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
2008

Table of Contents

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 2008).

Program activity for the period covered in this report includes the issuance of 96 decisions. The State Health Commissioner authorized 56 projects with a total expenditure of $1,091,191,529 and denied 10 projects with proposed capital expenditures of $356,221,200. 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: Computed Tomography, Magnetic Resonance Imaging, Positron Emission Tomography, Nuclear Medicine Imaging, and Magnetic Source Imaging. 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 each of these project types except for nuclear medicine imaging, which VDH recommends supporting efforts to deregulate.

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 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. Aggressive follow-up with non-reporting holders of conditioned COPNs has improved compliance.

During FY 2008 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 2008 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 (2008). 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 21 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 2008

Project Review

Decisions

During FY 2008, the Division of Certificate of Public Need (DCOPN), which assists the Commissioner in administering the COPN program, received 116 letters of intent to submit COPN requests and 97 applications for COPNs. There were four applications withdrawn by applicants during the year. 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 2008. Graph 1 puts this activity in historical context. The Commissioner issued 66 decisions on applications to establish new medical care facilities or modify existing medical care facilities in FY 2008. Fifty-six (85%) of these decisions were to approve or conditionally approve the request, for a total authorized capital expenditure of $1,091,191,529. Ten (15%) requests were denied. These ten denied projects had

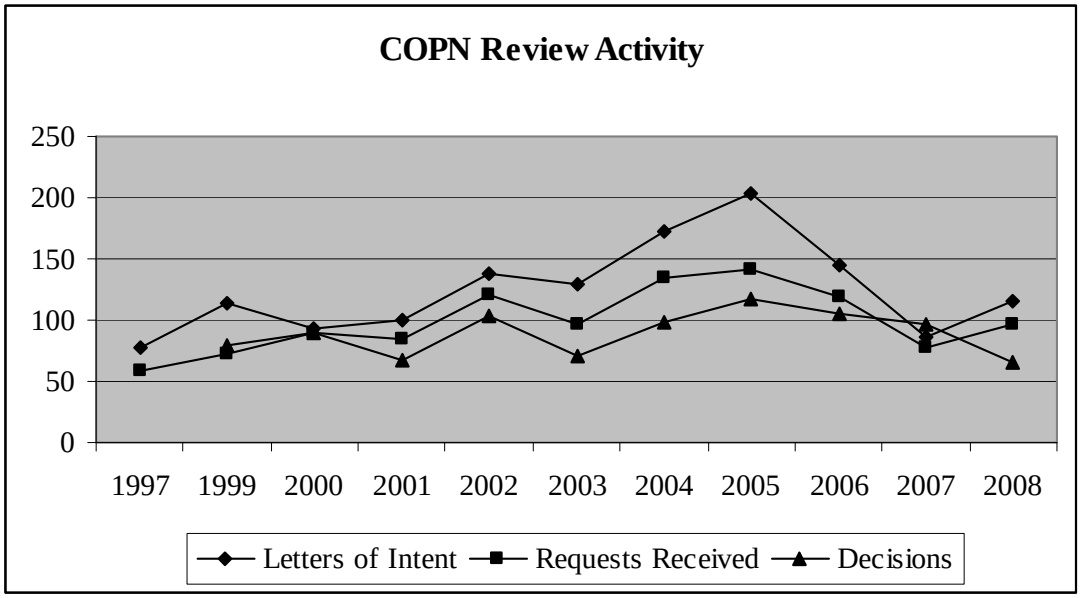
proposed total capital expenditures of $356,221,200. Approved COPN decisions in FY 2008 are profiled in Appendix D.

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
2008	116	97	4	56	10	7	0

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

Chart 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 prior to the end of the review.

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 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 36 COPN applications heard before a VDH Adjudication Officer at 21 individual IFFCs in FY 2008. An additional ten applications were exempted from participation in IFFCs with competing applicants due to an agreed upon stipulation agreement. Twelve of the COPN requests warranting an IFFC were approved in FY 2008. Ten requests were denied after the IFFC. Fourteen projects heard at an IFFC in FY 2008 still have decisions pending and will be resolved in the Fall of 2008.

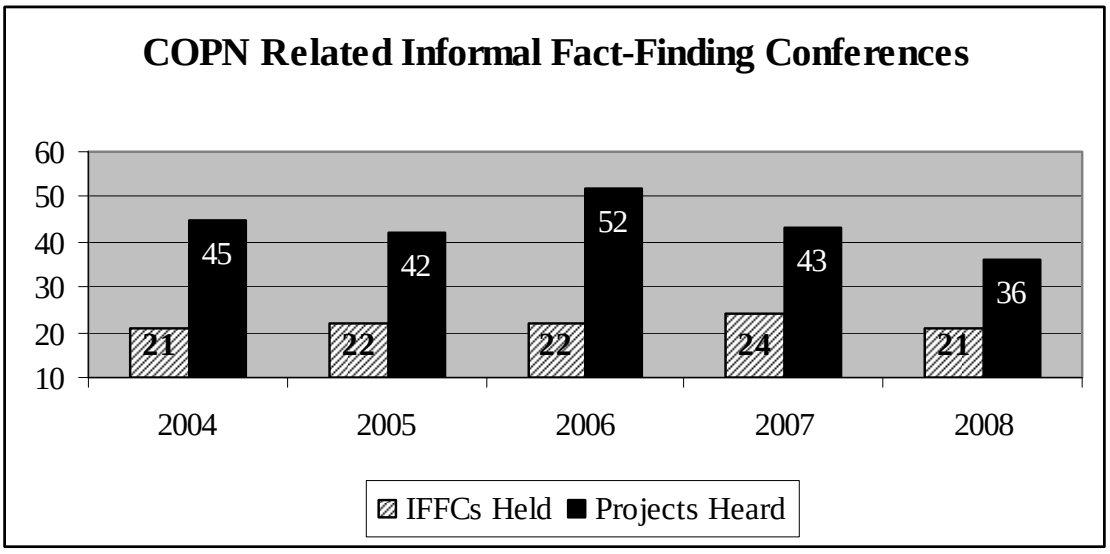
Table 2 illustrates the types of projects that were forwarded to an IFFC in FY 2008.

Table 2 Projects at IFFC in FY 2008

Project Type	Approved	Denied	Pending	Total
Establish/Relocate/Replace Hospital	1	3	1	5
Add Hospital Beds	1	0	3	4
Medical Rehabilitation Services	0	1	2	3
Magnetic Resonance Imaging	4	5	1	10
Computed Tomography Services	2	0	4	6
Positron Emission Tomography Services	2	0	0	2
Radiation Therapy / Establish Comprehensive Cancer Care Center	0	1	1	2
Establish Outpatient Surgery Hospital	1	0	0	1
Add Operating Rooms	1	0	1	2
Organ Transplant Program	0	0	0	0
Cardiac Catheterization	0	0	0	0
Neonatal Special Care	0	0	0	0
Nursing Home	0	0	1	1
TOTAL	12	10	14	36

Source: DCOPN

Chart 2



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 seven decisions in FY 2008. All of the appeals were perfected with a filed appeal.

Wellmont/HealthSouth IRF, LLC, appealed the State Health Commissioner's decision to deny a request to establish a 25-bed medical rehabilitation hospital in Planning District 3.

In March 2008 the Commissioner denied three requests from Bon Secours Hampton Roads to replace Bon Secours DePaul Medical Center at three different sites, one in the City of Virginia Beach, one in Suffolk County and one at the current Bon Secours DePaul Medical Center site in the City of Norfolk. In the same review the Commissioner approved a competing request by Sentara Hospitals to replace and relocate Sentara Bayside Hospital to the City of Virginia Beach and approved a competing request to 30 add acute care beds at Sentara Obici Hospital in Suffolk County. Bon Secours Hampton Roads has appealed the decision for all five competing requests.

Table 3 Prior COPN Appeals Still In Process

COPN Requests	Project	COPN Decision	Appellants	Court Status
COPN Request No.VA-7249	Request to add nursing home beds at an existing nursing home	Request not accepted for review.	NRV Real Estate, LLC	Denial of COPN application affirmed by Circuit Court, reversed by Court of Appeals. The Commissioner

				has filed a Petition for Appeal with the Supreme Court of Virginia
COPN Nos. VA-03986 and 03991	Request to relocate nursing home beds in accordance with HB 2316 authority.	Both requests were approved.	The Laurels of Bon Air, LLC, d/b/a The Laurels of Bon Air; Oak Healthcare Investors of Richmond, Virginia, Inc., d/b/a The Laurels of Willow Creek; Forest Hill Convalescent Center, L.P., d/b/a Ruxton Health and Rehabilitation Center of Westover Hills; Ruxton Health Care V, LLC, d/b/a Ruxton Health of Stratford Hills; and Westport Operations, LLC, d/b/a Westport Health Care Center	COPN decision affirmed at Circuit Court and Court of Appeals. The Laurels have filed a Petition for Appeal with the Supreme Court.

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 2008 one certificate, COPN number VA-03919, Hospital Corporation of Virginia Beach d/b/a Virginia Beach Psychiatric Center, the addition of 24 beds issued in March 2005, was 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 eighteen requests for significant changes to fourteen different COPN projects in FY 2008. Six requests were for extension of the schedule beyond the three-year generic time limit or the time authorized on the certificate, two of which also included a request to change the authorized site. Four requests were to increase the authorized capital cost by more than 10% but less than 20%, and one request, as provided by the 2007 session of the Virginia General Assembly's passage of House Bill 2546, was to increase the capital cost to 131% of that authorized on the COPN. Seven requests were to change the authorized site for the project. All eighteen reviewed significant change requests were authorized.

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 calendar year 2007 RFA was issued for the addition of 30 Medicaid-certified nursing facility beds in Planning District 14. Four applicants presented requests to develop the 30 nursing facility beds as additions to existing nursing homes in the planning district. A decision on these requests is expected in December of 2008.

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 2008 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 2008, all of the Commissioner's decisions were rendered within the statutory or applicant extended time limit.

Legislation

In the 2008 session of the General Assembly, there were seven 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 4 COPN Bills in the 2008 Session of the Virginia General Assembly

Bill	Patron	Topic in Relation to COPN	Status
HB 381	Del. O'Bannon	This bill exempted outpatient cardiac hospitals in the City of Richmond that provided certain outpatient services from the requirements of COPN when adding computed tomographic equipment.	Failed to Report

HB 396	Del. Hamilton	The bill established a task force to be appointed by the Board of Health to meet at least every two years and to update or validate the State Medical Facilities Plan, at least every four years.	Passed
HB 398	Del. Hamilton	The bill changes the definition of what a project requiring certificate of public need is by removing from the definition the relocation of beds from one facility to another at the same site and, under certain circumstances, from one nursing home to another nursing home under common ownership regardless of location.	Passed
HB 502	Del. Hamilton	The bill added a twenty-first consideration to the list of considerations the State Health Commissioner is required to take into account when making a determination of public need. This requires the State Health Commissioner to consider citizen accessibility, community support and the introduction of institutional competition in making the determination of need.	Passed
HB 819	Del. Albo	This bill would allow nursing homes in Planning District 8 that are part of a continuing care retirement community and that meet certain conditions to become certified under the Medical Assistance Program and accept public assistance funds for the care of residents after the end of the open admission period.	Passed
HB 1498	Del. Kilgore	Notwithstanding any other regulation or provision of a request for applications the bill allows the State Health Commissioner to issue a request for applications, accept applications and issue a certificate for 120 new nursing home beds in Planning District 3.	Passed
HB 1532	Del. Hogan	Notwithstanding any other regulation or provision of a request for applications the bill allows the State Health Commissioner to accept applications and issue a certificate for 30 new nursing home beds in each nursing home in Planning District 13 with at least a 99% occupancy rate in fiscal years 2006 and 2007.	Passed
SB 672	Sen. Houck	Notwithstanding any other regulation or provision of a request for applications the bill allows the State Health Commissioner to issue a request for applications, accept applications and issue a certificate for 90 new nursing home beds in Planning District 9.	Failed to Report

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, the Virginia Association of Regional Health Planning Agencies, the Virginia Association of Nonprofit Homes for the Aging, and other interested stakeholders. 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 to 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. The comments from the additional comment period were addressed. The final amendments to the SMFP were approved by the Board of Health in July 2008, and approved by the Governor in December 2008. VDH has convened the State Medical Facilities Task Force, which is meeting on a quarterly basis in order to begin the review of the SMFP as required by HB 398 of the 2008 Session.

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 35 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 2008, the project categories are:

Computed Tomography, Magnetic Resonance Imaging, Positron Emission Tomography, Nuclear Medicine Imaging, and Magnetic Source Imaging

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

- 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 or replacement 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 or replacement 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 or replacement 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 or replacement by an existing medical care facility of PET equipment

For each project type reviewed in this report three options are presented regarding the continued regulation of the service. While not exhaustive of the options available, the three actions represent a continuum of possibilities.

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.

Computed Tomography

The SMFP defines Computed Tomography (CT) as "the construction of images through the detection and computer analysis of numerous X-ray beams directed through a part of the body." Historically, CT scanners were either head only scanners or full body models capable of imaging any part of the body. Since July 1974 when the first COPN was issued authorizing a CT scanner in Virginia the technical capabilities and uses for CT have exploded. CT imaging capability is almost as common in health care today as plane film imaging. CT scanners are found in emergency departments where they are instantly available to clear cervical spines, for trauma management and for the diagnosis of stroke. CT scanners are used in radiation therapy programs for treatment simulation in setting up courses of therapy. CT technology has been combined with positron emission Tomography (PET) to better reference the PET image to anatomical landmarks. CT imaging is being used for non-invasive imaging of the heart and colon, potentially replacing procedures such as cardiac catheterization and colonoscopy.

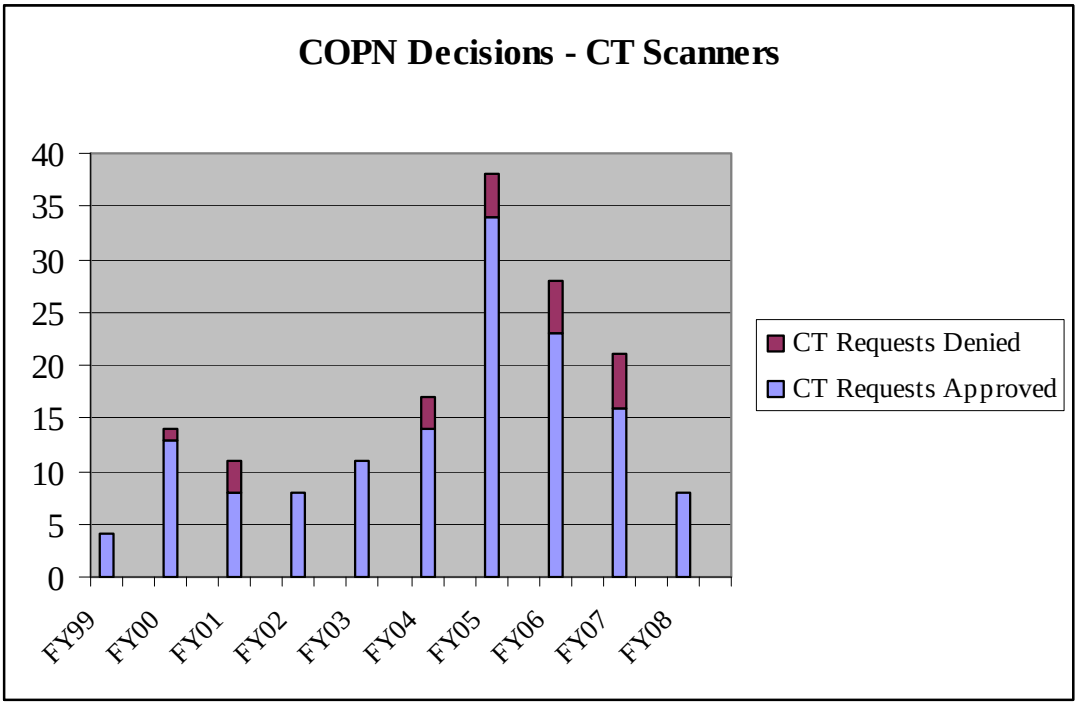
The *Code of Virginia*, at §32.1-102.1, (Appendix B) defines a project requiring COPN authorization, in part, as "the introduction into an existing medical care facility of any new … computed tomography (CT), … which the facility has never provided or has not provided in the

previous 12 months" and " the addition by an existing medical care facility of any medical equipment for the provision of …computed tomography (CT),…"

In the last five years, since the last Annual Report addressed CT scanners, there have been 112 requests to add or introduce CT scanners at existing medical care facilities or establish a new facility for CT imaging. Twenty-two, 19.6%, of those requests were denied. A third of the denied requests for CT were part of a larger request, e.g., to establish a specialized center for radiation therapy, and the over all project was denied. The 90 requests for new CT scanners approved over the last five years represent a capital commitment of approximately $168 million.

Chart 3 below shows the decisions involving CT imaging services for the last ten fiscal years. The vast majority of the decisions have been approvals. There was an upward trend in the number of requests, and approvals, peaking with 34 CTs added and 4 denied in FY 2005. The last three years have shown a dramatic decline with only eight requests for CT reviewed in FY 2008, all of which were approved.

Chart 3



The use of CT is expanding beyond simple diagnostic imaging. CT is quickly replacing traditional simulators for radiation therapy treatment planning. The CT scanner provides the radiation therapy team with more precise imaging, allowing the patient to benefit from the more precise capabilities of the radiation therapy machines. The result is more radiation delivered to the cancer where it's needed and less radiation delivered where it's not needed, minimizing damage to healthy tissue.

The speed of CT scanners has increased to the point that they are capable of performing real time imaging of the heart, allowing the use of a CT scanner to obtain much of the information previously only available through an invasive cardiac catheterization. This is allowing more patients to benefit from a heart screening procedure without the risk of an invasive catheterization procedure. There is evidence that, for at least a select portion of the population, CT angiography has a high degree of accuracy and is a reliable tool in cardiac screening and diagnostics. There is, however, evidence that CT angiography does not, at least not yet, provide the same degree of clinical information and assurance as invasive cardiac catheterization, which is considered the gold standard in diagnosing coronary artery disease.

CT imaging capability is being added as an integral part of positron emission tomography (PET) scanners, nuclear medicine imaging units and invasive cardiac catheterization units. The CT image, taken at the same time as the PET, nuclear medicine or catheterization image is then electronically overlaid on the PET, nuclear medicine or catheterization imaging to provide better anatomical definition, providing the physician with a clearer picture.

The increased speed and the expanding role of CT imaging come at the price of increased exposure to radiation for the patient. This increased exposure, as well as the increased cost of high end diagnostic imaging is of growing, but unresolved concern.

CT imaging has entered the dentist's office where it is finding a place in the imaging of the jaw and teeth. In FY 2008 it was determined that COPN requirements do not apply to dentist's offices. Since that determination 19 specialized dental CT scanners have been installed.

In Virginia there are currently 263 fixed site CT scanners and 8 mobile CTs. There are an additional nine CT scanners used for radiation therapy treatment planning and simulation. There are 29 hybrid PET/CT scanners authorized, 13 of which are operational.

Appropriateness of Continuing COPN for Computed Tomography Services

Diagnostic imaging, including CT, is a potentially lucrative service with a place in both the hospital and outpatient setting. Imaging centers outside the hospital can be developed without a requirement to be licensed and are not required to report their utilization to Virginia Health Information. Absent a requirement for COPN authorization to develop CT imaging services, imaging centers could be developed as freestanding or physician's office based services and compete directly with hospital services. Arguments have been advanced by hospitals that this would adversely affect their ability to provide emergency department and intensive care, as well as care for the indigent by reducing hospital revenue . This supports a contention that the use of COPN regulation is appropriate for these services. As mentioned earlier the presence of a COPN program is thought to serve as a deterrent to speculative requests. It must be further presumed that absent the tempering effect of a COPN program these otherwise un-requested 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 medical care facilities for CT imaging and the addition of CT scanners 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 physicians seeking to establish freestanding imaging centers, and perhaps the Medical Society of Virginia (MSV) who will continue to view COPN regulation of CT imaging as substantial barrier to entry to the market.

Minimal Change: CT for certain specific applications such as radiation therapy simulation, emergency department placement could be exempted from COPN review. This option would likely not be supported since follow-up and enforcement would be nearly impossible. Addition of an abbreviated or administrative review mechanism for such requests may improve the palatability of the partial de-regulation.

Deregulation: Support efforts to deregulate CT services. The physicians and other advocates will welcome this option, at least as it applies to outpatient services. Hospitals and other existing providers of the service will likely oppose it.

RECOMMENDATION: With appropriate standards in the State Medical Facilities Plan COPN regulation of CT imaging appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to CT services with the modification of the State Medical Facilities Plan, as needed.

Magnetic Resonance Imaging

The SMFP defines Magnetic Resonance Imaging (MRI) as "the construction of images through the detection and computer analysis of minute changes in magnetic properties of atomic particles within a strong magnetic field in response to the transmission of selected radiofrequency pulse sequences. Magnetic resonance imaging uses the magnetic spin properties of certain atomic nuclei to visualize and analyze body tissues." MRI scanners are generally full body models capable of imaging any part of the body. These closed architecture MRI scanners require the patient to be placed well within an enclosed gantry space. This tight space limits the use of these MRI units with patients who are claustrophobic, with pediatric patients or other patients who may need to be accessed during the imaging study. When the COPN Annual Report last reviewed MRIs in 2003, units with an "open architecture" design were generally of a lower magnetic field strength, with slower scan times and lower image quality than higher field strength units. Open architecture MRIs have since improved in image quality and still hold a place in meeting the needs of this segment of the population.

Since November 1984 when the first COPN was issued authorizing an MRI scanner in Virginia the technical capabilities and uses for MRI have also grown considerably. MRI imaging capability has become such an integral tool for clinical practice that it is difficult to envision a comprehensive medical care facility without one.

In response to the acceptance of MRI as a diagnostic tool in the treatment of conditions of the extremities, small, low field strength MRI units, capable of imaging just the distal extremities, have been developed. The COPN program does not differentiate between types of MRI, open or closed architecture, positional or recumbent, dedicated extremity or full body. Therefore, all MRI units are counted equally in considering the number of units available and all MRI requests are considered using the same use volume standards when making a determination of need. Restricted use units such as dedicated extremity MRIs have had limited success in gaining authorization, only one has been authorized in Virginia, (two others have been requested, one was denied in 2000 and the request for the second was withdrawn in 2001). Interest in "extremity MRIs" has been limited to physicians' offices, principally in the offices of orthopeadic surgeons.

Another innovation in MRI is the introduction of "intra-operative MRI" in which the MRI scanner is a small low field strength portable unit or a low field strength open architecture unit installed in the operating room (OR), or on a track between two ORs, or is a full strength unit installed in a room adjacent to the OR and the patient and OR table are moved to the MRI. Intra-operative MRI is currently being used primarily in neurosurgery for the removal of some brain tumors such as low grade gliomas and pituitary tumors. Development of this application for MRI

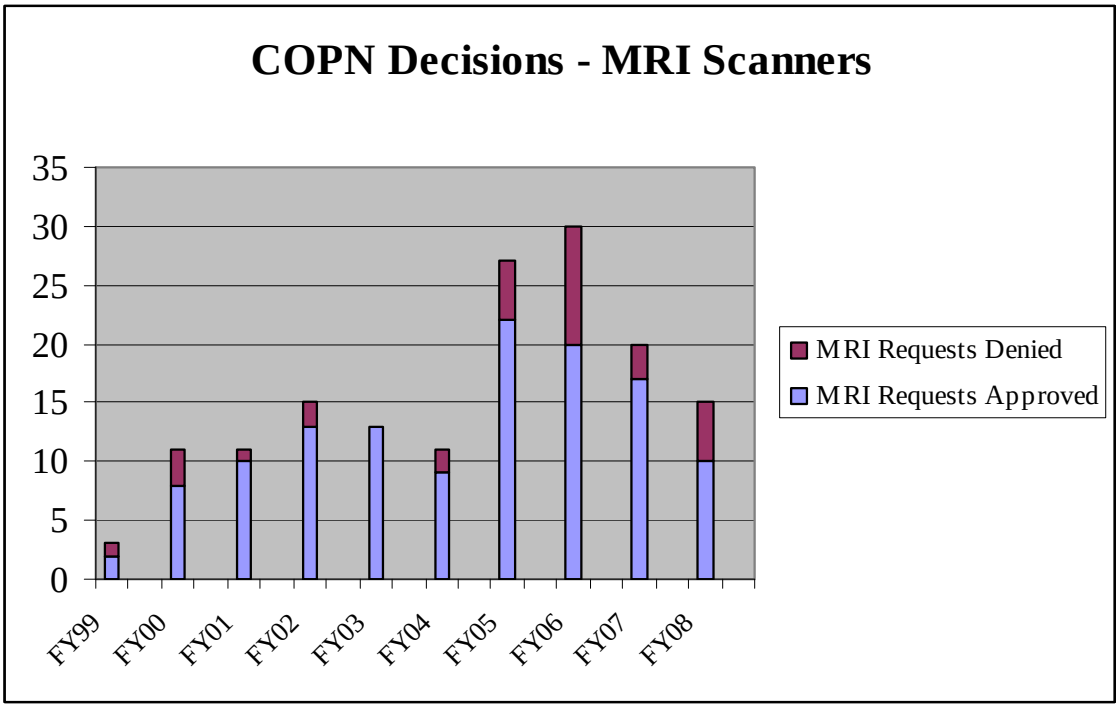
began in the mid-1990s. Virginia has only had three requests for intra-operative MRI, all occurring in FY 2008. In FY 2008 two intra-operative MRIs were authorized and a third is under review with a decision expected in late summer 2008.

The *Code of Virginia*, at §32.1-102.1, (Appendix B) defines a project requiring COPN authorization, in part, as "the introduction into an existing medical care facility of any new … magnetic resonance imaging (MRI), … 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 … magnetic resonance imaging (MRI),…"

In the last five years, since the last Annual Report addressed MRI scanners, there have been 103 requests to add or introduce MRI scanners at existing medical care facilities or establish a new facility for MRI imaging. Twenty-five, 24.3%, of those requests were denied. The 78 requests for new MRI scanners approved over the last five years represent a capital commitment of approximately $175 million. There are 116 fixed site MRIs and 17 mobile MRIs in Virginia, for a total of 133 authorized MRIs.

Chart 4 below shows the decisions involving MRI imaging services for the last ten fiscal years. The majority of the decisions have been approvals, however the denial rate for MRI requests is higher than for CT requests. There had been an upward trend in the number of MRI requests, peaking at 30 requests in FY 2006, that has for last three years gradually decreased to half the number of FY 2006. Experience from recent reviews indicates that the supply of MRI capacity in the planning districts is generally keeping pace with the forecast of need.

Chart 4



Appropriateness of Continuing COPN for Magnetic Resonance Imaging Services

Experience concerning MRI services also supports a contention that review under the COPN program is appropriate for these services. As mentioned earlier the presence of a COPN program is thought to serve as a deterrent to speculative requests. It must be further presumed that absent the tempering effect of a COPN program these otherwise un-requested 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 medical care facilities for MRI imaging and the addition of MRI scanners 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 physicians seeking to establish freestanding imaging centers, and perhaps the Medical Society of Virginia (MSV) who will continue to view COPN regulation of MRI imaging as substantial barrier to entry to the market.

Minimal Change: Certain specific types of MRI, such as dedicated extremity or intraoperative MRI could be exempted from COPN review. This option would likely not be supported since follow-up and enforcement would be nearly impossible. Addition of an abbreviated or administrative review mechanism for such requests may improve the palatability of the partial de-regulation.

Deregulation: Support efforts to deregulate MRI services. The physicians and other advocates will welcome this option, at least as it applies to outpatient services. Hospitals and other existing providers of the service will likely oppose it.

RECOMMENDATION: With appropriate standards in the State Medical Facilities Plan COPN regulation of MRI appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to MRI services with the modification of the State Medical Facilities Plan, as needed.

Positron Emission Tomography Services

The SMFP defines positron emission tomography (PET) as "a non-invasive diagnostic technology which enables the body's physiological and biochemical processes to be observed through the use of positron emitting radiopharmaceuticals which are injected into the body and whose interaction with body tissues and organs is able to be pictured through a computerized positron transaxial reconstruction tomography scanner." In short, PET scans produce an image based on the metabolic activity of tissue. PET scanning appears to have significant clinical value in the diagnosis and monitoring of cancer, in diagnosing Alzheimer's disease and other

neurological disorders, is useful in determining the perfusion of blood in the heart, and is showing promise as a tool in diagnosing Huntington's disease, dementia and Parkinson's disease. Unlike other imaging modalities like CT and MRI, PET scans can distinguish extremely small lesions (between 1.5 mm and 2.0 mm), aid in determination of whether the tumor is malignant and monitor the progress of cancer treatment. In cardiology, a PET scanner can indicate whether the heart is viable after a heart attack.

The first two COPNs for PET in Virginia were issued in 1997, even though the technology had been available for some time. No other PET scanners were requested until 2000. Starting in 2000 three developments motivated hospitals to develop and offer PET services;

- the number of approved clinical applications for PET in the treatment of cancer increased,
- the capital and operating costs of PET decreased significantly as commercial sources for the necessary radiopharmaceuticals became available, so providers no longer needed to purchase and operate a medical cyclotron for production of the radiopharmaceuticals,
- the Center for Medicare and Medicaid Services (CMS) and other third party payers began paying for PET procedures.

A scaled down version of PET, known as positron coincidence detection imaging (PCD) was developed as an add-on technology to single photon emission computed tomography (SPECT, a nuclear medicine imaging process). PCD was 90% as effective as PET at detecting large cancerous lesions and 40%-60% as effective as PET at detecting small lesions, and the technology was continuing to improve. PCD was substantially less expensive when compared to PET. As a result several facilities introduced PET by gaining COPN authorization for PCD. The improved clinical effectiveness of PET over PCD lead most PCD providers to upgrade, with COPN authorization, to PET and there have not been any requests for PCD since 2000.

PET units are now available with integrated CT scanners. The primary purpose for these "built in" CTs is to provide better anatomical definition to the PET imaging. The CT portion of the unit can, in at least some models, function independently. This allows the PET/CT scanner to take just CT imaging. Some facilities have elected to do this to serve as a backup to their routine diagnostic CT scanners. But most facilities find the utilization of the unit is such that use for PET imaging with CT definition is the main focus of the unit.

Recently organ specific PET scans and scanners have become available. In particular breast imaging specific PET scanners have become available for the performance of PET mammography. The use of PET mammography has been suggested as a screening tool, in addition to a primary diagnostic tool, since it can detect lesions as small as 2.0 mm. In the last year one PET mammography unit has been requested and authorized in Virginia.

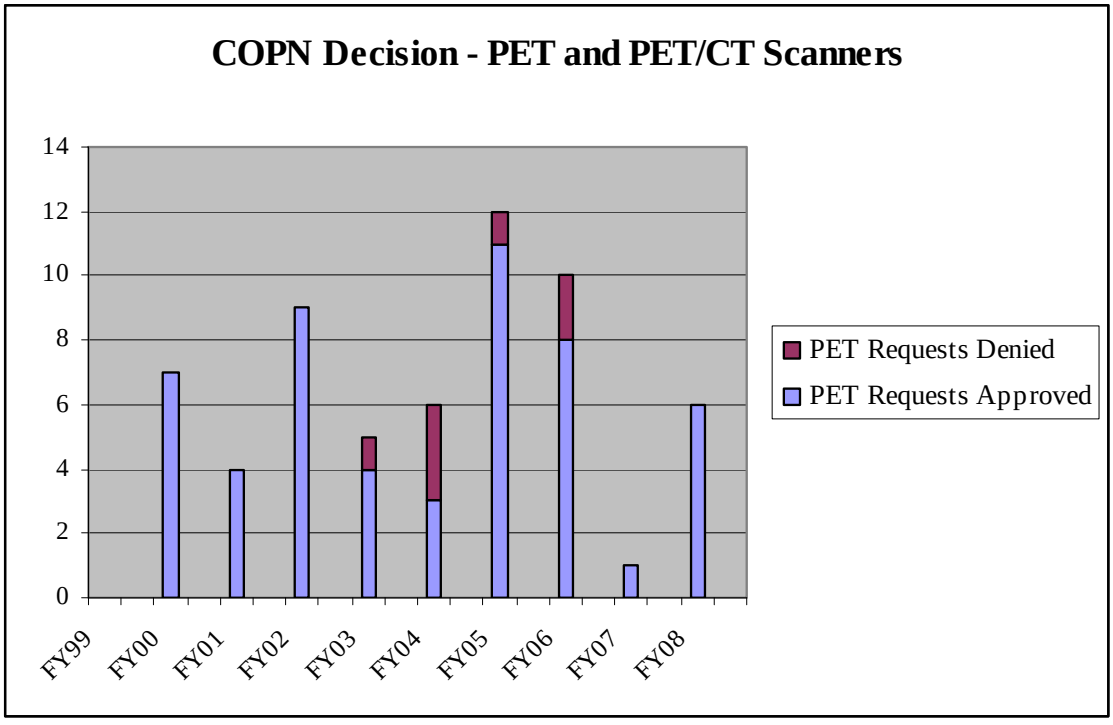
In the last five years, since the last Annual Report addressed PET scanners, there have been 35 requests to add or introduce PET scanners at existing medical care facilities, to establish a new facility for PET imaging or add a site for mobile PET imaging. Six, 17.1%, of those requests were denied. Sixteen of the 29 (55%) approved PET scanners were the hybrid type PET/CT

scanner. The 29 requests for new PET services approved over the last five years represent a capital commitment of approximately $54 million. There are 9 fixed site PET scanners and 15 mobile PET scanners in Virginia, for a total of 24 authorized PET scanners serving 53 individual imaging sites.

The *Code of Virginia*, at §32.1-102.1, (Appendix B) defines a project requiring COPN authorization, in part, as "the introduction into an existing medical care facility of any new … positron emission tomographic (PET) scanning, … 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 … positron emission tomographic (PET) scanning,…"

Chart 5 below shows the decisions involving PET imaging services for the last ten fiscal years. The majority of the decisions have been approvals. As the technology was introduced and third party payors began reimbursing for PET imaging there was an upward trend in the number of PET requests, peaking at 12 requests in FY 2005. The last three years have shown a gradual decrease in the annual number of requests, suggesting the market demand is generally being met.

Chart 5



Appropriateness of Continuing COPN for Positron Emission Tomography

The experience concerning PET services also supports a contention that the program is appropriate for these services. As mentioned earlier the presence of a COPN program is thought to serve as a deterrent to speculative requests. It must be further presumed that absent the tempering effect of a COPN program these otherwise un-requested projects would be carried forth, resulting in, potentially, gross duplication of services. PET is still fairly early in the life cycle of its clinical usefulness. One of the goals of the COPN program is the promotion of comprehensive health planning to meet the needs of the public. Planning which 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 medical care facilities for PET imaging and the addition of PET scanners 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 physicians seeking to establish freestanding imaging or cancer centers, and perhaps the Medical Society of Virginia (MSV) who will continue to view COPN regulation of PET imaging as substantial barrier to entry to the market.

Minimal Change: Certain specific types of PET, such as dedicated organ specific PET could be exempted from COPN review. This option would likely not be supported since follow-up and enforcement would be nearly impossible. Addition of an abbreviated or administrative review mechanism for such requests may improve the palatability of the partial de-regulation.

Deregulation: Support efforts to deregulate PET services. The physicians and other advocates will welcome this option, at least as it applies to outpatient services. Hospitals and other existing providers of the service will likely oppose it.

RECOMMENDATION: With appropriate standards in the State Medical Facilities Plan COPN regulation of PET appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to PET services with the modification of the State Medical Facilities Plan, as needed.

Nuclear Medicine Imaging Services

There were only three COPN requests for nuclear medicine imaging services in the five years since the technology was last reviewed in the Annual Report, and a total of four requests, all approved, in the last ten years. Two of the four requests were to include nuclear medicine imaging capability in new facilities, one was to add a fixed site imaging unit to replace a mobile service and only one was to introduce the service into an existing hospital. Legislation passed by the 2000 session of the General Assembly reduced the scope of nuclear medicine imaging subject to COPN regulation to include just those requests for nuclear medicine imaging services that will

not be used strictly for cardiac imaging. Most, if not all, sites that wish to offer nuclear medicine imaging for other than cardiac imaging are believed to already offer the service. It seems that continuing to regulate the non-cardiac imaging portion of nuclear medicine imaging under COPN seems to serve little purpose.

Like with PET imaging hybrid units combining nuclear medicine imaging and CT scanners have entered the market. Hybrid units are useful in developing attenuation maps and for providing anatomic definition to the nuclear medicine image. Some hybrid units use a low end CT scanner that is not useful in producing diagnostic quality images and some models use higher quality 16-slice CTs that can be used independently for diagnostic imaging. A request for a hybrid nuclear medicine/CT unit was received in FY 2008 with a decision expected in late summer 2008.

There are 72 planar and 119 single photon emission computed tomography (SPECT) nuclear medicine imaging systems in Virginia that are not dedicated solely to cardiac imaging, for a total of 191 non-cardiac nuclear medicine imaging systems.

The *Code of Virginia*, at §32.1-102.1, (Appendix B) defines a project requiring COPN authorization, in part, as "the introduction into an existing medical care facility of any new … nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, … which the facility has never provided or has not provided in the previous 12 months." There is no requirement for an existing provider of nuclear medicine imaging services to obtain COPN authorization to add capacity.

Options:

No Change: Continue applying the COPN program to nuclear medicine imaging as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP will address necessary changes to the review criteria. Current providers of nuclear medicine imaging services would probably be neutral to this option. There would probably be no opposition.

Minimal Change: Certain specific types of nuclear medicine imaging, such as hybrid units could be exempted from COPN review. This option would likely not be supported since follow-up and enforcement would be nearly impossible and because the technology is already substantially de-regulated in regards to COPN. Addition of an abbreviated or administrative review mechanism for such requests may improve the palatability of the partial de-regulation.

Deregulation: Support efforts to deregulate nuclear medicine imaging services. It is expected there would be no resulting proliferation of providers. Current providers of nuclear medicine imaging services would probably be neutral to supportive of this option. There would probably be no opposition. Hybrid units would still be reviewed under the umbrella of CT imaging.

RECOMMENDATION: Since nuclear medicine imaging has already be partially de-regulated in regards to COPN there seems to be little utility in continuing to require COPN authorization for the few circumstances still under COPN review. Therefore it is recommended that Virginia support any effort to complete the deregulation of nuclear medicine imaging services.

Magnetic Source Imaging Services

There has never been a request for magnetic source imaging (MSI) in Virginia. MSI uses "super-sensitive superconducting detectors (to) sample the tiny magnetic fields that come from electrical signals flowing through the body. MSI has some advantages over more established imaging methods such as MRI or PET in that it has a sharper time resolution (it can produce more images per second) and does not base its imaging on local blood flow (which can lag behind the actual activity of interest, in the heart or brain." (P.F. Schewe and B. Stein, The American Institute of Physics Bulletin of Physics News, number 369). Research into the uses for and refinements to the technology continue. MSI is showing some promise as a tool for pre-surgical localization of epileptic lesions and functional mapping of the brain. Third party payors still consider MSI investigational and generally do not reimburse for its use. Until such time as reimbursement is commonly available for MSI it is unlikely many, if any, requests for authorization to develop MSI will be received in Virginia.

The *Code of Virginia*, at §32.1-102.1, (Appendix B) defines a project requiring COPN authorization, in part, as "the introduction into an existing medical care facility of any new … magnetic source imaging (MSI), … 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 … magnetic source imaging (MSI),…"

Options:

No Change: Continue applying the COPN program to the establishment of new medical care facilities for MSI imaging and the addition of MSI scanners 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 since there is currently no demand for the service.

Deregulation: Support efforts to deregulate MSI services. Again, due to lack of demand there is likely to be little support or opposition to this option.

RECOMMENDATION: Since the technology has not yet become generally available in is recommended that Virginia continue to apply the COPN program to MSI services with the modification of the State Medical Facilities Plan, as needed until such time as the service comes into general use and then re-evaluate the need to regulate MSI.

Effectiveness of the COPN Application Review Procedures for FY 2008 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. 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 2008 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 2008 there were no requests deemed recommended for approval due to failure of a regional health planning agency to act in accordance with statutory timelines. There was one recommendation received from the Eastern Virginia Health Systems Agency that was made without the statutorily required reasons for the recommendation. 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 she 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 the 2007-2008 sessions there were 195 bills dealing with COPN filed nationwide in state legislatures. Georgia passed a measure providing that hospitals offering or seeking to offer emergency trauma services do not need a COPN to add additional beds or operating rooms. Massachusetts passed legislation that strengthened the Determination of Need process for outpatient capital projects and ambulatory surgery centers as an effort to quality and ensure the efficient development. In Washington a bill was passed that provides for the issuance of a certificate of need for cardiac care services that offer elective percutaneous coronary interventions at hospitals that do not otherwise provide on-site cardiac surgery. Other bills ranging from limiting COPN to sparsely populated areas or areas with critical access hospitals to modifying the fees charged for COPN applications were also considered.

Accessibility of Regulated Health Care Services by the Indigent

One of the 20 factors (21 as of 1 July, 2008) 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 2008 38 of 56 COPNs issued were issued with a condition for the performance of a certain level of charity, indigent and/or primary care. This represents 67.9% of all COPNs issued in FY 2008. The table presented in Appendix I lists all COPNs issued in FY 2008 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 142 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 and 128 in FY 2007. The increase reflects the number of conditioned projects that have been completed less the number of projects that no longer are required to report. By the end of FY 2008 only 84 active COPN projects (59.2%), reported compliance with conditions. 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. It is expected that reporting for FY 2008 will approach 100%.

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 for which each organization has reported compliance and the number of COPN projects for which a report of compliance on the condition was due in FY 2008 and was not received. There are a total of 55 organizations with conditioned projects that were 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. The concept of regionalization of services, which has been demonstrated to be a factor in the quality of cardiac and transplant services, is based on this premise.

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 2008, there were thirteen equipment replacement registrations (Table 5) and four registrations of capital expenditures in excess of $5 million but less than $15 million (Table 6). There was a dramatic decline in the number of capital expenditure registrations between FY 2007 and FY 2008, although the cumulative value of the expenditures remained virtually the same. The reduced number of registrations is primarily due to increasing the threshold requiring registration from $1M to $5M in accordance with legislation passed by the 2007 session of the Virginia General Assembly. All registered expenditures appeared to be appropriate to the mission of the facility and to the life cycle of the equipment being replaced.

Table 5 Equipment Registrations

Project Type	Number of Registrations	Capital Expenditure
Replace lithotripsy equipment	2	$378,936
Replace MRI Equipment	4	$36,913,002

Replace computed tomography equipment	5	$6,972,065
Replace linear accelerator	2	$6,842,147
TOTAL	13	$22,719,854

Table 6 Capital Expense Registrations

Project Type	Number of Registrations	Capital Expenditure
Hospital renovations, clinical departments	2	$23,686,690
Nursing home renovations	1	$7,780,142
Real estate purchase	1	$8,960,000
TOTAL	4	$40,426,832

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

Note: a change to the definition of project was made in the 2008 session of the Virginia General Assembly. The new definition becomes effective July 1, 2008.

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 $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 $5 million and $15 million shall be registered with the commissioner pursuant to regulations developed by the Board. The amounts specified in this subdivision shall be revised effective July 1, 2008, and annually thereafter to reflect inflation using appropriate measures incorporating construction costs and medical inflation.

Appendix C

Note: a 21st consideration was added in the 2008 session of the Virginia General Assembly. The 21st consideration becomes effective July 1, 2008.

§ 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 therefore 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.

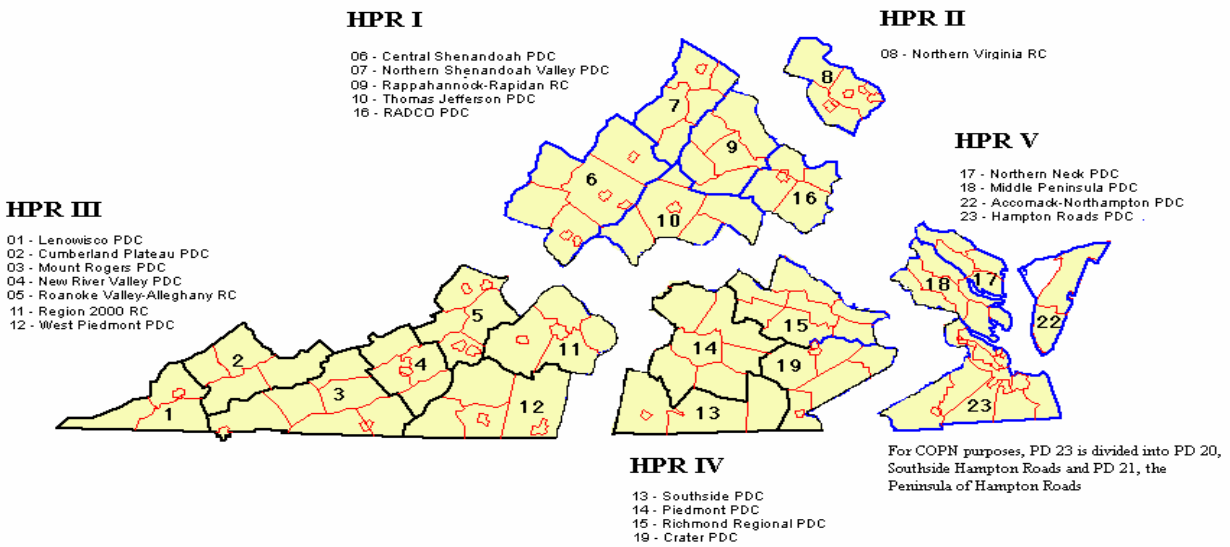
20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

21. In the case of proposed health services or facilities, the extent to which a proposed service or facility will increase citizen accessibility, demonstrate documented community support and introduce institutional competition into a health planning region.

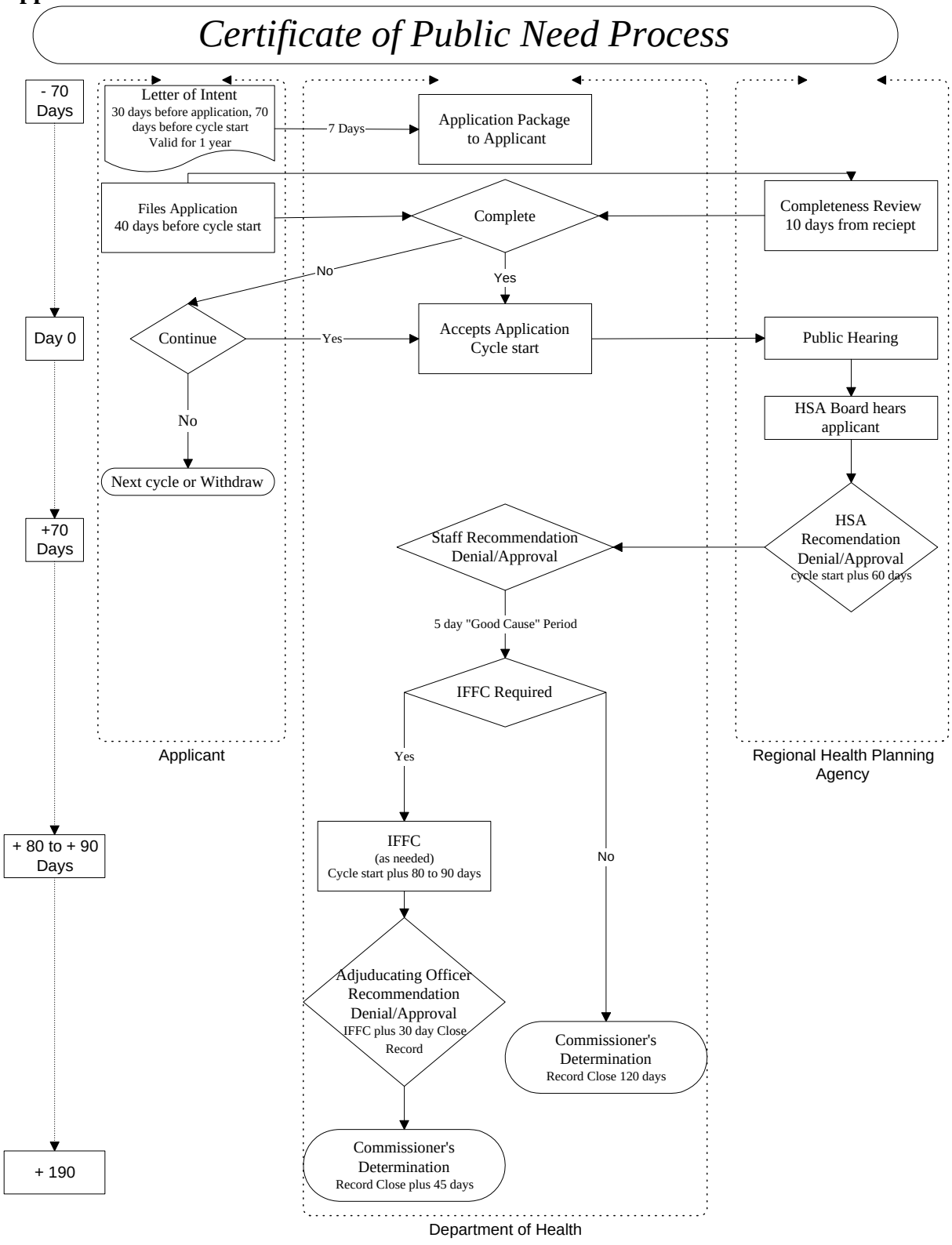
Appendix D

Authorized COPN Requests in Fiscal Year 2008				
	Authorized Projects		Denied Projects	
Project Categories	Number of Projects	Capital Costs	Number of Projects	Capital Costs
Batch Group A General hospitals, obstetrical services, neonatal special care services				
Subtotal	9	**$998,293,333**	3	**$328,218,695**
Batch Group B Open heart surgery, cardiac catheterization, ambulatory surgery centers, operating room additions, transplant services				
Subtotal	8	**$26,583,611**	0	**$0**
Batch Group C Psychiatric facilities, substance abuse treatment, mental retardation facilities				
Subtotal	1	**$200,000**	0	**$0**
Batch Group D Diagnostic imaging				
Subtotal	23	**$43,687,131**	5	**$13,599,103**
Batch Group E Medical rehabilitation				
Subtotal	1	**$6,000,000**	1	**$5,352,146**
Batch Group F Gamma knife surgery, lithotripsy, radiation therapy, comprehensive cancer care centers				
Subtotal	11	**$9,673,093**	1	**$9,051,256**
Batch Group G Nursing home beds, capital expenditures				
Subtotal	3	**$6,754,361**	0	**$0**
COPN Program Total	**56**	**$1,091,191,529**	**10**	**$356,221,200**
Total Reviewed	**66**	**$1,447,412,729**		

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

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

Seventeenth Annual Report – 2013

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

Project Categories Presented in the First Ten Years of Annual Reports (1997 – 2007)

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

Eleventh Annual Report - 2007

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

Appendix H

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 2008

Applicant/Project Location	Project	PD	COPN #	Decision Date	Conditions
Abingdon Surgical Centre, LLC	Establish an Outpatient Surgical Hospital (2 ORs)	3	VA- 04098	08/15/2007	2.4% indigent / primary care
Center for Surgical Excellence, LLC	Establish an Outpatient Surgical Hospital	5	VA- 04100	08/10/2007	2.5% indigent / primary care
Chesapeake Diagnostic Imaging Centers	Add a Second MRI Unit	20	VA- 04101	09/07/2007	3.2% indigent / primary care
Martha Jefferson Hospital	Establish a General Acute Care Hospital (Replace and Relocate MJH)	10	VA- 04103	09/21/2007	2.4% for 1st 2 yrs then regional avg
Bon Secours-St. Mary's Hospital of Richmond, Inc.	Add a Third MRI (Intra-operative)	15	VA- 04104	09/10/2007	2.9% indigent / primary care
Henrico Doctors' Hospital	Add 1 MRI Scanner at the Forest Campus	15	VA- 04105	09/10/2007	2.9% indigent / primary care
Cancer Centers of Virginia, LLC	Expand Radiation Therapy Services at Sentara CarePlex by the Addition of one Intrabeam Radiation Therapy Device	21	VA- 04109	10/19/2007	3.2% indigent / primary care
Riverside and University of Virginia Radiosurgery Center, LLC	Add Equipment to Existing Synergy-S Radiosurgery Unit to Enable it to Provide Radiation Therapy Treatments	21	VA- 04110	10/19/2007	3.2% indigent / primary care
Reston Hospital Center, LLC	Add One Linear Accelerator and Introduce 1 Stereotactic Radiosurgery	8	VA- 04111	10/19/2007	3.0% indigent / primary care
LTACH of Northern Virginia, LLC	Establish a 50-bed LTACH within Inova Mount Vernon Hospital	8	VA- 04113	10/09/2007	3.0% indigent / primary care
Augusta Health Care, Inc. d/b/a Augusta Medical Center	Establish an Outpatient Surgical Hospital (4 ORs - shell 1, add 1 and relocate 2)	6	VA- 04114	12/21/2007	2.4% indigent / primary care, increase to regional avg in 3rd yr
Martha Jefferson Outpatient Surgery Center, LLC	Add 2 ORs	10	VA- 04118	12/13/2007	2.4% indigent / Primary care, change to benchmark in 3rd yr
Drs. Mark and Christine Rausch	Establish an Outpatient Surgical Hospital (1 OR)	15	VA- 04120	12/14/2007	2.9% indigent / primary care
Prince William Health System	Add 2 ORs at the Prince William Hospital Ambulatory Surgery Center at Market Center	8	VA- 04122	12/28/2007	2.0% indigent / primary care
Orthopaedic Surgery and Sports Medicine Specialists	Relocate MRI Services	21	VA- 04123	03/05/2008	3.3% indigent / primary care
Ellen Shaw de Paredes Institute for Women's Imaging	Establish a Specialized Center for MRI Imaging (Breast)	15	VA- 04125	03/05/2008	5.0% indigent / primary care
Chippenham & Johnston-Willis Hospitals, Inc	Add a second MRI Scanner (JW Campus)	15	VA- 04126	03/05/2008	3.3% indigent / primary care
Riverside Tappahannock Hospital	Replace Mobile MRI Service with Fixed Equipment	18	VA- 04128	03/05/2008	3.0% indigent / primary care

Danville Regional Medical Center	Add 2nd CT Scanner	12	VA- 04129	03/05/2008	2.5% indigent / primary care
Prince William-Fauquier Cancer Center d/b/a The Cancer Center at Lake Manassas	Introduce PET/CT Services (Mobile Site)	8	VA- 04131	03/05/2008	3.2% indigent / primary care
Inova Fairfax PET/CT, LLC	Establish a Specialized Center for PET/CT Services	8	VA- 04132	03/05/2008	3.2% indigent / primary care
Sentara Obici Hospital	Establish a Specialized Center for CT and MRI Imaging (Through Relocation of Equipment)	20	VA- 04133	03/05/2008	3.2% indigent / primary care
Sentara Leigh Hospital	Add one MRI Scanner	20	VA- 04134	03/05/2008	3.2% indigent / primary care
Martha Jefferson Hospital	Introduce Stereotactic Radiosurgery Services	10	VA- 04137	04/14/2008	3.4% indigent / primary care
Sentara Hospitals	Establish a General Acute Care Hospital through Partial Replacement & Relocation of Sentara Bayside Hospital & Introduce OB & Intermediate Level Nursery	20	VA- 04138	03/21/2008	3.2% indigent / primary care
Sentara Obici Hospital	Addition of 30 to 40 Acute Care beds including Medical/surgical, Intensive Care and Obstetric beds	20	VA- 04139	03/21/2008	3.2% indigent / primary care
Falls Church Lithotripsy, L.L.C.	Add One Mobile Renal Lithotripter	8	VA- 04140	04/14/2008	3.2% indigent / primary care
Virginia Hospital Center	Introduce Stereotactic Radiosurgery Services	8	VA- 04141	04/11/2008	3.2% indigent / primary care
Inova Health System	Introduce Stereotactic Radiosurgery at Inova Alexandria Hospital	8	VA- 04142	04/11/2008	3.2% indigent / primary care
Prince William Health System	Introduce Brachytherapy Services	8	VA- 04145	04/14/2008	2.0% indigent / primary care
Riverside Regional Medical Center	Introduce Lithotripsy Services at two Sites (Mobile Sites)	21	VA- 04146	04/17/2008	3.3% indigent / primary care
Culpeper Surgery Center, LLC	Introduce Lithotripsy Services (Mobile Site)	9	VA- 04147	04/17/2008	3.4% indigent / primary care
Johnston Memorial Hospital	Establishment of a General Acute Care Hospital through the Replacement and Relocation of Johnston Memorial Hospital	3	VA- 04148	05/14/2008	2.4% indigent / primary care
Smyth County Community Hospital	Establishment of a General Acute Care Hospital through the Replacement and Relocation of Smyth County Community Hospital	3	VA- 04149	05/14/2008	2.4% indigent / primary care
Virginia Hospital Center (Virginia Hospital Center Arlington Health System)	Addition of a Fixed PET/CT Scanner	8	VA- 04151	05/14/2008	3.2% indigent / primary care
Alliance Imaging, Inc.	Add a Mobile PET/CT Scanner	8	VA- 04152	05/14/2008	3.2% indigent / primary care
Open MRI of Southern Virginia, LLC	Establish a Specialized Center for MRI Imaging (Mobile Site)	15	VA- 04153	05/23/2008	3.3% indigent / primary care
Daleville Imaging, L.P.	Establish a Specialized Center for CT Imaging	5	VA- 04161	06/20/2008	2.5% indigent / primary care

Appendix I

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

(As of June 30, 2008 for reports due during FY 2008)

COPNs With		
No Report Submitted	Conditions Reported Met	Organization
1		Alliance Imaging
	3	Augusta Hospital Corporation
1		Bath County Community Hospital
1	1	Bon Secours Hampton Roads
1	10	Bon Secours Richmond
	2	Carilion Clinic
	3	Chesapeake General Hospital
	1	Central Virginia Imaging
1		Community Memorial Health Center
	1	Community Radiology of Virginia, Inc.
2		Culpeper Regional Hospital
1		Danville Regional Medical Center
	2	Fairfax Radiology Consultants, P.C.
1		Falls Church Lithotripsy Associates, L.L.C.
	1	First Hospital Corporation of Virginia Beach d/b/a Virginia Beach Psychiatric Center
1		Greensville Memorial Hospital, now Southern Virginia Regional Medical Center
	1	Halifax Regional Hospital, Inc.
	1	Hampton Roads Orthopaedics & Sports Medicine
5	13	HCA facilities
	2	HealthSouth
7		Inova facilities
	1	Insight Health Corporation
2		Lee Regional Medical Center
	6	Martha Jefferson Hospital
	6	Medicorp
1		MedQuest
	1	McGuire Medical Group (now Virginia Physicians, Inc.)
3		Northern Virginia Imaging, L.L.C.
1		Norton Community Hospital
2	1	Odyssey IV, LLC, dba the Center for Advanced Imaging
	1	Osteopathic Surgical Centers, LLC
1		PET of Reston LP
1		Potomac Hospital Corporation of Prince William
	2	Prince William Hospital
1		R Joy LLC and R Joy II LLC (Eye Surgery Limited &/or Beach Surgicenter for Eyes)

1		Rappahannock General Hospital
5	2	Riverside Health System
	1	Roanoke Ambulatory Surgery Center, LLC
	1	Roanoke Valley Center for Sight, L.L.C.
2		Rockingham Memorial Hospital
	1	Royal Medical Health Services
7	7	Sentara Healthcare
1		Surgical Care Affiliates, Inc., now Regional Surgical Services, LLC
1		The Center for Cosmetic Laser & Dermatologic Surgery
1		The Skin Cancer Surgery Center
3		The Urosurgical Center of Richmond
	1	Tuckahoe Orthopaedic Associates, LTD
1		Twin County Family Care Centers, Inc.
4		Valley Health
	1	Virginia Cancer Institute, Inc.
4		Virginia Hospital Center Arlington Health System
	1	Warren Memorial Hospital
2		Washington Radiology Associates, P.C.
	1	Winchester Eye Surgery Center, LLC
1		Winchester Radiologists, PC, Winchester Open MRI, LLC