is scheduled with the date communicated to the applicant and all other parties to the review at the time the request is accepted for review, 80 – 90 days prior to the date for the conference. Frequently, it appears that an applicant makes no effort to plan their calendar to accommodate the scheduled conference. This results in a flurry of activity to find, on short notice, another date suitable to all parties, extending the review by weeks or even months. Keeping to the scheduled conference date will speed the review process.

§ 32.1-102.6. Administrative procedures. E.

3. Any person seeking to be made a party to the case for good cause at a necessary informal fact-finding conference shall notify the Department of his request and the basis therefor on or before the eightieth calendar day following the day which begins the appropriate batch review cycle.

Paragraph 2 of this section establishes a deadline for a determination of a need for an informal fact-finding conference. Paragraph 3 sets a date for parties seeking good cause for a conference to submit their petition that is later than the date required to determine if a conference is necessary. This housekeeping change makes it clear that the eightieth day deadline for good cause submissions only applies if it was determined that the conference was necessary.

§ 32.1-102.6. Administrative procedures. E.

4. In any case in which an informal fact-finding conference is held, the informal fact-finding conference shall not be a de novo review of the request and shall be based on the material in the record on the 60th day of the review cycle, any material submitted prior to the informal fact-finding conference by a party with good cause and any informal fact-finding conference testimony made regarding the material in the record. Following the 60th day of the review cycle only the analysis and recommendation of the Regional Health Planning Agency, the analysis and recommendation of the Division of Certificate of Public Need, the transcript of the informal fact finding conference, the analysis and recommendation of the adjudication officer and the Commissioner's decision may be added to the record. The date for the close of the record shall not be more than 45 days after the date the informal fact-finding conference is concluded. ~~date shall be established for the closing of the record which shall not be more than 30 calendar days after the date for holding the informal fact-finding conference.~~

Informal fact-finding conferences generally result in the addition of twice as much material to the record than was available to the Regional Health Planning Agency and the DCOPN for their review. This holdback of information by the applicant hampers the ability of the reviewing agencies to conduct a fair and complete assessment of the request. Potentially, requests have been reviewed at an informal fact-finding conference that would not have had to go that far had the supplemental information been available to the reviewing agencies for analysis.

This leads to informal fact-finding conferences often being new reviews, from scratch, increasing the burden on the adjudication officer. This change makes the adjudication officer's review based on the same material available to the other reviewing agencies. This would most likely result in applicant's providing full disclosure to the reviewing agencies and not holding information back for the informal fact-finding conference.

Informal fact-finding conferences typically include a 30-day period after the conference for the submission of additional material, proposed findings, and rebuttals. There then remains 45-days for the adjudication officer to complete his analysis and for the Commissioner to make his decision. Ending the submission of additional material to the record, except to specific documents, with the date of the Regional Health Planning Agency's review negates the need for the 30-day post conference filing period, shortening the review time by another 30 days. If the shortening of the pre-application phase is also accepted, combined the total review time is shortened from 260 days to 205 days (8⅔ months to 6¾ months).

§ 32.1-102.6. Administrative procedures. E.

5. In any case in which an informal fact-finding conference is not held, the record shall be closed for additional information on ~~the earlier of (i) the date established for holding the informal fact-finding conference or (ii)~~ the date that the Department determines an informal fact-finding conference is not necessary, only the Commissioner's decision may be added to the record.

Additional language changes needed to support the proposed change to the close of the record and reduction in supplemental material.

§ 32.1-102.10. Commencing project without certificate grounds for refusing to issue license. Commencing any project without a certificate required by this article shall constitute grounds for refusing to issue a certificate or a license for such project.

Only a fraction of projects involve a licensed facility. This change expands the available penalty for commencing a project without a certificate and establishes a penalty that will reach all potential applicants

Appendix I

Certificates of Public Need Issued With Conditions Requiring the Provision of Indigent Care and/or the Development and/or Operation of Primary Care For Underserved Populations in FY 2007

Applicant/Project Location	Project	PD	COPN		Date	Conditions
Cumberland Hospital for Children and Adolescents	Add 10 Acute Care Beds	15	VA-	04021	7/3/2006	All pts w/o regard to ability to pay
Hospice of Central Virginia	Establish a 15-bed Free Standing Hospice Care Facility	15	VA-	04022	7/5/2006	All pts w/o regard to ability to pay
Insight Health Corp. d/b/a Medical Imaging Center of Arlington	Relocate an Existing and an Approved MRI to Establish a New Specialized Center for MRI Imaging	8	VA-	04024	8/15/2006	2.9% indigent / primary care
Riverside Regional Medical Center	Add MRI Unit (Replace Mobile Site with Fixed Equipment)	21	VA-	04025	8/15/2006	2.6% indigent / primary care
Riverside Regional Medical Center	Establish a Specialized Center for MRI Services (Mobile Site in Hampton)	21	VA-	04026	8/15/2006	2.6% indigent / primary care
Bon Secours Hampton Roads	Establish a Mobile MRI Service Using New MRI Equipment to Serve Multiple Sites	21	VA-	04028	8/15/2006	2.6% indigent / primary care
University of Virginia Medical Center	Addition of one CT Scanner	10	VA-	04029	8/14/2006	2.4% indigent / primary care
Wellmont Lonesome Pine Hospital	Add a Fixed MRI Unit	1	VA-	04031	8/14/2006	2.5% indigent / primary care
Richmond Radiation Oncology Center, Inc.	Add CT Equipment for Radiation Therapy Simulation	15	VA-	04032	9/6/2006	2.7% indigent / primary care
Northern Virginia Eye Surgery Center, LLC	Establish an Outpatient Surgical Hospital	8	VA-	04033	9/15/2006	3.0% indigent / primary care
MediCorp Health System and MediCorp at Stafford, LLC	Establish a General Acute Care Hospital	16	VA-	04035	8/25/2006	2.4% indigent / primary care
Spotsylvania Medical Center, Inc.	Establish a General Acute Care Hospital	16	VA-	04036	8/25/2006	2.4% indigent / primary care, maintain 10 psych beds
Bon Secours - St. Mary's Hospital of Richmond, Inc.	Add 64 General Medical/Surgical Acute Care Beds	15	VA-	04037	9/15/2006	2.7% indigent / primary care
Sentara Healthcare	Relocate Acute Rehabilitation Beds from Norfolk General to a site within HPR V	V	VA-	04038	9/15/2006	2.6% indigent / primary care
First Meridian Medical Corporation t/a MRI and CT Diagnostics	Addition of fourth MRI Unit	20	VA-	04039	10/1/2006	2.6% indigent / primary care
Sentara Healthcare	Establish a Specialized Center for MRI Services	20	VA-	04040	9/15/2006	2.6% indigent / primary care
Chesapeake General Hospital	Add a 4th CT Scanner	20	VA-	04041	9/15/2006	2.6% indigent / primary care
Petersburg Hospital Company, LLC d/b/a Southside Regional Medical Center	Establish an Outpatient Surgical Hospital (2 ORs in Colonial Heights)	19	VA-	04042	9/11/2006	2.7% indigent / primary care

Colonial Heights Ambulatory Surgery Center, L.P.	Establish a 3 OR Outpatient Surgical Hospital	19	VA-	04043	9/11/2006	2.7% indigent / primary care
Stafford Health Investors, LLC	Establish a 90 Bed Nursing Home Comprised of 34 Beds Currently located at the Brooke Nursing Home and 56 New Beds	16	VA-	04044	9/22/2006	effective once Stafford Health Investors is licensed operator
Bon Secours St. Francis Medical Center	Introduce Neonatal Special Care Services - Specialty Level	15	VA-	04045	9/20/2006	3.0% indigent / primary care
Pulaski Community Hospital, Inc.	Introduce Lithotripsy Services (Mobile)	III	VA-	04047	10/15/2006	2.5% indigent / primary care
Loudoun Hospital Center	Add 16 Medical/Surgical Beds	8	VA-	04049	10/3/2006	2.9% indigent / primary care, delicense 1 yr after Broadlands
Surgi-Center of Winchester	Addition of a 6th OR	7	VA-	04050	10/18/2006	2.4% indigent / primary care
University of Virginia - HealthSouth, L.L.C. II	Establish a 40-Bed LTACH	10	VA-	04053	11/15/2006	2.4% indigent / primary care
Rockingham Memorial Hospital	Establish a General Acute Care Hospital (Replace and Relocate RMH and Add 2 ORs)	6	VA-	04059	11/15/2006	2.4% indigent / primary care
Northern Virginia Imaging, L.L.C.	Introduce CT Services through Relocation of Existing Equipment	8	VA-	04064	11/16/2006	2.9% indigent / primary care
Sentara Leigh Hospital	Capital Expenditure of $5 Million or More (Renovate Surgery Space)	20	VA-	04066	12/27/2006	2.7% indigent / primary care
Shenandoah Shared Hospital Services, Inc.	Addition of Mobile MRI Equipment to Serve Rockingham Memorial Hospital and Augusta Medical Center	6	VA-	04069	2/15/2007	2.4% indigent / primary care
First Meridian Medical Corporation t/a MRI and CT Diagnostics	Addition of Second CT Scanner	20	VA-	04072	3/9/2007	3.2% indigent / primary care
HealthSouth Diagnostic Center - Virginia Beach	Relocate CT and MRI Services Within PD 20	20	VA-	04073	3/9/2007	3.2% indigent / primary care
Bon Secours Memorial Regional Medical Center	Addition of Second MRI Scanner	15	VA-	04076	2/16/2007	2.9% indigent / primary care
Sentara Healthcare	Relocate 8 Acute Rehabilitation Beds from Norfolk General Hospital to VA Beach General Hospital	20	VA-	04081	3/28/2007	3.2% indigent / primary care
Eye Surgery Limited, LLC	Establish an Outpatient Surgical Hospital (2 ORs dedicated to eye surgery)	20	VA-	04082	3/28/2007	3.2% indigent / primary care
Tazewell Community Hospital	Introduce Lithotripsy Services (Mobile Site)	2	VA-	04083	4/11/2007	2.4% indigent / primary care
Henrico Doctors' Hospital	Introduce Lithotripsy Services at Forest and Parham (2 Mobile Sites)	15	VA-	04084	4/11/2007	2.9% indigent / primary care
Chesapeake General Hospital	Increase Nursery from Intermediate to Specialty Level of Care	20	VA-	04087	4/3/2007	2.6% indigent / primary care
Tyson's Corner Diagnostic Imaging, Inc.	Establish a Specialized Center for MRI Imaging	8	VA-	04088	4/25/2007	3.0% indigent / primary care
Healthsouth Diagnostic Center - Tysons	Addition of an MRI Scanner	8	VA-	04089	4/25/2007	3.0% indigent / primary care

Sentara Leigh Hospital	Capital Expenditure of $5 Million or More (Renovate Emergency Department)	20	VA-	04091	5/15/2007	3.2% indigent / primary care
Wythe County Community Hospital, Inc.	Capital Expenditure of $5 Million or More (Expand and Renovate ED and Registration)	3	VA-	04092	5/15/2007	2.4% indigent / primary care
Danville Regional Medical Center	Capital Expenditure of $5 Million or More (Build out Shelled Space)	12	VA-	04094	5/16/2007	2.4% indigent / primary care
Cancer Centers of Virginia	Add a Linear Accelerator at Sentara CarePlex Hospital (w/o SRS)	21	VA-	04097	6/28/2007	3.2% indigent / primary care

Appendix J

Condition Compliance Reporting Status of Facilities / Organizations / Systems with Certificates of Public Need Issued With Conditions Requiring the Provision of Indigent Care and/or the Development and/or Operation of Primary Care for Underserved Populations

(for reports due during FY 2007)

Not Reported	Met	Facility / System
1		Associates in Radiology Oncology, P.C.
	3	Augusta Hospital Corporation
	3	Bon Secours Hampton Roads
4		Bon Secours Richmond Health System
1		Cancer Center of Central Virginia, LLC
1	1	Carilion
	1	CDL Medical Technologies, Inc
1		Centra Health
	2	Central Virginia Imaging
1		Columbia Healthcare of Southwest Virginia
	1	Community Memorial HealthCenter
1		Community Radiology of Virginia, Inc.
1		Culpeper Regional Hospital
3		Danville Regional Health System
1		Fairfax Radiology Centers
1		Fairfax Radiology Consultants, P.C.
4		Falls Church Lithotripsy
1	1	First Hospital Corporation of Virginia Beach
1		First Meridian Medical Corporation t/a MRI and CT Diagnostics
1		Greensville Memorial Hospital
1		Guild Lithotripsy
	1	Halifax Regional Hospital, Inc.
	1	Hampton Roads Orthopaedics & Sports Medicine
12	4	HCA Virginia
6		Inova Health System
	1	Insight Health Corporation
2		Lee Regional Medical Center
5	1	Martha Jefferson Hospital
1		Mary Washington Hospital
	1	McGuire Medical Group (now Virginia Physicians, Inc.)
	1	Medical Imaging of Fredericksburg, LLC
2		MRI of Reston
	1	Northern Virginia Imaging Limited Partnership
1		Norton Community Hospital
1		Peninsula Surgery Centers II, LLC
1		PET of Reston LP
1		Potomac Hospital Corporation of Prince William
1		R Joy LLC and R Joy II LLC d/b/a Beach Surgicenter for Eyes)

1		Rappahannock General Hospital
	1	Rehabilitation Hospital of Petersburg, Inc.
1		Richmond Medical Commons, LLC
	1	Richmond West End Diagnostic Imaging, L.L.C.
2		Riverside Radiation Therapy Centers, LLC
1		Roanoke Ambulatory Surgery Center, LLC
	1	Roanoke Valley Center for Sight, L.L.C.
2	1	Rockingham Memorial Hospital
	1	Royal Medical Health Services
9		Sentara
1		Shenandoah Memorial Hospital
1		Southwest Virginia Regional Open MRI Center
1		Surgical Care Affiliates, Inc., now Regional Surgical Services, LLC
1		Surgi-Center of Central Virginia, Inc
1		The Center for Advanced Imaging
1		The Center for Cosmetic Laser & Dermatologic Surgery
1		The Skin Cancer Surgery Center
2		The Urosurgical Center of Richmond
1		Twin County Family Care Centers, Inc.
1	2	University of Virginia Health System
3		Valley Health System
1		Virginia Cancer Institute, Inc.
3	1	Virginia Hospital Center
	1	Virginia Imaging, LLC (Heart Imaging Center of Virginia)
1		Virginia Oncology Associates
	1	Washington Radiology Associates, P.C.
1		Williamsburg Radiation Therapy Center, Inc.
	2	Winchester Radiologists, PC