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
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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 2003).

Program activity for the period covered in this report includes the issuance of 71 decisions. The State Health Commissioner authorized 64 projects with a total expenditure of $480,603,871 and denied 7 projects with proposed capital expenditures of $94,309,996. 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: 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.

The section on project analysis addresses the history of COPN regulation for these project categories, the nature of the specific services, and three potential options for the future of each of the categories with a recommended action.

The Virginia Department of Health (VDH) recommends continuing to employ the COPN program as it has been used in the regulation of computed tomography, magnetic resonance imaging, positron emission Tomography and magnetic source imaging. VDH recommends completing the partial deregulation of nuclear medicine imaging initiated in 2000.

Compliance with the conditions to provide indigent care remains relatively poor. 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. 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. 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. This removes the barrier to compliance most often cited by facility managers as their reason for failing to satisfy indigent care conditions.

During FY 03 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. This year one request reviewed by a regional health planning agency and VDH staff was automatically deemed approved when the court determined that no decision had been made and the statutory time limit on review was exceeded.

Preface

This 2003 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 (2003). 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 law states the objectives of the program are: (i) promoting comprehensive health planning to meet the needs of the public; (ii) promoting the highest quality of care at the lowest possible cost; (iii) avoiding unnecessary duplication of medical care facilities; and (iv) providing an orderly procedure for resolving questions concerning the need to construct or modify medical care facilities. In essence, the program seeks to contain health care costs while ensuring financial and geographic access to quality health care for Virginia citizens at a reasonable cost. The current regulatory scope of the COPN program is shown in Appendix B.

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

SUMMARY OF THE STATE HEALTH COMMISSIONER'S ACTIONS AND OTHER COPN PROGRAM ACTIVITY DURING FISCAL YEAR 2003

Project Review

Decisions

During FY03, the Division of Certificate of Public Need (DCOPN), which assists the Commissioner in administering the COPN program, received 130 letters of intent to submit COPN requests and 97 applications for COPNs. There were 25 letters of intent or applications withdrawn by applicants or which lapsed 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 based on the information, 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.

The Commissioner issued 71 decisions on applications to establish new medical care facilities or modify existing medical care facilities. Sixty-four of these requests were approved or conditionally approved, for a total authorized capital expenditure of $480,603,871. Seven requests were denied. These seven denied projects had proposed total capital expenditures of

$94,309,996. Two requests were determined to not require COPN review. COPN decisions in FY03 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
2003	130	97	14	64	7	3	2

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

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

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

Adjudication

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

There were 29 COPN applications warranting IFFCs heard before a VDH Adjudication Officer in FY03. Sixteen of the COPN requests warranting an IFFC were approved in FY03. Seven requests were denied after the IFFC. Six projects heard in an IFFC in FY03 still have decisions pending and will be resolved in the Fall of 2003.

Table 2 illustrates the types of projects that were forwarded to an IFFC in FY03.

Table 2 Projects at IFFC in FY02

Project Type	Approved	Denied	Total
Nursing Home	3	0	3
Outpatient Surgery Hospitals	2	0	2
Magnetic Resonance Imaging	3	0	3
Computed Tomography Services	3	0	3
Radiation Therapy	0	1	1
Relocate/Replace Hospital	1	1	2
Medical Rehabilitation Services	1	2	3
Add Hospital Beds	1	2	3
Positron Emission Tomography Services	0	1	1
Cardiac Catheterization	1	0	1
Establish Open Heart Surgery Service	1	0	1
TOTAL	16	7	23

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. Three actions were appealed in FY03, resulting in five competing requests being heard at court.

Botetourt Health Investors appealed the determination made at IFFC that their request to acquire and relocate 90 nursing home beds should not have been accepted for review as a valid application. Based on that determination, the review of the request was terminated by the adjudication officer. The Court ruled that such a determination constituted a decision, an action reserved to the Commissioner. The Court further noted that as the 190-day review cycle had expired the lack of a decision constituted a deemed approval under the *Code*. A COPN was issued to Botetourt Health Investors. As a deemed approval constitutes a case decision, the Botetourt Health Investors case decision was appealed by Medical Facilities of America (MFA). The MFA appeal is still pending

The second judicial review resulted from the Commissioner's denial of a request for the establishment of a new hospital in western Planning District 8 to replace Northern Virginia Community Hospital and Dominion Hospital, both from eastern Planning District 8. The Court's decision is still pending.

The final decision appealed in FY03 was the Commissioner's approval of Sentara Healthcare's request to establish a mobile renal lithotripsy service. The appeal was filed by Fayetteville Lithotripsy Virginia I, L.P. The Court dismissed the appeal since Fayetteville Lithotripsy Virginia I, L.P., had not properly established themselves as a party to the COPN request.

The Circuit Court decided an appeal filed by Riverside Health System in late 2001. The appeal involved two competing applicants requesting MRI services in Planning District 20.

Riverside Health System appealed the Commissioner's decision to deny their request to expand their mobile MRI service. The Circuit Court upheld the Commissioner's decision.

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 FY03, three certificates were surrendered: (a) a certificate to introduce CT services into an existing medical care facility in Planning District 10 was surrendered because the applicant's plans for the service changed and were met through another, more comprehensive authorization; (b) a certificate to introduce PET imaging into an existing medical care facility in Planning District 6 through the purchase of a positron coincidence detection imaging system was surrendered because the applicant's plans for the service changed, possibly in response to changes in reimbursement for positron coincidence detection imaging, (c) a certificate authorizing the addition of 60 beds to an existing nursing home in Planning District 19 was allowed to expire when the owner decided to sell the nursing home for relocation prior to completing the authorized bed addition.

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 reviewed five requests for significant changes in FY03. All five of the significant changes were authorized. Two of the significant change requests involved an increase of authorized capital expenditure by 10% or more. The first was for a 13% increase in capital costs for a project to add 20 beds to a nursing home. The second increased the approved capital cost amount by 20% for the establishment of a new 240-bed nursing home. That significant change also changed the site for the project and extended the time allowed for completion of the project.

The remaining three authorized significant changes were for changes in the site of the proposed project. The first site change was to add sites to an authorized mobile lithotripsy service. Both of the other two site changes involved moving the site of authorized services (an outpatient surgical hospital and an MRI scanner) to sites better suited to the service.

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), which will target geographic areas for consideration of increased bed supply and establish competitive review cycles for the submission of applications.

On July 29, 2002, an RFA for 60 nursing home beds in Planning District 11 and 120 nursing home beds in Planning District 13 was issued. The beds were authorized through the passage of Senate Bill 490 (Chapter 168, Acts of Assembly) by the 2002 session of the General Assembly. In April 2003 a COPN was issued authorizing a new 120-bed nursing home in Planning District 13. In May 2003 two COPNs were issued authorizing a total of 58 of the 60 possible nursing home beds in Planning District 11.

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. In FY03 all COPN applications were reviewed within the statutory 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 90 days to render a decision. Failure to do so results in a deemed approval of the request. In FY03, all but one of the Commissioner's decisions were rendered within this time period. One request was determined at IFFC to not be an appropriate application and was excluded from further review by the adjudication officer. On appeal it was determined that the action of excluding the request from further review constituted a decision, an action reserved solely to the Commissioner. The case was remanded to the Commissioner. Since the statutory time period for making a decision had passed by the time the request was returned to the Commissioner the request was deemed approved and a COPN was issued.

Although the timeliness for COPN application review represents a success, there remain opportunities for improvement in the timeliness of action on project registrations and extensions of certificates, as well as in response time to significant change requests. DCOPN's response to registrations, extensions and significant change requests continues to improve, but there continues to be opportunities to improve the timeliness of responses. Changes in internal processes and personnel should have a marked impact on the timeliness of responses.

LEGISLATION

In the 2003 session of the General Assembly, there were two Senate bills and three House bills that addressed some aspect of the COPN program. The bills centered around three basic issues: the combining of radiation therapy requests and diagnostic imaging requests in a single batch to facilitate applications for comprehensive cancer care centers; special exemptions for specific, existing continuing care retirement communities to allow the continued direct admission of non-contract holders; and authorization of beds for a nursing home without an RFA. Three of these bills were passed by the General Assembly. HB 1621 (Hamilton) and SB 1226 (Williams) were passed, authorizing the review of requests for radiation therapy and diagnostic imaging requests in a single application in the radiation therapy review cycle. SB 1331 (Houck), which would have allowed a nursing home to add 34 beds without the issuance of an RFA was stricken at the request of the patron. HB 1747 (Suit) granted Atlantic Shores Cooperative Association a second three year extension to the provision allowing the continuing care retirement community to admit residents who have not been contract holding residents of the continuing care retirement community directly to their nursing home. HB 2776 (Black), which would have granted Falcon's Landing continuing care retirement community a second three year extension to the provision allowing the continuing care retirement community to admit residents who have not been contract holding residents of the continuing care retirement community directly to their nursing home, failed to report from the Senate.

REGULATION

Emergency changes to the COPN regulations as required by legislation in 1999 expired in January 2001 without the permanent version being in place. The permanent regulations became effective February 3, 2003.

The State Medical Facilities Plan (SMFP) is being reviewed and revised with the assistance of an advisory committee consisting of industry representatives and representatives of the Virginia Association of Regional Health Planning Agencies. The revised SMFP is expected to be ready for issuance as a Notice of Intended Regulatory Action later this year.

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 30 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, a plan was developed by the Joint Commission on Health Care (JCHC) for the phased deregulation of COPN in a manner that preserves 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. No action was taken regarding the plan in either the 2002 or the 2003 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 2003, 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

In addition to the JCHC comprehensive plan for deregulation of the COPN program that has already been presented to the General Assembly, another option for the modification of the program is presented below as an alternative for each of the services reviewed. The option, which would require legislative approval, expands the current concept of an RFA by applying a prospective need analysis to the regulated service and accepting COPN applications for only

those services proposed in locations identified in the RFA. These targeted RFAs would limit COPN review to just those services and areas in which an identified public need exists, potentially stimulating development in some areas and limiting submission of more speculative applications elsewhere.

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. The next generation of CT imaging, known as electron beam tomography, or EBT, allows the relative 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 FY03 there were seven COPN requests to add a total of eight new CT scanners at existing programs and four requests to establish new CT program sites. All eleven requests were authorized. All but two of the requests to add new equipment were made by acute care hospitals. The resultant authorized capital expenditure amount was $23,829,979.

The following requests to establish new CT services or sites (Table 3) and to add CT scanners to existing CT imaging services (Table 4) were issued COPN authorization in FY03. No requests for CT services were denied in FY03.

Table 3 Authorizations to Establish an New CT Imaging Service or Site FY 03

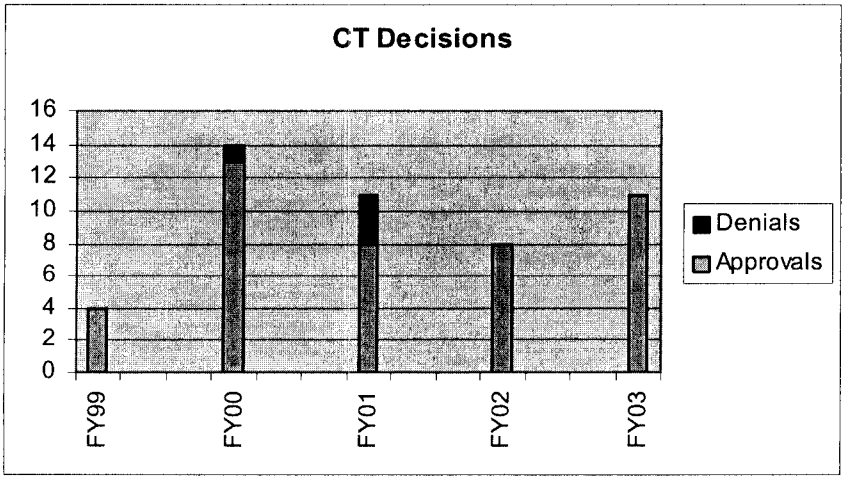
Applicant	Project	Authorized Capital Expenditure	COPN Authorization Number	Date COPN Issued
University of Virginia Health System	Establish a Specialized Center for 2 MRI and 2 CT Scanners	$5,995,800	VA-03689	8/16/2002
Sentara Norfolk General Hospital	Relocation of a CT Scanner	$1,192,344	VA-03719	2/11/2003
Riverside Regional Medical Center	Establish Fixed CT Services and Introduce Mobile MRI Services at an Existing Medical Care Facility	$1,080,189	VA-03733	5/27/2003
Williamsburg Community Hospital	Introduce CT Services into an Existing Medical Care Facility	$1,349,402	VA-03735	5/27/2003

Table 4 Authorization to Add CT Scanners to Existing Services in FY 03

Applicant	Project	Authorized Capital Expenditure	COPN Authorization Number	Date COPN Issued
Loudoun Hospital Center	Addition of a CT Scanner	$1,705,165	VA-03686	8/13/2002
Winchester Radiologists, PC	Addition of Computed Tomography Imaging Equipment	$1,290,177	VA-03688	8/14/2002
Pratt Medical Center	Addition of a MRI and CT Scanner at an Outpatient Diagnostic Center	$3,087,219	VA-03683	8/15/2002
Mary Washington Hospital	Addition of 2 CT Scanners	$2,189,153	VA-03682	8/15/2002
Southside Regional Medical Center	Addition of a Third CT Scanner	$2,365,530	VA-03691	9/9/2002
Sentara Bayside Hospital	Addition of a Second CT Scanner	$1,925,000	VA-03718	2/11/2003
Maryview Medical Center	Addition of Second CT Scanner	$1,650,000	VA-03720	2/11/2003

Chart 1 below shows the decisions involving CT imaging services for the last five fiscal years. The vast majority of the decisions have been approvals. There is a slight upward trend in the number of approvals with fewer over all decisions. Experience from recent reviews indicate that a number of planning districts in the Commonwealth show a calculated need for additional CT capacity, making reasonable requests for additional services in those areas approvable.

Chart 1



Appropriateness of Continuing COPN for Computed Tomography Services

The FY03 COPN experience concerning CT services 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. 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).

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

Deregulation: Support efforts outside the comprehensive JCHC plan 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: 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. The high strength 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. Lower strength MRIs, with an "open

architecture" design are occasionally requested to meet 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 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.

Recently small MRI units, capable of imaging just the distal extremities, have been developed. These restricted use units have limited acceptance in the community and none have been authorized in Virginia, (two have been requested, one was denied in 2000 and the request for the second was withdrawn in 2001).

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 FY03 there were six COPN requests to add a total of six new MRI scanners at existing programs and seven requests to establish new MRI program sites. All thirteen requests were authorized. All but one of the requests to add new equipment were made by acute care hospitals and two of the applicants for new sites were not hospitals. The resultant authorized capital expenditure amount was $27,514,057.

The following requests to establish new MRI services or sites (Table 5) and to add MRI scanners to existing MRI imaging services (Table 6) were issued COPN authorization in FY03. No requests for MRI services were denied in FY03.

Table 5 Authorization to Establish an New MRI Imaging Service or Site FY 03

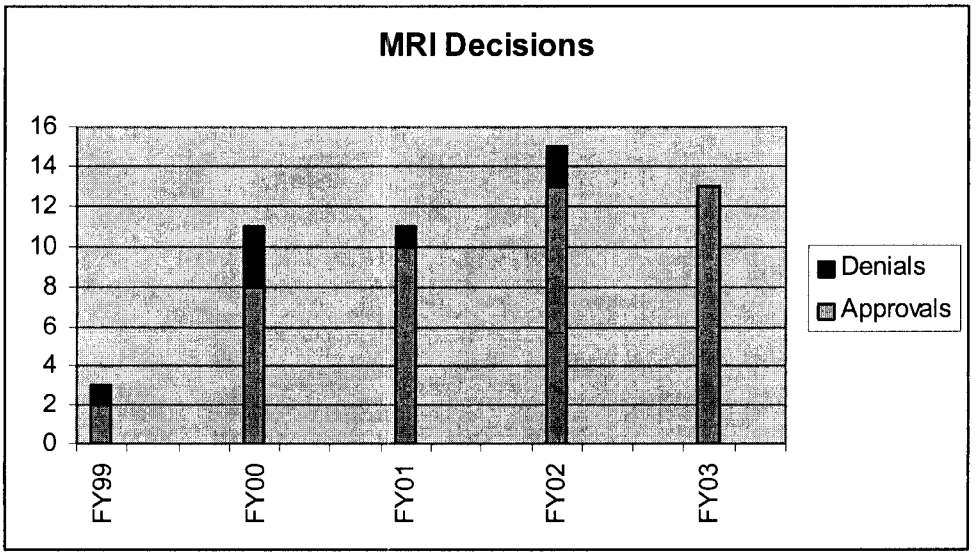
Applicant	Project	Authorized Capital Expenditure	COPN Authorization Number	Date COPN Issued
University of Virginia Health System	Establish a Specialized Center for MRI (2 MRI Scanners) and CT (2 CT Scanners) Services	$5,995,800	VA-03689	8/16/2002
Southside Regional Medical Center	Establish a Specialized Center for MRI Imaging	$0	VA-03690	9/6/2002
Southwest Virginia Regional Open MRI Center	Establish a Specialized Center for MRI Services	$1,490,999	VA-03701	10/8/2002
Warren Memorial Hospital	Introduce Mobile MRI Services	$68,465	VA-03715	2/14/2003
Shenandoah Shared Hospital Services, Inc.	Establish a Mobile MRI Service	$1,886,280	VA-03714	2/14/2003
Riverside Regional Medical Center	Establish Fixed CT Services and Introduce Mobile MRI Services at an Existing Medical Care Facility	$1,080,189	VA-03733	5/27/2003
Williamsburg Community Hospital	Introduce MRI Services into an Existing Medical Care Facility	$2,208,210	VA-03734	5/27/2003

Table 6 Authorization to Add MRI Scanners to Existing Services in FY 03

Applicant	Project	Authorized Capital Expenditure	COPN Authorization Number	Date COPN Issued
Virginia Hospital Center Arlington Health System	Addition of a 2nd MRI	$2,076,841	VA-03685	8/13/2002
Inova Health System	Addition of an MRI Scanner	$2,889,473	VA-03684	8/13/2002
Medical Imaging of Fredericksburg, LLC	Addition of a second MRI Scanner	$2,009,430	VA-03681	8/15/2002
Pratt Medical Center	Addition of a MRI Scanner and a CT Scanner at an Outpatient Diagnostic Center	$3,087,219	VA-03683	8/15/2002
Johnston Memorial Hospital	Addition of a MRI Scanner	$2,371,310	VA-03687	8/16/2002
Lewis-Gale Medical Center, LLC	Addition of a second MRI Scanner	$2,349,841	VA-03700	10/8/2002

Chart 2 below shows the decisions involving MRI imaging services for the last five fiscal years. The vast majority of the decisions have been approvals, however there have been more MRI requests denied than CT requests. There is an upward trend in the number of MRI requests approved. 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 2



Appropriateness of Continuing COPN for Magnetic Resonance Imaging Services

The FY03 COPN experience concerning MRI 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. 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).

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

Deregulation: Support efforts outside the comprehensive JCHC plan 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: 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." PET scanning appears to have significant clinical value in treating cancer patients. Unlike other imaging modalities like CT and MRI, PET scans can distinguish extremely small lesions (between 2.0 cm and 1.8 cm), determine 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. A relatively new use of the PET scanner is very early diagnosis of atherosclerosis.

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 several PCD providers to upgrade, with COPN authorization, to PET and there have not been any requests for PCD since 2000.

Since 2000 25 PET projects, ranging from new fixed site machines to multiple sites for mobile units to PCD units have been authorized. PET is becoming the standard diagnostic and staging tool for some cancers. The Commonwealth is now fairly well covered by PET providers so it is not expected that many additional requests will be authorized until the utilization of the existing units has had time to approach capacity.

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,..."

The following requests to establish new PET services or sites (Table 7) were decided in FY03. There were no decisions involving requests to add PET scanners to existing PET imaging services in FY03. One request for PET services was denied in FY03.

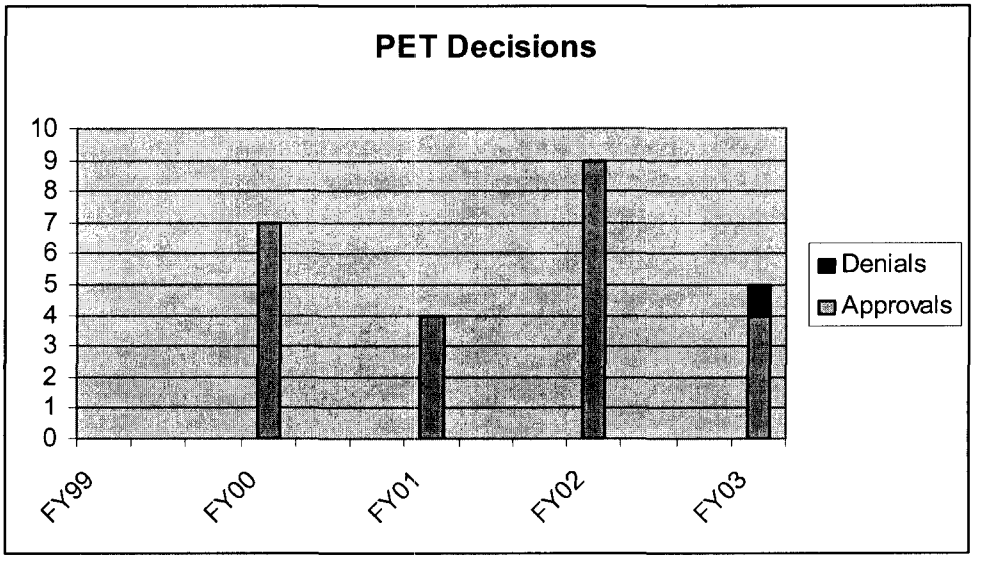
Table 7 Decisions Regarding Positron Emission Tomography in FY 03

Applicant	Project	Authorized Capital Expenditure	COPN Authorization Number	Date COPN Issued
Danville Regional Medical Center	Introduce Positron Emission Tomography Imaging Services Through a Mobile Provider	$0	VA- 03680	8/15/2002
PET of Reston LP	Establish a Specialized Center for Positron Emission Tomography Imaging Services		VA- **Denied**	9/23/2002
Inova Health System	Introduce Positron Emission Tomography Imaging Services	$87,526	VA- 03693	9/23/2002
Community Radiology of Virginia, Inc.	Introduce Positron Emission Tomography Imaging Services Through a Mobile Provider	$1,000	VA- 03717	2/11/2003
Halifax Regional Hospital, Inc.	Introduce Mobile Positron Emission Tomography Services	$0	VA- 03716	2/15/2003

Requests with $0 authorizations use existing authorized mobile providers and existing mobile parking pads.

Chart 3 below shows the decisions involving PET imaging services for the last five fiscal years (no decisions in FY99). The vast majority of the decisions have been approvals. There is an upward trend in the number of PET requests approved, but that trend is expected to decline now that the market nears saturation. Experience from recent reviews indicates that the supply of PET capacity in the planning regions is generally keeping pace with the forecast of need.

Chart 3



Appropriateness of Continuing COPN for Positron Emission Tomography

The FY03 COPN 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 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 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 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).

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

Deregulation: Support efforts outside the comprehensive JCHC plan 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: 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 no COPN requests for nuclear medicine imaging services in FY03. The last nuclear medicine imaging requests were in FY00. 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.

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: In collaboration with the hospital industry, physicians, consumers and advocates, VDH could produce a comprehensive assessment of the State's needs for nuclear medicine imaging services and by way of a targeted RFA publicize the locations where a demonstrated need for new nuclear medicine imaging services exists as a means of stimulating interest in requesting authorization for development of the service. This option has little utility as it is believed the Commonwealth is well served by this imaging modality. Current providers of nuclear medicine imaging services would probably be neutral to this option. There would probably be no opposition.

Deregulation: Support efforts outside the comprehensive JCHC plan 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

RECOMMENDATION: 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. Perhaps there will come a time when MSI is clinically practical and, like PET, will be a necessary tool for the clinician.

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.

Minimal Change: In collaboration with the hospital industry, physicians, consumers and advocates, VDH could produce a comprehensive assessment of the State's needs for the various facilities and service capacity subject to COPN regulation and by way of a targeted RFA, publicize the locations where a demonstrated need for new or additional facilities/capacity exists as a means of stimulating interest in requesting authorization for development of the service. This option may be impractical since the technology is not yet widely available. As such it would probably be opposed by most providers.

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

RECOMMENDATION: 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 use and then re-evaluate the need to regulate MSI.

Effectiveness of the COPN Application Review Procedures for FY03 Project Categories

The statute defining the contents of this study requires an analysis of the effectiveness of the application review procedures used by the regional health planning agencies and VDH. An analysis of effectiveness must detail the review time required during the past year for various project categories. To ensure consistency, the project categories for purposes of this document are the same project categories that were selected for review during FY03. 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 FY03 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 dictated by the *Code*. 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. The number of requests automatically considered as recommended for approval from the regional health planning agency or DCOPN due to their failure to act in accordance with statutory timelines was zero in FY03. Where appropriate, projects were authorized, but more importantly, projects were denied and prevented from proceeding when there was no need for the project demonstrated. This avoided duplication of services and costs without adversely impacting access to care.

Other Data Relevant to the Efficient Operation of COPN Program

The final consideration in the analysis of project categories is that the Commissioner include any other data he determines to be relevant to the efficient operation of the COPN program.

There were no authorizations or requests in FY03 for the addition of psychiatric beds at existing medical care facilities or for the introduction of inpatient psychiatric services at an existing medical care facility. Three new intermediate care facilities for mental retardation (ICF/MR) were authorized in FY03, adding 23 ICF/MR beds in the Commonwealth. This increase in ICF/MR beds, while substantially smaller than that experienced in FY02, continues to indicate a trend for alternative placement sites as the proposed closure of the three state operated mental hospitals approaches (expected to be completed by the end of 2006).

Accessibility of Regulated Health Care Services by the Indigent

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

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 outlet 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. The response from applicants and the community has been positive. With the new language there should be no reason for a facility to not be able to satisfy the requirements of a conditioned COPN.

There were 37 COPNs issued with conditions to provide free or reduced rate care for indigent patients. All but three of these COPNs included the new primary care language. The table presented in Appendix H lists all COPNs issued with a condition for provision of free or reduced cost care for the indigent and those containing the new language that includes the development and operation of primary care for special populations.

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.

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 FY03, there were 33 equipment replacement registrations (Table 7) and thirteen to register capital expenditures in excess of $1 million (Table 8). All registered expenditures appeared to be appropriate to the mission of the facility and to the life cycle of the equipment being replaced.

Table 7 Equipment Registrations

Project Type	Number of Registrations	Capital Expenditure
Replace cardiac catheterization equipment	11	$15,502,703
Replace MRI Equipment	5	$10,054,881
Replace Mobile PET Equipment	1	$1,567,732
Replace cardiac catheterization equipment	8	$12,623,468
Replace Mobile Lithotripter	2	$667,700
Replace linear acccelerator	6	$14,102,525
TOTAL	33	$54,519,009

Table 8 Capital Expense Registrations

Project Type	Number of Registrations	Capital Expenditure
Hospital Renovations	8	$24,863,459
Nursing Home Renovations	2	$6,548,135
Purchase a da Vinci Surgical Robot	1	$1,340,000
Major Software Upgrades	2	$3,959,366
TOTAL	13	$36,710,960

Appendix A

§ 32.1-102.12. Report required.

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

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

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

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

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

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

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

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

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

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

Appendix B

12VAC5-220-10. Definitions.

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

1. General hospitals.

2. Sanitariums.

3. Nursing homes.

4. Intermediate care facilities.

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, or such other specialty services as may be designated by the board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

For purposes of this chapter, the following medical care facility classifications shall not be subject to review:

1. Any facility of the Department of Mental Health, Mental Retardation and Substance Abuse Services.

2. 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.

3. Any physician's office, except that portion of the physician's office which is described in subdivision 9 of the definition of "medical care facility."

4. The Woodrow Wilson Rehabilitation Center of the Virginia Department of Rehabilitative Services.

"Project" means:

1. The establishment of a medical care facility. See definition of "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% 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 of the Code of Virginia.

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 except when such medical care facility is an existing nursing home as defined in §32.1-123 of the Code of Virginia.

5. The introduction into an existing medical care facility of any new cardiac catheterization, computed tomography (CT), 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, organ or tissue transplant service, radiation therapy, nuclear medicine imaging, psychiatric or 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), 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, except for the replacement of any medical equipment identified in this part which the commissioner has determined to be an emergency in accordance with 12VAC5-220-150 or for which it has been determined that a certificate of public need has

been previously issued for replacement of the specific equipment according to 12VAC5-220-105.

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

Appendix C

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

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

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

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

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

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

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

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

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

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

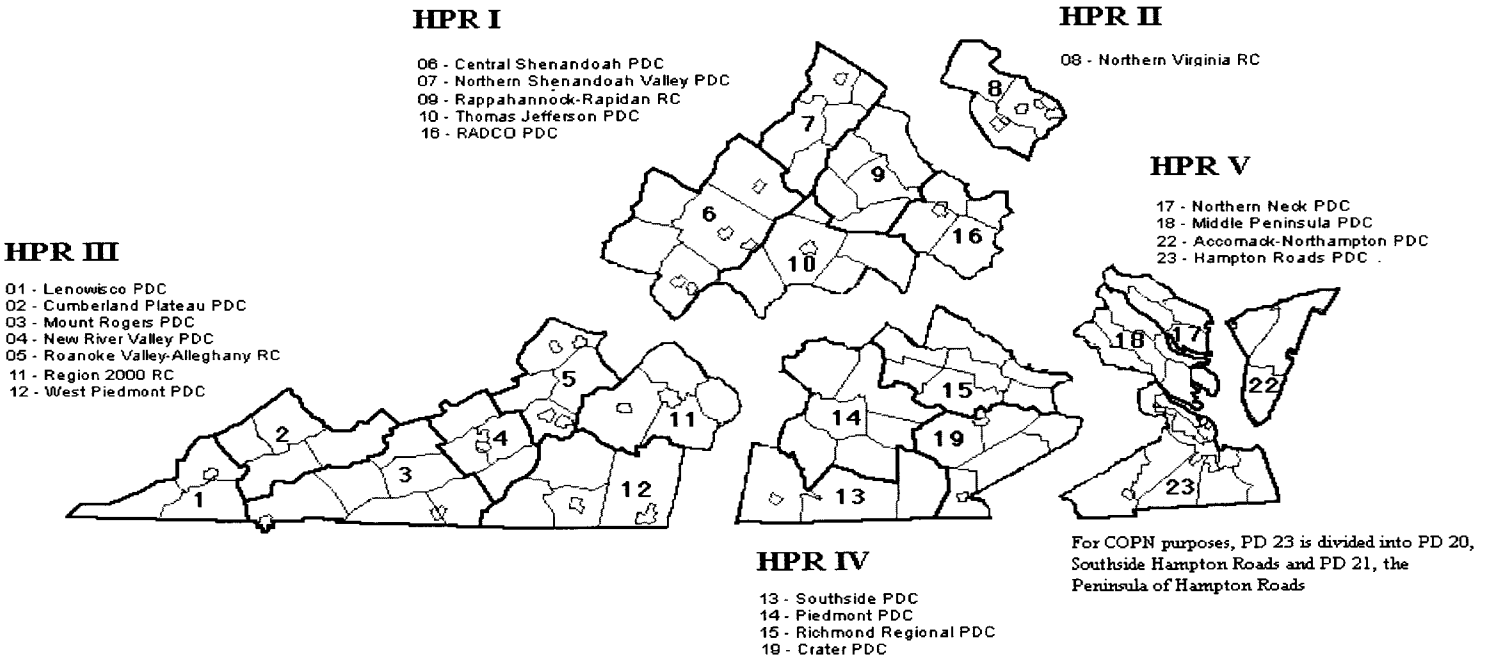
Appendix D

Authorized COPN Requests in Fiscal Year 2003

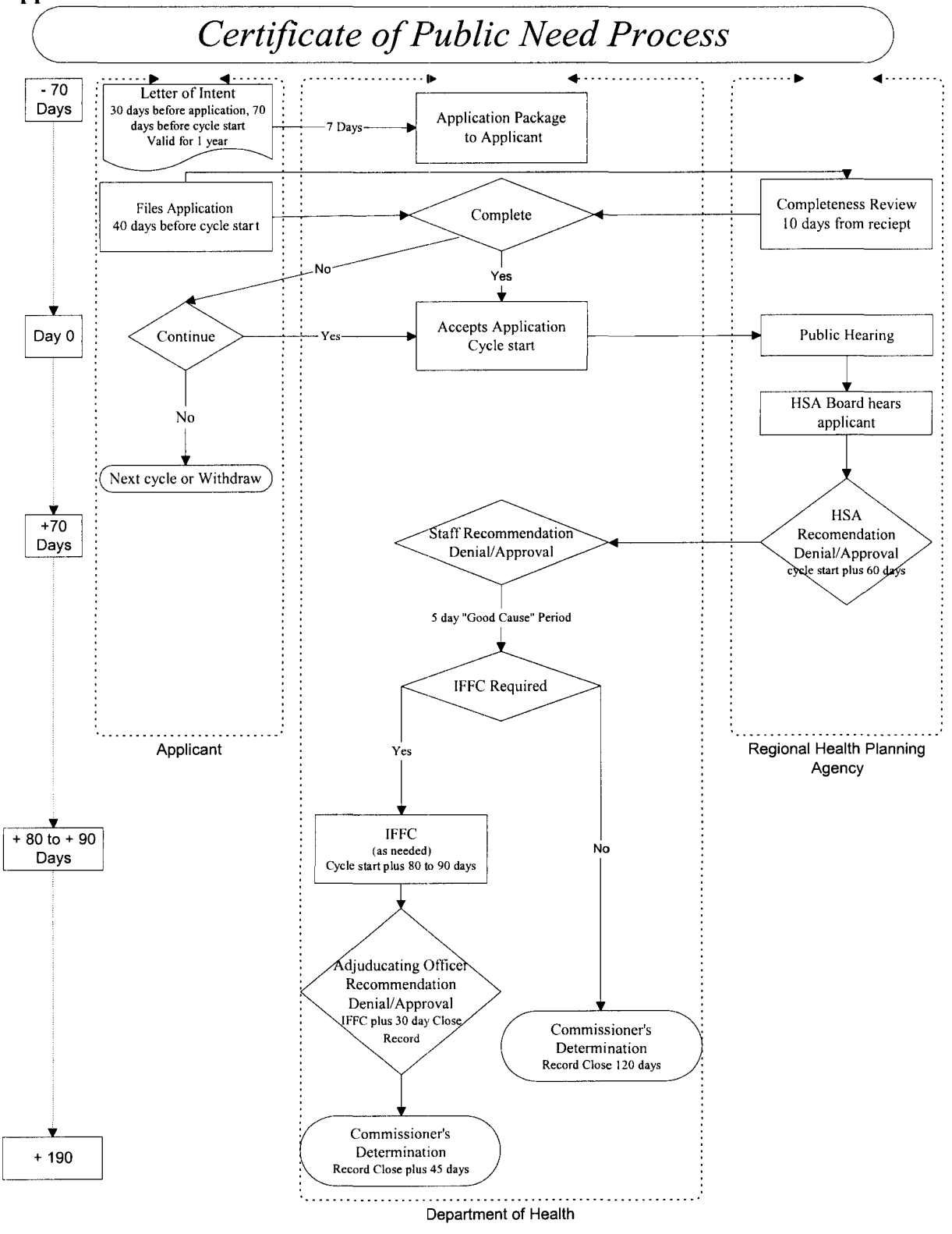
Project Categories	Number of Projects	Capital Costs
Batch Group A General hospitals, obstetrical services, neonatal special care services	9	
Subtotal		**$375,860,539**
Batch Group B Open heart surgery, cardiac catheterization, ambulatory surgery centers, operating room additions, transplant services	12	
Subtotal		**$24,123,603**
Batch Group C Psychiatric facilities, substance abuse treatment, mental retardation facilities	3	
Subtotal		**$448,500**
Batch Group D Diagnostic imaging	25	
Subtotal		**$41,269,354**
Batch Group E Medical rehabilitation	1	
Subtotal		**$64,000**
Batch Group F Gamma knife surgery, lithotripsy, radiation therapy	7	
Subtotal		**$18,586,523**
Batch Group G Nursing home beds, capital expenditures	7	
Subtotal		**$20,251,352**
COPN Program Total	**64**	**$480,603,871**

Appendix E

Virginia's Health Planning Regions
Virginia's Planning Districts



Appendix F


Certificate of Public Need Process
- 70 Days
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
Day 0
Continue
Yes
Accepts Application
Cycle start
Public Hearing
HSA Board hears applicant
No
Next cycle or Withdraw
+70 Days
Staff Recommendation
Denial/Approval
HSA Recomendation
Denial/Approval
cycle start plus 60 days
5 day "Good Cause" Period
IFFC Required
Yes
No
Applicant
Regional Health Planning Agency
+ 80 to + 90 Days
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
+ 190
Department of Health

Appendix G

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

Eighth Annual Report - 2004

Group 8 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 intermediate care facility
- 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
- Establishment of a mental retardation facility

Ninth Annual Report - 2005

Group 9 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 or replacement 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 or replacement 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

Tenth Annual Report – 2006

Group 10 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

Eleventh Annual Report - 2007

Group 6 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 or replacement 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

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 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

Project Categories Presented in the First Six Years of Annual Reports (1997 – 2002)

First Annual Report – 1997

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 or replacement 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

Second Annual Report – 1998

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 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

Third Annual Report – 1999

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 intermediate care facility
- 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
- Establishment of a mental retardation facility

Fourth Annual Report – 2000

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 or replacement 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 or replacement 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

Fifth Annual Report - 2001

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

Sixth Annual Report - 2002

Group 6 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 or replacement 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

Appendix H

FY 2003 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

COPN #	Applicant	Batch	Project	Indigent and Primary Care Conditions Rate Applied to Gross Patient Revenues
VA-03704	Lewis-Gale Medical Center	A	Capital Expenditure of More Than $5 Million	1.4% indigent / primary care
VA-03706	Williamsburg Community Hospital	A	Establish a General Hospital	1.8% indigent / primary care
VA-03708	Potomac Hospital	A	Add 30 Acute Care Beds	1.4% indigent / primary care
VA-03713	Bon Secours Richmond Health System, Bon Secours St. Francis Medical Center	A	Establish a 130 bed acute care hospital, replace Bon Secours Sturat Circle Hosptial	3% indigent care
VA-03730	Winchester Medical Center	A	Capital Expenditure of More Than $5 Million	1.9% indigent / primary care
VA-03731	Henrico Doctors' Hospital-Parham	A	Capital Expenditure of More Than $5 Million	1.6% indigent / primary care
VA-03732	Sentara Healthcare (VA Beach Gen.)	A	Capital Expenditure of More Than $5 Million	1.8% indigent / primary care
VA-03709	The Urosurgical Center of Richmond	B	Establish an Outpatient Surgical Hospital	1.7% indigent / primary care
VA-03710	Bon Secours Richmond Health System	B	Add 4 ORs at St. Francis Medical Center	1.7% indigent / primary care
VA-03724	Chesapeake General Hospital	B	Addition of Second Cardiac Catheterization Lab	1.8% indigent / primary care
VA-03727	Memorial Hospital of Martinsville and Henry County	B	Establish a 4-OR Outpatient Surgical Hospital	1.7% indigent / primary care
VA-03736	Lewis-Gale Medical Center	B	Addition of Cardiac Catheterization Equipment	1.6% indigent / primary care
VA-03737	Roanoke Valley Center for Sight, L.L.C.	B	Addition of 1 General Operating Room	1.6% indigent / indigent care
VA-03738	Bon Secours Memorial Regional Medical Center	B	Addition of 3rd Cardiac Catheterization Laboratory	1.6% indigent / indigent care
VA-03680	Danville Regional Medical Center	D	Introduce Positron Emission Tomography Imaging Services Through a Mobile Provider	1.5% indigent / primary care
VA-03681	Medical Imaging of Fredericksburg, LLC	D	Addition of a second MRI Scanner	2.2% indigent / primary care
VA-03682	Mary Washington Hospital	D	Addition of 2 CT Scanners	2.2% indigent / primary care
VA-03683	Pratt Medical Center	D	Addition of a MRI Scanner and a CT Scanner at an Outpatient Diagnostic Center	2.2% indigent / primary care
VA-03684	Inova Health System	D	Addition of an MRI Scanner	1.4% indigent / primary care

COPN #	Applicant	Batch	Project	Indigent and Primary Care Conditions Rate Applied to Gross Patient Revenues
VA-03685	Virginia Hospital Center Arlington Health System	D	Addition of a 2nd MRI	1.4% indigent / primary care
VA-03686	Loudoun Hospital Center	D	Addition of a CT Scanner	1.4% indigent / primary care
VA-03688	Winchester Radiologists, PC	D	Addition of Computed Tomography Imaging Equipment	2.0% indigent / primary care
VA-03689	University of Virginia Health System	D	Establish a Specialized Center for MRI (2 MRI Scanners) and CT (2 CT Scanners) Services	8.3% indigent / primary care
VA-03700	Lewis-Gale Medical Center, LLC	D	Addition of a second MRI Scanner	1.5% indigent care
VA-03701	Southwest Virginia Regional Open MRI Center	D	Establish a Specialized Center for MRI Services	2% indigent care
VA-03715	Warren Memorial Hospital	D	Introduce Mobile MRI Services	1.9% indigent / primary care
VA-03716	Halifax Regional Hospital, Inc.	D	Introduce Mobile PET Services	1.6% indigent / primary care
VA-03717	Community Radiology of Virginia, Inc.	D	Introduce Positron Emission Tomography Imaging Services Through a Mobile Provider	5.0% indigent / primary care
VA-03718	Sentara Bayside Hospital	D	Addition of a Second CT Scanner	1.8% indigent / primary care
VA-03733	Riverside Regional Medical Center	D	Establish Fixed CT Services and Introduce Mobile MRI Services at an Existing Medical Care Facility	1.8% indigent / primary care
VA-03734	Williamsburg Community Hospital	D	Introduce MRI Services into an Existing Medical Care Facility	1.8% indigent / primary care
VA-03735	Williamsburg Community Hospital	D	Introduce CT Services into an Existing Medical Care Facility	1.8% indigent / primary care
VA-03695	Falls Church Lithotripsy	F	Addition of Mobile Lithotripsy Equipment	Indigent / primary care - diff % in each HPR
VA-03697	Prince William Hospital and Fauquier Hospital	F	Establish a Specialized Center for Radiation Therapy Services	1.4% indigent / primary care
VA-03698	Loudoun Hospital Center	F	Introduction of Radiation Therapy into an Existing Medical Care Facility	1.4% indigent / primary care
VA-03725	Culpeper Regional Hospital	F	Introduce Mobile Lithotripsy Services (renal)	1.9% indigent / primary care
VA-03726	Sentara Healthcare	F	Establish Mobile Lithotripsy Services (renal)	1.8% charity / primary care