REPORT OF THE
DEPARTMENT OF HEALTH

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

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
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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 2009).

Program activity for the period covered in this report includes the issuance of 49 decisions. The State Health Commissioner authorized 39 projects with a total expenditure of $190,876,551 and denied 10 projects with proposed capital expenditures of $48,140,076. 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: radiation therapy services, extracorporeal shockwave lithotripsy, inpatient obstetric services and neonatal special care. The section on project analysis addresses the history of COPN regulation for these project categories, the nature of the specific services, the current state of the service in the Commonwealth and three potential options for the future of each of the categories with a recommended action. The Virginia Department of Health (VDH) recommends maintaining the current COPN review process for the review of radiation therapy and neonatal special care project types and supporting any discussion about deregulating from COPN lithotripsy and inpatient obstetric 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 indigent care placed upon any COPNs they are awarded. Compliance with the conditions to provide indigent care has improved considerably. Historically, many conditioned COPN holders have either not reported their compliance with conditions or have reported that they have been unable, for various reasons, to reach the required level of indigent care. Language for the "conditioning" of COPNs includes 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. Aggressive follow-up with non-reporting holders of conditioned COPNs has dramatically improved compliance.

During FY 2010 the application review process was completed as directed by the *Code*. There were no delays in receiving recommendations from regional health planning agencies that adversely affected timely decision-making.

Preface

This 2010 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 (2010). A copy of the enabling *Code* section is provided in Appendix A.

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

The statute establishing Virginia's COPN program is found in Article 1 of Chapter 5 of Title 32.1 of the *Code* (§ 32.1-102.1 et seq.). The State Health Commissioner (Commissioner) authorizes capital projects regulated within the COPN program prior to implementation. The Commissioner must be satisfied that the proposed project meets public need criteria. The *Code* specifies 8 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 2010

Project Review

Decisions

During FY 2010, the Division of Certificate of Public Need (DCOPN), which assists the Commissioner in administering the COPN program, received 106 letters of intent to submit COPN requests and 71 applications for COPNs. There were seven applications withdrawn by applicants during the year. The balance of letters of intent and applications are those for which the appropriate review cycles have crossed fiscal years. Letters of intent are required of all persons intending to become applicants for COPNs. These letters describe the proposed project in enough detail to enable DCOPN to batch the project in an appropriate review cycle and provide the applicant with the appropriate COPN application package for the proposed project. A letter of intent will lapse if a COPN application is not submitted within a year of the time the letter of intent was submitted.

Table 1 summarizes COPN review activity for FY 2010. Graph 1 puts this activity in historical context. The Commissioner issued 49 decisions on applications to establish new medical care facilities or modify existing medical care facilities in FY 2010. Thirty-nine (80%) of these decisions were to approve or conditionally approve the request, for a total authorized capital expenditure of $190,876,551. Ten (20%) requests were denied. These ten denied projects had proposed total capital expenditures of $48,140,076. An additional decision was vacated and

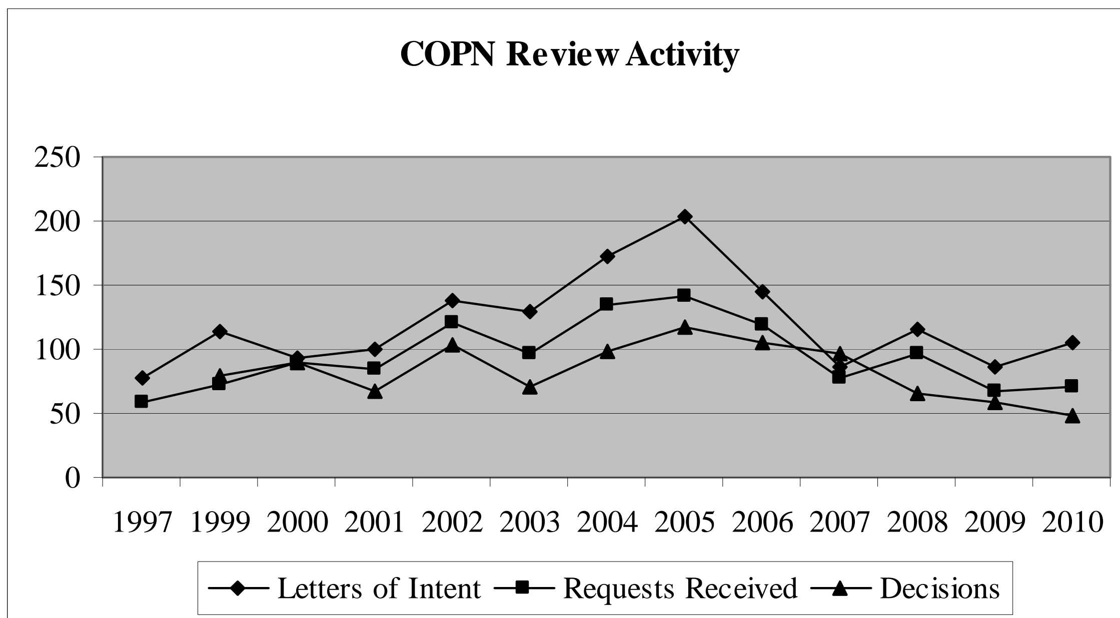
later approved following further review. Approved COPN decisions in FY 2010 are profiled in Appendix D.

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
2010	106	71	7	39	10	3	0

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

Chart 1



Source: DCOPN

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

COPN reports and recommendations are also provided to the Commissioner by the regional health planning agencies. The regional health planning agencies are not-for-profit corporations that 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, when appropriately designated, conduct public hearings and make recommendations to the Commissioner concerning the public's need for proposed projects in their respective regions. In the absence of an appropriately designated regional health planning agency, the DCOPN conducts the public hearing and solicits local input. The five health planning regions in Virginia are shown on the map in Appendix E. As of the close of the fiscal year Health

Planning Region II, Northern Virginia, is the only region with a health planning agency designated. The health planning agencies for the other four regions have either closed or terminated their status as a designated health planning agency.

Adjudication

If the DCOPN or a designated regional health planning agency 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. The adjudicatory process, held before the Commissioner's Adjudication Officer, is a mechanism for providing full due process to applicants before a final agency decision is made. These conferences, conducted in accordance with the Administrative Process Act, are held to provide the applicant an opportunity to submit information and testimony in support of a project application. An IFFC is also held when two or more requests are competing to provide the same or similar services in the same jurisdiction and one or more of the requests are recommended for denial. Another purpose for IFFCs is to permit persons opposed to a project, who have shown good cause, to voice their concerns. Following an IFFC, the Adjudication Officer reviews the entire agency record and prepares a recommended decision for the Commissioner's consideration and, should it meet with her agreement, adoption.

There were 25 COPN applications heard before a VDH Adjudication Officer at 15 individual IFFC's in FY 2010. An additional three applications were exempted from participation in IFFC's with competing applicants due to an agreed upon stipulation agreement. Eight of the COPN requests warranting an IFFC were approved in FY 2010. Nine requests were denied after the IFFC. Eight projects heard at an IFFC in FY 2010 still have decisions pending and will be resolved in the Fall of 2010.

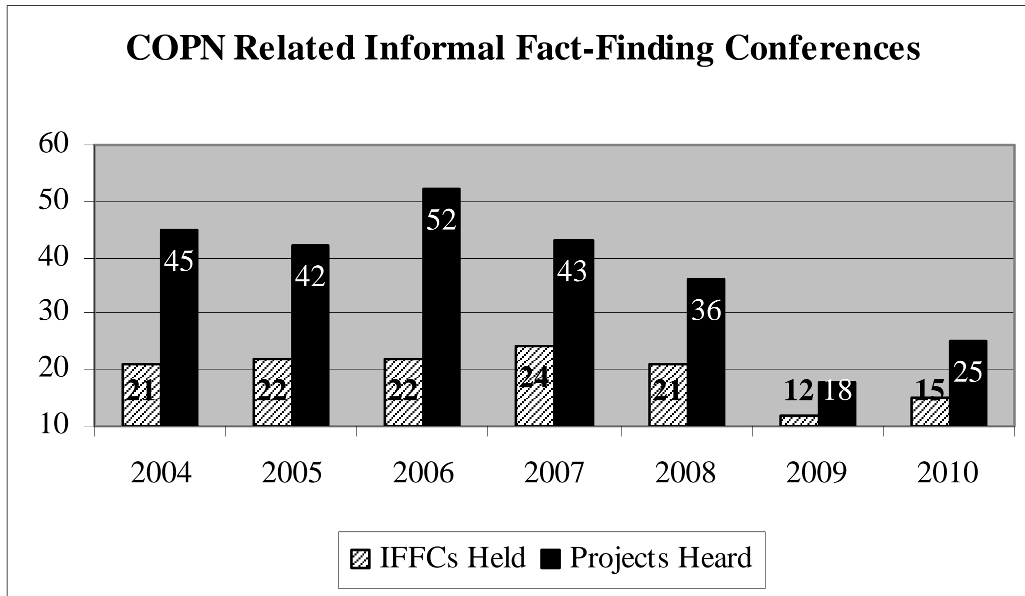
Table 2 illustrates the types of projects that were forwarded to an IFFC in FY 2010.

Table 2 Projects at IFFC in FY 2010

Project Type	Approved	Denied	Pending	Total
Establish/Relocate/Replace Inpatient Hospital			1	1
Establish/Relocate/Replace Outpatient Surgical Hospital		3	3	6
Diagnostic Imaging	1	4		5
Medical Rehabilitation Services	1			1
Radiation Therapy / Establish Comprehensive Cancer Care Center	2		2	4
Cardiac Catheterization	1	1		2
Establish or Add Psychiatric Service	2		2	4
Nursing Home	1	1		2
TOTAL	8	9	8	25

Source: DCOPN

Chart 2



Source: DCOPN

Judicial Review

COPN decision challenges are not limited to administrative appeals. Once an applicant has exhausted his administrative remedies, he can take his claim to state court for judicial review. In five separate actions notice of appeal was filed for five decisions in FY 2010. All of the appeals were perfected with a filed appeal.

In May 2009 the State Health Commissioner approved a petition from Chippenham & Johnston-Willis Hospital demonstrating good cause in the review of a COPN request from the Petersburg Hospital Company LLC, d/b/a Southside Regional Medical Center. Southside Regional Medical Center was seeking COPN authorization to introduce open heart surgery services. The approval of Chippenham & Johnston-Willis Hospital's petition of good cause gave them standing as a party in the review. Southside Regional Medical Center appealed the Commissioner's decision to grant good cause standing to Chippenham & Johnston-Willis Hospital.

In June 2009 the State Health Commissioner denied Southside Regional Medical Center's COPN request to introduce open heart surgery services. Southside Regional Medical Center appealed the Commissioner's decision denying their COPN request.

In May 2009 Spotsylvania Medical Center submitted a letter of intent to file a COPN request seeking authorization to introduce radiation therapy services after the established deadline for such filings for entry in the July review cycle. Spotsylvania Medical Center filed an appeal claiming their filing was timely and petitioning for review in the July cycle. Spotsylvania Medical Center ultimately withdrew their appeal and filed the COPN request in the following review cycle and was approved for the service.

In August 2009 the State Health Commissioner approved a petition from Reston Hospital demonstrating good cause in the review of a COPN request from Inova Health System. Inova Health System was seeking COPN authorization to introduce radiation therapy, including stereotactic radiosurgery, at Inova Fair Oaks Hospital. The approval of Reston Hospital's petition of good cause gave them standing as a party in the review. Inova Health System appealed the Commissioner's decision to grant good cause standing to Reston Hospital.

In March 2010 Spotsylvania Medical Center appealed the State Health Commissioner's February 2010 decision approving Medicorp Health System's COPN request to expand the radiation therapy program and introduce stereotactic radiosurgery at Mary Washington Hospital. Spotsylvania Medical Center ultimately withdrew the appeal.

Table 3 Prior COPN Appeals Determined in FY 2010 or Still In Process

COPN Requests	Project	COPN Decision	Appellants	Court Status
COPN Request Nos.VA-7467, 7473, 7474, 7475, and 7476	Requests to establish 3 new hospitals through the replacement of Bon Secours DePaul Medical Center, establish a new hospital through the replacement of Sentara Bayside Hospital, and add beds at Sentara Obici Hospital, all in PD 20.	The two Sentara requests were approved, the three Bon Secours requests were denied.	Bon Secours DePaul Medical Center	An agreement to settle is pending.
COPN Request No. VA-7541	Petersburg Hospital Company, LLC d/b/a Southside Regional Medical Center requested authorization to introduce open heart surgery services at the hospital.	Good cause party standing was granted and the COPN was denied.	Petersburg Hospital Company, LLC d/b/a Southside Regional Medical Center	In 2 separate appeals Southside Regional Medical Center appealed the granting of good cause status and the denial of the COPN. The Circuit Court's decision pending.

Certificate Surrenders

Infrequently, an applicant awarded a COPN may have reasons to surrender it. Typical reasons for certificate surrenders are the applicant's inability to proceed with the project or changes in business direction. In FY 2010 five certificates were surrendered: COPN numbers VA-03705, Lee Regional Medical Center, the introduction of medical rehabilitation issued in November 2002; VA-03935, Establish a new outpatient surgical hospital in Planning District 15 issued in June 2005; VA-04014 Patient First's addition of a CT scanner issued in May 2007; VA-04028 issued in August 2008 to Bon Secours Hampton Roads to establish a mobile MRI service; and VA-04054 issued in November 2006 to VCU Medical Center to construct a parking deck.

Significant Changes

A significant change results when there has been an alteration, modification, or adjustment to a reviewable project for which a COPN approval has been issued. To be considered a significant change, the alteration, modification, or adjustment must change the site, increase the authorized capital expenditure by 10% or more, change the service proposed to be offered, or extend the schedule for completion of the project beyond three years (36 months) from the date of certificate issuance or beyond the time period approved by the Commissioner at the date of certificate issuance.

The Commissioner received sixteen requests for significant changes to twelve different COPN projects in FY 2010. Nine requests were for extension of the schedule beyond the three-year generic time limit or the time authorized on the certificate. Four requests were to increase the authorized capital cost, and three requests were to change the authorized site for the project. All sixteen reviewed significant change requests were authorized.

Competitive Nursing Home Review

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

An RFA was published in the Virginia Register of Regulations for the addition of 60 Medicaid-certified nursing facility beds in Planning District 9, 60 Medicaid-certified nursing facility beds in Planning District 10, and 30 Medicaid-certified nursing facility beds in Planning District 18 on May 24, 2010. The final RFA will be published in August 2010. Decisions on any applications received are expected by July 2011 for the Planning Districts 10 and 18 RFAs and September 2011 for the Planning District 9 RFA.

Timeliness of COPN Application Review

All COPN recommendations by DCOPN must be completed by the 70th day of the review cycle, with the final decision due by the 190th day of the review cycle. Review cycles begin on the 10th day of each month. Only the applicant has the authority to extend the review schedule. In FY 2010 all COPN applications were reviewed within the statutory or applicant extended time limit. A flow chart illustrating COPN timelines as a result of these and other bills can be found at Appendix F. The flow chart identifies the time periods within which VDH is to perform certain COPN functions.

The *Code* also specifies that the Commissioner has up to 70 days from the close of the record to render a decision unless the schedule is extended by the applicant. Failure to do so results in a deemed approval of the request. The average time to review a COPN request in FY 2010, from

the start of the cycle to a decision being made, was 169 days. The average time for requests that were not heard at an IFFC was 121 days. Requests that needed to be heard at IFFC had an average review time of 234 days. In FY 2010, all of the Commissioner's decisions were rendered within the statutory or applicant extended time limit.

Legislation

In the 2010 session of the General Assembly, there were five House bills and four Senate bills that addressed some aspect of the COPN program. There was no central theme to the types of bills considered during the session.

Table 4 COPN Bills in the 2010 Session of the Virginia General Assembly

Bill	Patron	Topic in Relation to COPN	Status
HB 148	Del. O'Bannon	This bill authorized a request for applications to add up to 10 nursing facility beds in Planning District 15. Was a companion Bill to SB 58.	Left in Appropriations
HB 371	Del. Shuler	The bill authorized the review and approval of requests to establish a psychiatric service in Planning District 5 through the relocation of existing psychiatric beds.	Passed
HB 410	Del. Oder	The bill exempted from COPN the relocation of nursing home beds from one planning district to another when certain conditions were met.	Withdrawn
HB 415	Del. Oder	The bill exempted from COPN the relocation of nursing home beds from one planning district to another when certain conditions were met. Was a companion Bill to SB 470.	Passed
HB 1285	Del. Orrock	The bill clarified language added during the 2009 session of the General Assembly regarding the responsibilities of VDH and the regional health planning agencies, especially the assumption of duties assigned to the regional health planning agencies when one is not designated for a particular health planning area..	Passed
SB 58	Sen. Martin	This bill authorized a request for applications to add up to 10 nursing facility beds in Planning District 15. Was a companion to HB 148.	Left in Finance
SB 358	Sen. Howell	The bill increased the maximum fee for filing a certificate of public need application and increased the fee revenue available to the Regional Health Planning Agencies.	Withdrawn
SB 470	Sen. J. Miller	The bill exempted from COPN the relocation of nursing home beds from one planning district to another when certain conditions were met. Was a companion Bill to HB 415.	Passed
SB 653	Sen. Northam	This bill provided a special exception which allowed a continuing care retirement community in the City of Norfolk meeting certain condition to continue to admit residents who are not continuing care contract	Passed

		holders to the cooperative until December 2013.	

Source: Virginia Legislative Information System

Regulation

House bill 396, passed by the 2008 session of the Virginia General Assembly, requires the formation of a Task Force to meet at least every two years. The Task Force is to review, and where appropriate, update the SMFP at least every four years. The Task Force has been established and met three times in FY 2009 and twice in FY 2010. Several work groups were formed to address the technical issues of various specific issues including; the acute care bed need methodology, inpatient medical rehabilitation criteria, ways to address evolving technology, and radiation therapy criteria.

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 37 years can be segmented into three distinct periods. These periods can be characterized as regulatory, non-regulatory, and return to regulation. Those periods are: 1) 1973 to 1986, a period of relatively consistent regulation; 2) 1986 to 1992, a period of dramatic deregulation; and 3) 1992 to the present, a period in which Virginia not only revived COPN regulation but also began, in 1996, a process of review and consideration of the scope of the new regulatory environment.

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

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

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

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

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

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

PROJECT CATEGORY ANALYSES

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

- The review time required during the past year for various project categories;
- The number of contested or opposed applications and the categories of these proposed projects;
- The number of applications upon which the 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;
- The number of applications reviewed from health planning regions for which not regional health planning agency was appropriately designated; 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 2010, the project categories are:

Radiation therapy, lithotripsy, obstetrical services and neonatal special care

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 radiation therapy, including gamma knife surgery

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

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

As the following discussions will note, the majority of COPN requests are approved. This does not imply that the COPN process is ineffective at limiting the number of new services or capital expenditures. Indications are that, for the most part, applicants are only submitting requests for projects that meet the criteria for approval and that the number of speculative requests has declined.

Radiation Therapy

The SMFP defines radiation therapy as a "treatment using ionizing radiation to destroy diseased cells and for the relief of symptoms. Radiation therapy may be used alone or in combination with surgery or chemotherapy." It includes megavoltage radiation therapy, stereotactic radiosurgery, as well as gamma knife® procedures.

Gamma knife® is further defined to refer to the brand name specific instrument used to provide stereotactic radiosurgery, which in turn is defined as "the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume." Stereotactic radiosurgery, or SRS, can be delivered in a single session or in a fractionated course of treatment of up to five sessions.

Substantial advances have been made in radiation therapy technology and its application to the treatment of cancer. When the proprietary name gamma knife® was included as a technology that required COPN authorization it was the only form of stereotactic radiosurgery available. Several additional forms of stereotactic radiosurgery have entered clinical practice in the last few years.

The hybridizing and combining of technologies, as well as the introduction of multifunction radiation therapy machines has presented a challenge for the assessment of these technologies. It would appear that, given the current development of radiation therapy equipment, the technology should be broken out into at least three separate categories: (1) Conventional radiation therapy,

(2) stereotactic radiotherapy, and (3) stereotactic radiosurgery. The distinguishing characteristics of the modalities is in the use of imaging machines such as computed tomography (CT) and the resulting precision with which the radiation can be delivered to the tumor, with a resulting variance in the number of treatment sessions required. The following is an overview of terms commonly associated with radiation therapy and stereotactic radiosurgery technology.

Conventional Radiation Therapy – A low dose of radiation commonly given over 10-35 treatments via a linear accelerator. It is also known as fractionated radiotherapy. Radiation therapy may or may not utilize an enhanced targeting device.

Intensity Modulated Radiation Therapy (IMRT) – A type of 3-dimensional conformal radiation therapy that uses computer-generated images to show the size and shape of a tumor. Thin beams of radiation of different intensities are aimed at the tumor from many angles. IMRT is enhanced conventional radiation therapy in that it is not as spatially precise as radiosurgery. Because it is imprecise, a full course of IMRT treatment is typically administered over 20 – 30+ treatments sessions.

Stereotactic Radiotherapy – A more precisely administered course of hypofractionated radiation therapy, delivered based on a detailed plan developed from CT images, which is completed in between two and five treatment sessions.

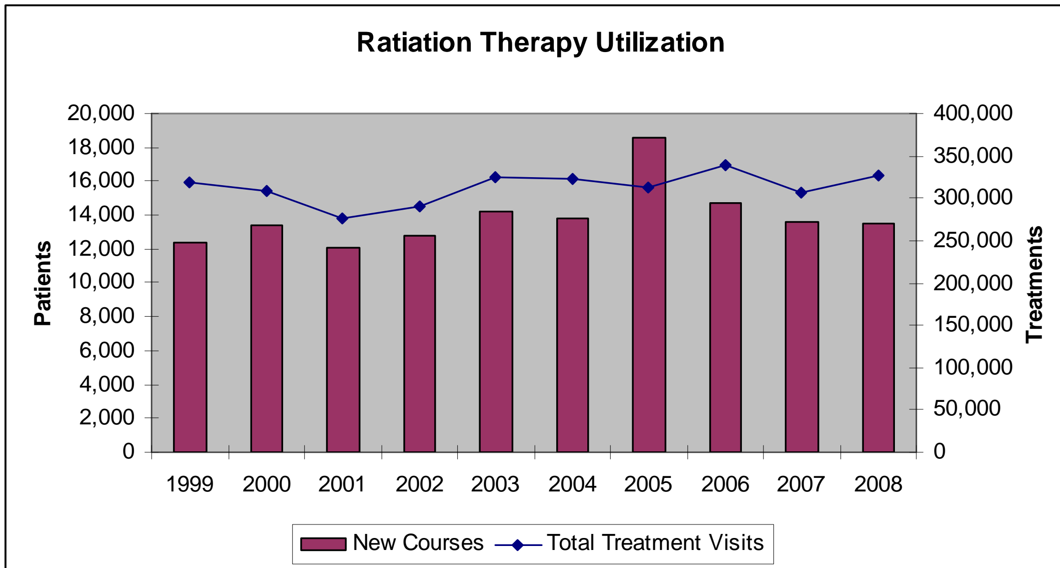
Image Guided Adaptive Radiation Therapy (IGART) – A linear accelerator based three dimensional tumor targeting and tracking system, similar to missile technology, that non-invasively pinpoints tumor targets at the time of a radiation therapy treatment. IGRT is a radiotherapy system designed to track and verify the location of a tumor, and enable automatic compensation for tumor movement. IGART differs from image guided radiation therapy (IGRT) in that IGART has the ability to change the treatment plan in response to changes in the tumor.

Stereotactic Radiosurgery – A radiation therapy technique for brain and spinal tumors (generally) that uses a rigid head frame that is attached to the skull. The frame is used to help aim high-dose radiation beams directly at the tumors and not at normal brain tissue. This procedure does not involve open surgery and is referred to as surgery only because it is completed in a single treatment session, like surgery. All gamma knife® therapy is stereotactic radiosurgery, but not all stereotactic radiosurgery is gamma knife®.

Proton Particle Beam Accelerator – A highly specialized, large system of delivery using a cyclotron to produce therapeutic beams for the treatment of a wide range of cancers. Treatments are delivered in up to 25 sessions. The size and expense (greater than $100M) are limiting factors in its use.

There are 105 authorized radiation therapy machines delivering care at 51 sites throughout the Commonwealth. Since the last review of radiation therapy in 2005 seven new delivery sites have been authorized, including the proton beam accelerator in Hampton, 12 new linear accelerators have been authorized and stereotactic radiosurgery has been authorized at 13 sites.

Table 5



Source: Virginia Health Information

For the most recent 10 year period for which data is available, 1999 – 2008, there has been a gradual increase in the number of new cancer cases treated with radiation therapy and in the number of treatments performed. Growth in supply appears to have been matched to the modest growth in need. Beyond the radiation therapy projects that were authorized in the last 10 years, COPN requests have been denied for the addition of 10 linear accelerators, and for the establishment of 10 additional treatment locations, avoiding unnecessary duplication of these services.

There is at least one provider of radiation therapy services in every planning district except for two, Planning Districts 13, and 14. In the 2005 report three planning districts, accounting for 4.2% of Virginia's population, had no radiation therapy. Radiation therapy was authorized in Planning District 9 in 2008. The remaining two planning districts without radiation therapy account for 2.3% of the 2010 population of Virginia. The SMFP calls for radiation therapy services to be within one hour's drive under normal driving conditions for 95% of the population. The major population centers of Planning Districts 13 and 14 live within an hour of radiation therapy services in Planning Districts 10, 11, 12, 15, and 19. Given this distribution of services, greater than 95% of Virginia's population does live within an hour's drive of a radiation therapy provider, even given that there are small pockets within individual planning districts that are not within an hour's drive.

Appropriateness of Continuing COPN for Radiation Therapy Services

The COPN experience concerning radiation therapy 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 resulting in the decision to not pursue the development of a service is the successful meeting of that goal. However, there are alternatives to consider. Modest growth in the number of cases treated with radiation therapy suggests that additional capacity should be added judiciously in response only to local specific needs.

Options:

No Change: Continue applying the COPN program to the establishment of new medical care facilities for radiation therapy and the addition of radiation therapy capacity at existing programs as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. All key stakeholders would likely support this option.

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. Some providers, except some providers seeking competitive advantage despite actual public need, would likely support this option.

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

RECOMMENDATION: Make changes to the review criteria in the State Medical Facilities Plan necessary to remain current and continue applying the COPN program to the establishment of new medical care facilities for radiation therapy and the addition of radiation therapy capacity at existing programs as currently mandated.

Lithotripsy

The Code of Virginia establishes that a COPN is required to introduce “lithotripsy” into an existing medical care facility, establish a medical care facility for “lithotripsy” or add equipment for “lithotripsy.” The SMFP defines “lithotripsy” under the term “extracorporeal shock wave lithotripsy (ESWL)” as “a noninvasive therapeutic procedure to (i) crush renal and biliary stones using shock waves, i.e., renal lithotripsy or (ii) treat certain musculoskeletal conditions and to relieve the pain associated with tendonitis, i.e., orthopedic lithotripsy.”

ESWL was developed for the non-invasive treatment of kidney, or renal, stones. Early machines, few if any of which are still in use, were large and required the patient to get into a warm water bath. Newer technology is portable and patients lie on a treatment table, avoiding the need for a large water tank. The technology works by using sound waves, generated outside the body, to pulverize or shatter the stones so they can pass out of the body more easily.

In the late 1980’s ESWL began to be used for the treatment of stones in the gall bladder. While effective in some patients, the expense and the apparent lack of long-term success of

biliary lithotripsy caused this therapy to not gain wide favor and laparoscopic cholecystectomy (surgery) remains the treatment of choice.

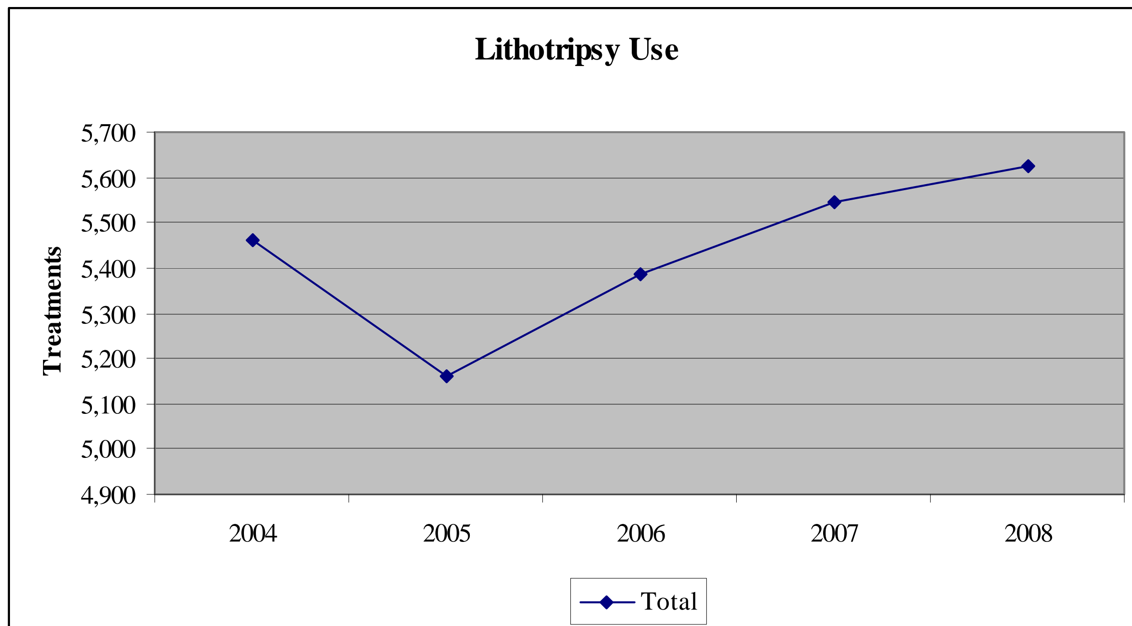
Around 2000 ESWL began to be applied to the treatment of heel spurs, tennis elbow and golfers elbow. Unlike its use in the treatment of renal and gall stones, orthopedic lithotripsy does not shatter anything. The real mechanism behind why it works remains unknown. While very different in what it does and how it is applied, orthopedic lithotripsy has been reviewed under COPN since the technology is essentially the same, externally applied sound waves, as for renal and gall stones, and is a form of ESWL, or lithotripsy, as listed in the Code of Virginia.

The cost to add a lithotripter machine authorized in 2008 was $260,000. Most services in Virginia are mobile, with a single piece of equipment serving several service sites. The average cost to establish a new site using an existing mobile lithotripter machine, for the three sites that actually incurred a cost to prepare the site, was $64,133. For 11 COPNs issued authorizing new sites using existing mobile lithotripter machines the capital cost of the project was $0.

There are 89 authorized lithotripsy sites in Virginia (80 renal sites and 9 orthopedic sites). Over 85% of the sites are served by mobile providers. All nine orthopedic lithotripsy sites utilize mobile vendors. Every planning district in Virginia is served by at least one lithotripsy site.

Since 2005 utilization of lithotripsy has shown a steady, but modest, increase, with nearly all of the growth being in outpatient renal lithotripsy. Since 2004 the use of renal lithotripsy has remained between 5,100 and 5,600 cases per year. Orthopedic lithotripsy, for those facilities required to report their utilization, patient volume has yet to exceed a total of 100 cases per year.

Table 6



Source: Virginia Health Information

Since 2005 there have been 23 COPNs authorizing additional lithotripsy services. Only one of those COPNs was for orthopedic lithotripsy. One COPN was to add a lithotripsy machine to an existing service and the rest, 13 COPNs, were to establish 15 new service sites for existing mobile lithotripsy machines. All lithotripsy COPN requests received in the last five years were approved.

Appropriateness of Continuing COPN for Lithotripsy

The COPN experience concerning lithotripsy suggests that the program is no longer appropriate for this service. The cost of the technology and the ready availability and acceptability of mobile technology leaves little to be gained by continuing to require COPN authorization for lithotripsy. Unlike with radiation therapy, the denial of requests for lithotripsy does not represent a substantial savings to the marketplace. Utilization of the equipment is fairly low, and the availability of the service at a site one day every couple of weeks, as is the common practice with this mobile service, is adequate to meet the needs of patients, and makes the purchase of a machine for each provider site unattractive. The deterrent effect of COPN on speculative lithotripsy requests is probably of little consequence. However, there are alternatives to consider.

Options:

No Change: Continue applying the COPN program to the establishment of new sites for lithotripsy and the addition of lithotripsy equipment as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria to accommodate evolving uses for the technology. Key stakeholders would likely be neutral to this option.

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. Key stakeholders would likely be neutral to this option.

Deregulation: Support efforts outside the comprehensive JCHC plan to deregulate lithotripsy. Existing providers of mobile lithotripsy will likely oppose it.

RECOMMENDATION: Support efforts to deregulate COPN as it applies to lithotripsy.

Obstetrical Services

In 2005 sixty-six Virginia general acute care hospitals offered inpatient obstetric services. By 2008 fifty-nine hospitals reported operating licensed obstetric beds. In 2008 (the most recent year for which Virginia Health Information data is available) Virginia hospitals reported 1,406 licensed obstetric beds. Between 2004 and 2008 an average of 89.8% of the licensed obstetric

beds in Virginia were staffed. The average occupancy rate of the licensed beds for the five year period was 54.3%. Only planning districts 17 and 18 have no inpatient obstetric service.

Since FY 2005 there have been twenty-three requests for new or expanded obstetric services. Fifteen of the requests were to include obstetrics in relocated replacement hospitals, two were to include obstetric beds in new hospitals, and six were to add beds to an existing service. Four of the requests to add beds were approved, one request was withdrawn and one is still in review. COPNs were issued for both new hospital requests that included obstetric service and seven of the replacement, or partial replacement, hospitals that included obstetrics. Of the eight remaining requests involving replacement hospitals with obstetric services, two were denied, two were withdrawn, three were delayed and one is still in review. Since 2005 101 obstetric beds have been added through the COPN process, all in either planning district 15, 16 or 8, in a line running roughly from Richmond to Reston.

Appropriateness of Continuing COPN for Obstetrics

Denial of COPN has not been a factor in inhibiting access to obstetric care in Virginia. The urban and suburban market appears to be well served with regard to obstetrical care. There has been little interest in the further development of additional obstetrical services in rural areas, while replacement hospitals in rural areas have preserved their established obstetric programs. There has been sustained interest in improving access to obstetric care, stemming from the 2004 *Report of the Governor's Work Group on Rural Obstetrical Care.* Use of the COPN program to restrain the growth of obstetric services seems counter to that interest.

Options:

No Change: Continue applying the COPN program to obstetric services as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP, will address necessary changes to the review criteria. Key stakeholders would likely be neutral to this option.

Minimal Change: Partially deregulate obstetric services by allowing the introduction of obstetric services and the addition of obstetric beds, but require COPN authorization to convert any obstetric bed to any other type of bed. Key stakeholders would likely be neutral to this option.

Deregulation: Support efforts to deregulate obstetric services. Key stakeholders would likely be supportive of this option.

RECOMMENDATION: Support efforts to deregulate COPN as it applies to the addition of obstetrical services while controlling the conversion of obstetric beds to prevent deregulation of obstetric services from being used as a means for circumventing COPN for the addition of other bed types.

Neonatal Special Care

The Code of Virginia requires COPN authorization to introduce neonatal special care into any existing medical care facility. Neonatal special care is defined in the SMFP as "care for infants in one or more of the higher service levels designated in 12VAC5-410-443 of the Rules and Regulations for the Licensure of Hospitals."

Neonatal special care is a service that has typically been established as a regional service, recognizing that with effective maternal and neonatal transport programs not every facility providing obstetric services needs the expense of a capital and labor-intensive specialty or sub-specialty neonatal special care unit. A well-trained and experienced staff is critical to the success of these programs. Regionalization of this service concentrates patients at the most appropriate sites, which in turn creates the most experienced staff. The American Academy of Pediatrics advocates the regionalization of neonatal care in order to optimize the care and outcomes of all newborn infants. The SMFP recognizes that intermediate level neonatal care should be more readily available, within 30 minutes drive time of hospitals with only general level newborn care, while specialty and sub-specialty care need only be within 90 minutes drive time of hospitals providing general or intermediate level newborn care.

No requests for neonatal special care were reviewed between 1992 and 2005. Since 2005 nine COPN requests were made involving neonatal special care, four to introduce the service at an existing hospital, one to change from intermediate level to specialty level care, one to add licensed neonatal care beds and three to include intermediate level neonatal care in a new or replacement hospital. Two of the requests to introduce the service are still under review; the remaining seven requests were all authorized.

There are 23 hospitals authorized to provide neonatal special care in Virginia. There is at least one neonatal special care provider in each Health Planning Region, with Health Planning Region IV, Central Virginia, having the most neonatal special care providers (8).

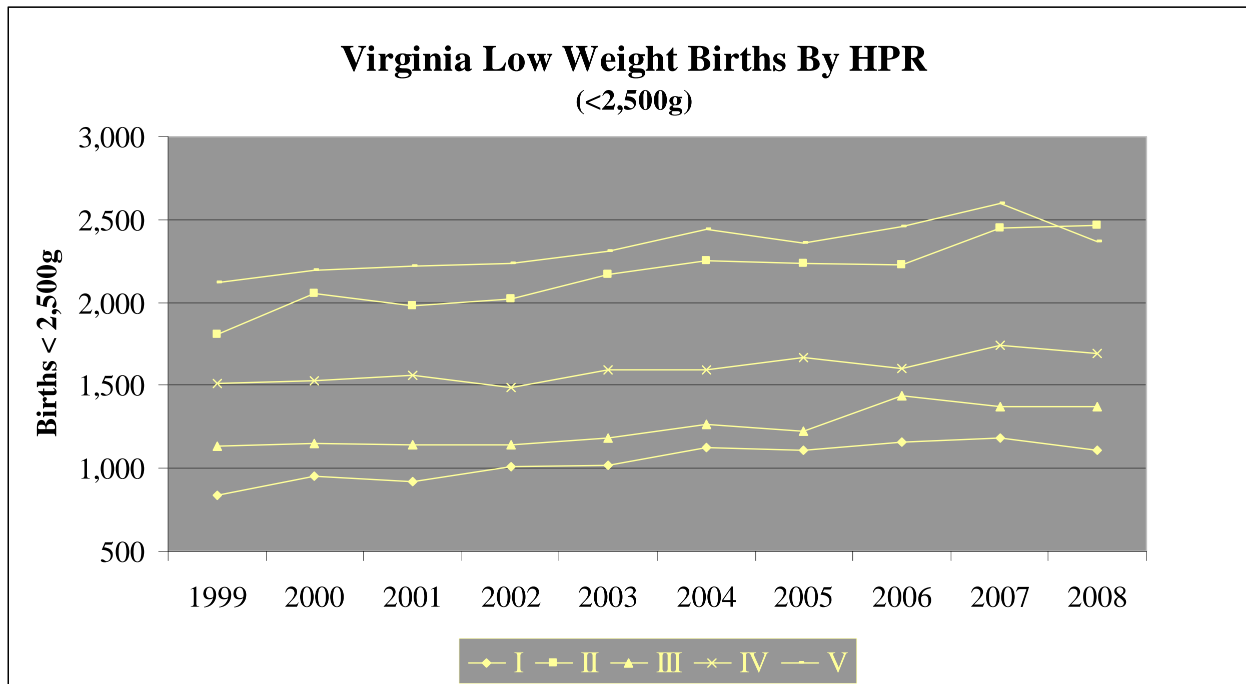
Table 7 Authorized Neonatal Special Care Providers in Virginia

Provider	Planning District
Carilion Roanoke Memorial Hospital	5
Winchester Medical Center	7
Inova Fairfax Hospital	8
Loudoun Hospital Center	8
Reston Hospital Center	8
Virginia Hospital Center	8
Martha Jefferson Hospital	10
University of Virginia Medical Center	10
Bon Secours St. Francis Medical Center	15
Bon Secours St. Mary's Hospital	15
Chippenham Medical Center	15
Henrico Doctors Hospital - Forrest	15
Johnston-Willis Hospital	15
Virginia Commonwealth University Health	15
West Creek Medical Center	15
Mary Washington Hospital	16
Spotsylvania Medical Center	16

Stafford Hospital	16
Southside Regional Medical Center	19
Chesapeake General Hospital	20
Children’s Hospital of Kings Daughters	20
Sentara Virginia Beach General Hospital	20
Sentara/Bon Secours Princess Anne Hospital	20

Low birth weight (i.e., birth weigh less than 2,500 grams) is a reasonable indicator of demand for neonatal special care services. All five Health Planning Regions have shown modest increases in the number of low weight births over the ten year period ending in 2008 (the most recent year in which data is available). HPR V, Tidewater, has the highest number of low weight births and HPR I, Northwestern Virginia, has the lowest number.

Chart 2



Source: VDH Division of Health Statistics

The reported occupancy of neonatal special care bassinets in Virginia averaged 75.2% in 2008 (range 60.7% in HPR IV to 89.1% in HPR III). Neonatal special care bassinets are generally not licensed as beds in Virginia and therefore capacity can be expanded or contracted, within the authorized level of care, as needed without COPN or license authorization. Given the ability to change capacity to meet demand and the reasonable occupancy level, no shortage of capacity is apparent.

Appropriateness of Continuing COPN for Neonatal Special Care

Denial of COPN requests has not been a factor in inhibiting access to neonatal special care in Virginia. There does not appear to be a general difficulty in accessing the appropriate level of neonatal special care. Authorized centers are well distributed across the state, although not in proportion to population density. Many hospitals see the availability of intermediate care, in addition to the basic well baby nursery, as being required from the standpoint of marketing their obstetrics service. However, the competition for obstetric patients, particularly in urban and suburban areas, has resulted in development of neonatal special care services to support obstetrics programs. Given the potential harm that may result from the undermining of the overall neonatal special care system by an inappropriate proliferation of neonatal special care services, continued regulation under COPN is appropriate.

Options:
No Change: Continue applying the COPN program to neonatal special care as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP will address necessary changes to the review criteria. Current providers of neonatal special care services would probably support this option.

Minimal Change: In collaboration with the hospitals, physicians, consumers and advocates, VDH could produce a comprehensive assessment of the State's needs for neonatal special care services and by way of a targeted RFA publicize the locations where a demonstrated need for new or higher levels of neonatal special care exist as a means of stimulating interest in requesting authorization for development of the service. Current providers of neonatal special care services would probably be neutral to this option.

Deregulation: Support efforts to fully deregulate neonatal special care services. It is expected there would be no resulting proliferation of providers at the specialty and sub-specialty levels, but that there very well may be at the intermediate level. Current providers of neonatal special care services would probably be neutral to supportive of this option.

***RECOMMENDATION**: Make changes to the review criteria in the State Medical Facilities Plan necessary to remain current and continue applying the COPN program to the introduction of neonatal special care as currently mandated.*

Effectiveness of the COPN Application Review Procedures for FY 2010 Project Categories

The statute defining the contents of this report requires an analysis of the effectiveness of the application review procedures used by the regional health planning agencies and VDH. An analysis of effectiveness must detail the review time required during the past year for various project categories. The statute also dictates that this report address the number of contested or opposed applications and the project categories of these contested or opposed projects. Information concerning all contested or opposed COPNs for FY 2010 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.

On July 1, 2009 the Chairman of the Eastern Virginia Health Systems Agency notified the State Health Commissioner that the agency would suspend operations as a designated regional health planning agency effective July 1, 2009. A letter was received from the Chair of the Northwestern Virginia Health Systems Agency on August 14, 2009 as notification that the agency would suspend operations as a designated regional health planning agency effective August 14, 2009. A similar letter was received from the Health Planning Agency of Southwest Virginia on September 11, 2009 and from the Central Virginia Health Planning Agency on November 23, 2009, likewise suspending their operations as designated regional health planning agencies. In each case the reason stated for the termination of operations was a lack of funding from the Commonwealth of Virginia.

Following several years of declining appropriations, the 2008 General Assembly eliminated the general fund component of the state appropriation to the regional health planning agencies. This left the regional health planning agencies with two sources of funding: their own revenue from grants and consulting, and the excess COPN application fee revenue not spent in support of VDH's administration of the program. However, the excess application fee revenue has declined in response to 1) a decrease in the number of applications received, 2) a decrease in the average value of the projects applied for, and, to a much lesser extent, 3) an increase in VDH's expenses for rent and information technology. In FY 2009, the total excess application fee revenue available to the five regional health planning agencies was $122,771. Currently, the Health Systems Agency of Northern Virginia remains the only designated regional health planning agency in the Commonwealth, serving Health Planning Region II, Northern Virginia.

The application review process was completed in a timely manner as mandated by the *Code*. In FY 2010 25 of 49 decisions (51%) were made without a recommendation from a designated Regional Health Planning Agency. An additional 15 COPN requests have either been placed on hold by the applicant or withdrawn by the applicant after the recommendation was made by the Division of Certificate of Public Need, of which 10 (66%) had no recommendation from a designated Regional Health Planning Agency. 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.

Other Data Relevant to the Efficient Operation of COPN Program

The final consideration in the analysis of project categories is that the Commissioner include any other data she determines to be relevant to the efficient operation of the COPN program. Nationally, the debate continues as to the usefulness of COPN, with no clear conclusions drawn. Like Virginia other states are adjusting their certificate of public need programs. During 2009 and 2010, legislatures in five other states enacted legislation modifying their COPN programs. Washington passed bills that exempt certain hospice and hospital swing beds from certificate of need. West Virginia modified the review process, set standards for ambulatory surgery centers and modified the application fee schedule. Both Maryland and New Jersey passed legislation with a narrow, project specific focus.

Accessibility of Regulated Health Care Services by the Indigent

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

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

Beginning in June 2002, the DCOPN began recommending that the certificate language for the "conditioning" of COPNs be augmented to include the second type of condition allowed in the *Code*, namely that the applicant facilitate the development and operation of primary care for special populations. This added condition requirement allows an applicant a further opportunity for meeting the conditions placed on a COPN. Facilities not able to meet the conditioned requirement to provide service directly as charity care to the indigent can meet the obligation by supporting, including by direct monetary support, the development and operation of primary care through safety net providers such as the free clinics or community health centers. COPN holders opting to meet their condition obligation in this manner do so by making their contribution to the Virginia Association of Free Clinics, the Virginia Health Care Foundation, and/or the Virginia Primary Care Association, Inc., each of which has a memorandum of understanding with the Virginia Department of Health to distribute all such funds received.

During the 2009 session, the General Assembly passed House Bill 1598 which, among other changes, codified the process by which the holder of a conditioned COPN could satisfy the condition. The codified process generally follows the process that had been in practice, such as allowing direct monetary donations to safety net providers when the direct provision of the conditioned service failed to achieve the required level of indigent care. The option of making direct payments to private nonprofit foundations that fund basic health insurance for indigents was added to the list of alternatives available to the holders of conditioned COPNs in satisfying their obligations.

In FY 2010, 31 of 39 COPNs issued were issued with a condition for the performance of a certain level of charity, indigent and/or primary care. This represents 79.5% of all COPNs issued in FY 2010. The table presented in Appendix H lists all COPNs issued in FY 2010 with a condition that the applicant provide free or reduced cost care for the indigent and facilitate the development and operation of primary care for special populations.

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

There are 201 active COPN authorized and conditioned projects, (i.e., those that are operational and have annual reporting requirements). This number is up from 128 in FY 2007, 142 in FY 2008 and 182 in FY 2009. The increase reflects the number of conditioned projects that have been completed less the number of projects that no longer are required to report. By the end of FY 2010, 175 (of 196 due by the end of the fiscal year) active COPN projects reported compliance with conditions. The non-reporting facilities are being contacted with reminders and those failing to meet their conditioned obligation are being reminded of the options in the Guidance Document. It is expected that reporting compliance for FY 2010 will again be 100%.

Attachment I is a list of organizations holding COPNs that were issued conditioned on the performance of a certain level of charity, indigent and/or primary care. The list also shows the number of conditioned COPN projects for which each organization has reported compliance and the number of COPN projects for which a report of compliance on the condition was due in FY 2010 and was not received. There are a total of 65 organizations with conditioned projects that were expected to report compliance.

Relevance of COPN to Quality of Care Rendered by Regulated Facilities

One of the features attributed to the COPN program is its goal of assuring quality by instituting volume thresholds. One study from the University of California at San Francisco concluded that there is scientific evidence supporting the contention that, for some procedures or diagnoses, higher hospital volume is associated with lower patient mortality. Other studies refute any correlation between COPN programs and quality of services rendered. However, there is little dispute about the relationship between quality and patient volume in open-heart surgery, cardiac catheterization and organ transplant services. By using COPN to limit the number of service providers, patient care is concentrated in centers where the service volume is maintained at a high level, which statistically allows for better patient outcomes. This is the idea behind the concept of regionalization of services and has been demonstrated as a factor in the quality of cardiac and transplant services.

Equipment Registration

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

In FY 2010, there were eighteen equipment replacement registrations (Table 8) and three registrations of capital expenditures in excess of $5 million but less than $16.1 million (Table 9). All registered expenditures appeared to be appropriate to the mission of the facility and to the life cycle of the equipment being replaced.

Table 8 Equipment Registrations

Project Type	Number of Registrations	Capital Expenditure
Replace cardiac catheterization equipment	3	$3,535,140
Replace MRI Equipment	6	$5,776,790
Replace PET Scanner	1	$ 892,284
Replace computed tomography equipment	5	$4,434,167
Replace linear accelerator	1	$4,710,176
Replace Gamma Knife	1	$3,574,000
Replace Renal Lithotripsy Equipment	1	$ 364,245
TOTAL	18	$21,925,530

Table 9 Capital Expense Registrations

Project Type	Number of Registrations	Capital Expenditure
Hospital renovations, clinical departments	2	$22,123,881
Additional Administrative Space	1	$14,154,790
TOTAL	3	$36,278,971

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 regional health planning agencies, if any, 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 regional health planning agencies have failed to act in accordance with the timelines of § 32.1-102.6 B, the number of applications reviewed in health planning regions for which no regional health planning agency was designated, and the number of deemed approvals from the Department because of their failure to comply with the timelines required by subsection E of § 32.1-102.6, 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; 2009, c. 175.)

Appendix B

12VAC5-220-10. Definitions.

"Medical care facility," as used in this title, means any institution, place, building or agency, whether or not licensed or required to be licensed by the Board or the Department of Behavioral Health and Developmental Services, whether operated for profit or nonprofit and whether privately owned or privately operated or owned or operated by a local governmental unit, (i) by or in which health services are 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 article, only the following medical care facilities shall be subject to review:

1. General hospitals.

2. Sanitariums.

3. Nursing homes.

4. Intermediate care facilities, except those intermediate care facilities established for individuals with mental retardation that have no more than 12 beds and are in an area identified as in need of residential services for individuals with mental retardation in any plan of the Department of Behavioral Health and Developmental Services.

5. Extended care facilities.

6. Mental hospitals.

7. Mental retardation facilities.

8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.

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, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, nuclear medicine imaging, except for the purpose of nuclear cardiac imaging, or such other specialty services as may be designated by the Board by regulation.

10. Rehabilitation hospitals.

11. Any facility licensed as a hospital.

The term "medical care facility" shall not include any facility of (i) the Department of Behavioral Health and Developmental Services; (ii) any nonhospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the Department of Behavioral Health and Developmental Services' Comprehensive State Plan; (iii) an intermediate care facility for individuals with mental retardation that has no more than 12 beds and is in an area identified as in need of residential services for people with mental retardation in any plan of the Department of Behavioral Health and Developmental Services; (iv) a physician's office, except that portion of a physician's office described above in subdivision 9 of the definition of "medical care facility"; (v) the Woodrow Wilson Rehabilitation Center of the Department of Rehabilitative Services; or (vi) the Department of Corrections. "Medical care facility" shall also not include that portion of a physician's office dedicated to providing nuclear cardiac imaging.

"Project" means:

1. Establishment of a medical care facility;

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

3. Relocation of beds from one existing facility to another; provided that "project" shall not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less, (i) from one existing facility to another existing facility at the same site in any two-year period, or (ii) in any three-year period, from one existing nursing home facility to any other existing nursing home facility owned or controlled by the same person that is located either within the same planning district, or within another planning district out of which, during or prior to that three-year period, at least 10 times that number of beds have been authorized by statute to be relocated from one or more facilities located in that other planning district and at least half of those beds have not been replaced; provided further that, however, a hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing home beds as provided in § 32.1-132;

4. Introduction into 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;

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

6. 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 tomographic (CT) scanning, stereotactic radiosurgery, lithotripsy, magnetic resonance imaging (MRI), magnetic source imaging (MSI), open heart

surgery, positron emission tomographic (PET) scanning, radiation therapy, stereotactic radiotherapy, proton beam therapy, or other specialized service designated by the Board by regulation. Replacement of existing equipment shall not require a certificate of public need;

8. Any capital expenditure of $15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or in behalf of a medical care facility. However, capital expenditures between $5 and $15 million shall be registered with the Commissioner pursuant to regulations developed by the Board. The amounts specified in this subdivision shall be revised effective July 1, 2008, and annually thereafter to reflect inflation using appropriate measures incorporating construction costs and medical inflation; or

9. Conversion in an existing medical care facility of psychiatric inpatient beds approved under § 32.1-102.3:2 to nonpsychiatric inpatient beds.

Appendix C

§32.1-102.3

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

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care;

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following: (i) the level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served; (ii) the availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner; (iii) any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6; (iv) any costs and benefits of the project; (v) the financial accessibility of the project to the residents of the area to be served, including indigent residents; and (vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project;

3. The extent to which the application is consistent with the State Medical Facilities Plan;

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served;

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) the introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) the potential for provision of services on an outpatient basis; (iii) any cooperative efforts to meet regional health care needs; and (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and

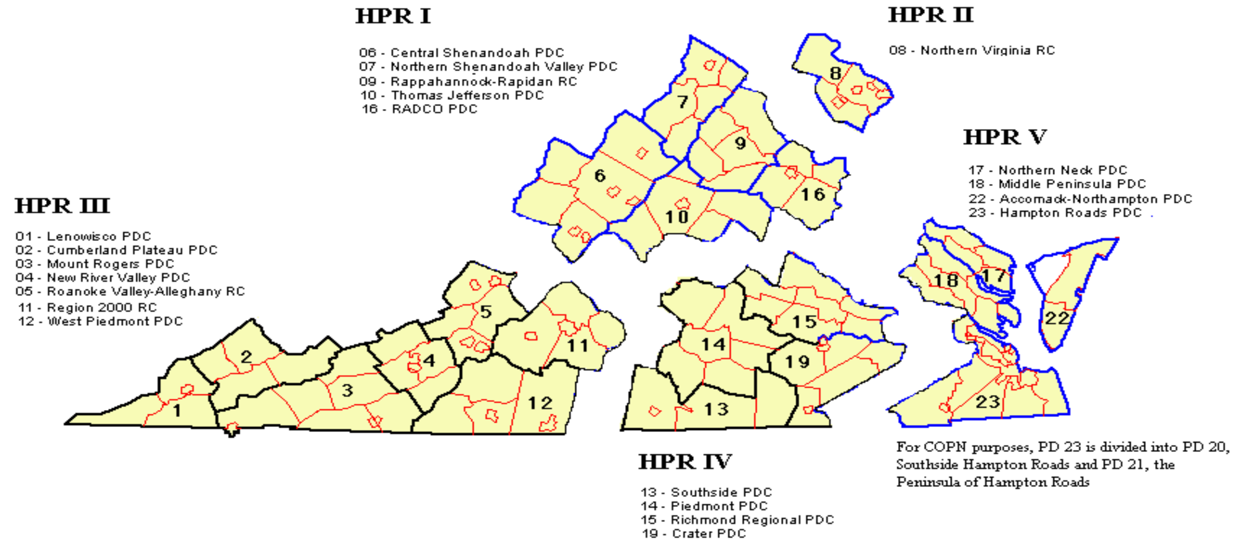
8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served, (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

(1982, c. 388; 1984, c. 740; 1993, c. 704; 1999, c. 926; 2000, c. 931; 2004, cc. 71, 95; 2008, c. 292; 2009, c. 175.)

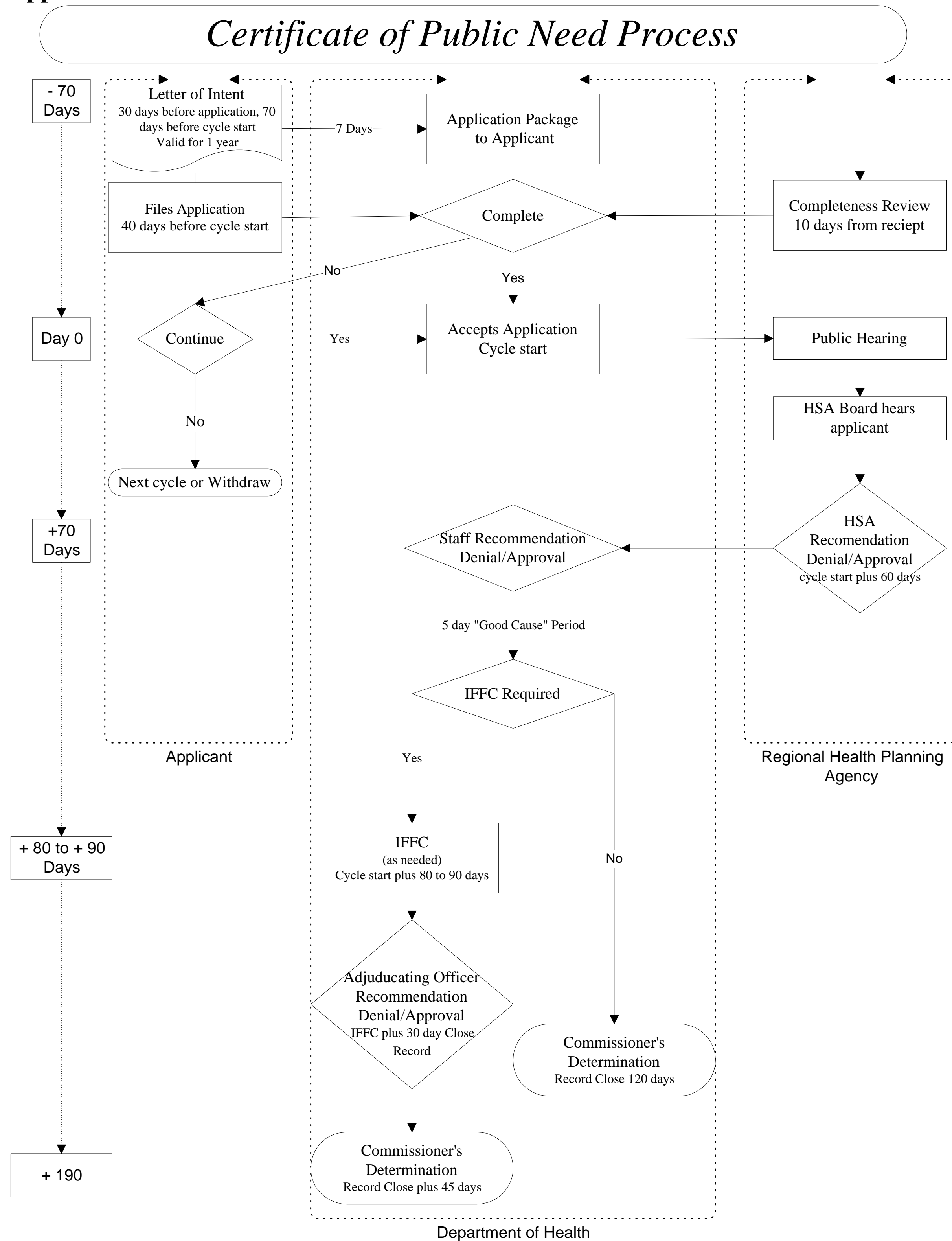
Appendix D

COPN Decisions in Fiscal Year 2010				
	Authorized Projects		**Denied Projects**	
Project Categories	**Number of Projects**	**Capital Costs**	**Number of Projects**	**Capital Costs**
Batch Group A General hospitals, obstetrical services, neonatal special care services				
Subtotal	2	**$42,296,424**	0	**$0**
Batch Group B Open heart surgery, cardiac catheterization, ambulatory surgery centers, operating room additions, transplant services				
Subtotal	9	**$25,817,936**	4	**$9,494,649**
Batch Group C Psychiatric facilities, substance abuse treatment, mental retardation facilities				
Subtotal	4	**$58,748,287**	0	**$0**
Batch Group D Diagnostic imaging				
Subtotal	11	**$7,569,410**	3	**$2,760,000**
Batch Group E Medical rehabilitation				
Subtotal	2	**$4,664,521**	2	**$21,585,427**
Batch Group F Gamma knife surgery, lithotripsy, radiation therapy, comprehensive cancer care centers				
Subtotal	9	**$40,815,494**	0	**$0**
Batch Group G Nursing home beds, capital expenditures				
Subtotal	2	**$10,850,280**	1	**$14,300,000**
COPN Program Total	**39**	**$190,762,352**	**10**	**$48,300,000**
Total Reviewed	**49**	**$238,902,428**		

Virginia's Health Planning Regions
Virginia's Planning Districts



Appendix F



Appendix G

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

Fourteenth Annual Report – 2010
Group 4 Radiation therapy, lithotripsy, obstetrical services and neonatal special care

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

Fifteenth Annual Report – 2011
Group 5 Psychiatric services, substance abuse treatment services and miscellaneous capital expenditures

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

Sixteenth Annual Report - 2012
Group 1 General hospitals, general surgery, specialized cardiac services and organ and tissue transplantation

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

- Introduction into an existing medical care facility of any new open heart surgery service
- Addition by an existing medical care facility of equipment for the provision of open heart surgery
- Introduction into an existing medical care facility of any new organ or tissue transplantation service

Seventeenth Annual Report – 2013
Group 2 Diagnostic Imaging

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

Eighteenth Annual Report – 2014
Group 3 Medical Rehabilitation, long-term care hospital services, nursing home services and mental retardation facilities

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

Project Categories Presented in the Last Five Years of Annual Reports (2005 – 2009)

Ninth Annual Report - 2005

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

Tenth Annual Report - 2006

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

Eleventh Annual Report - 2007

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

Twelfth Annual Report - 2008

Group 2 Diagnostic Imaging

Thirteenth Annual Report – 2009

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

Appendix H

Certificates of Public Need Issued With Conditions Requiring the Provision of Indigent Care and/or the Development and/or Operation of Primary Care For Underserved Populations in FY 2010

Applicant	Project	PD	COPN #		Decision Date	Conditions
Inova Reston MRI Center, LLC	Establish a Specialized Center for MRI Imaging	8	VA-	04218	08/11/2009	3.7% indigent / primary care
Tidewater Physicians Multispecialty Group	Establish a Specialized Center for MRI Imaging in Williamsburg & Newport News as mobile sites	21	VA-	04220	08/21/2009	4.0% indigent / primary care
Martha Jefferson Hospital	Establish two Specialized Centers for MRI Imaging	9&10	VA-	04221	09/15/2009	3.4% indigent / primary care
Hampton Roads Otolaryngology Associates, PLLC	Establish a Specialized Center for CT Imaging	21	VA-	04222	09/17/2009	4.0% indigent / primary care
Inova Health System	Introduce Radiation Therapy and Stereotactic Radiosurgery Services at Inova Fair Oaks Hospital	8	VA-	04223	08/26/2009	3.7% indigent / primary care
Associates in Radiation Oncology PC	Expand Radiation Therapy Services through the addition of a High Dose Rate Afterloader	8	VA-	04224	08/26/2009	3.7% indigent / primary care
Psychiatric Solutions, Inc.	Establish a 48-Bed Child and Adolescent Psychiatric Hospital	20	VA-	04225	10/05/2009	4.0% indigent / primary care
HCA Health Services of Virginia, Inc.	Add One Cardiac Cath Lab at Henrico Doctors' Hospital - Forest	15	VA-	04227	10/14/2009	3.0% indigent / primary care
MediCorp Health System	Introduce Cardiac Catheterization Services at Stafford Hospital Center	16	VA-	04228	10/29/2009	3.4% indigent / primary care
Rappahannock General Hospital	Add 6 Psychiatric Beds	17	VA-	04229	11/05/2009	4.0% indigent / primary care
Virginia Hospital Center	Add 8 Obstetrical Beds	8	VA-	04230	11/20/2009	subject to facility wide in 03977
Bon Secours - St. Francis Medical Center, Inc.	Add One General Purpose Operating Room	15	VA-	04231	12/21/2009	facility wide
Chippenham Ambulatory Surgery Center, L.L.C.	Establish a Four OR Outpatient Surgical Hospital	15	VA-	04232	12/21/2009	3.0% indigent/primary care
Johnston Memorial Hospital	Add One General Purpose Operating Room	3	VA-	04234	01/05/2010	2.4% indigent / primary care
Mary Immaculate Hospital	Add Four General Purpose Operating Rooms	21	VA-	04235	12/21/2009	4.0% indigent / primary care
Culpeper Regional Hospital	Add One General Purpose Operating Room	9	VA-	04236	01/05/2010	3.8% indigent / primary care
Smyth County Community Hospital	Introduce Inpatient Medical Rehabilitation Services (18-beds)	3	VA-	04238	12/17/2009	2.4% indigent / primary care, then facility wide
Pioneer Community Hospital	Introduce MRI Services (mobile site)	12	VA-	04239	02/17/2010	2.5% indigent / primary care
Shenandoah Shared Hospital Services, Inc.	Establish a Mobile CT Service	6 & 7	VA-	04240	02/17/2010	3.4% indigent / primary care
Mary Immaculate Hospital	Add Second CT Scanner	21	VA-	04241	02/17/2010	Bon Secours System Wide

Riverside Hospital, Inc. dba Riverside Regional Medical Center	Introduce PET/CT Imaging at an Existing Medical Care Facility (mobile site)	20	VA-	04242	02/17/2010	4.0% indigent / primary care
Sentara Hospitals	Introduce Mobile PET/CT 3 Sites	20	VA-	04244	02/17/2010	4.0% indigent / primary care
Medicorp Health System and Mary Washington Hospital	Expand Radiation Therapy & Introduce Stereotactic Radiosurgery	16	VA-	04245	02/04/2010	3.4% indigent / primary care
Bon Secours Maryview Medical Center, Inc.	Capital Expenditure and add 21 Psychiatric Beds	20	VA-	04246	02/17/2010	4.0% indigent / primary care
Rehabilitation Hospital of Petersburg, Inc.	Add 15 Medical Rehabilitation Beds	19	VA-	04247	03/15/2010	3.0% indigent / primary care
John Randolph Medical Center	Introduce Lithotripsy Services (Mobile Site for Renal)	19	VA-	04249	05/03/2010	3.1% indigent / primary care
Fairfax Surgical Center, L.P.	Introduce Lithotripsy Services (Mobile Site for Renal)	8	VA-	04250	05/03/2010	4.1% indigent / primary care
Reston Surgery Center, L.P.	Introduce Lithotripsy Services (Mobile Site for Renal)	8	VA-	04251	05/03/2010	4.1% indigent / primary care
Spotsylvania Medical Center, Inc.	Introduce Radiation Therapy, Stereotactic Radiosurgery, CT Simulation, and PET/CT Services	16	VA-	04253	04/07/2010	3.4% indigent / primary care
Bon Secours-St. Mary's Hospital of Richmond, Inc., Richmond Radiation Oncology Center, Inc., and Richmond Radiation Oncology Center I, LLC	Add One Linear Accelerator at Bon Secours - St. Francis Medical Center	15	VA-	04255	04/28/2010	3.0% indigent / primary care
Augusta Health Care, Inc. d/b/a Augusta Health	Capital Expenditure of $16,083,450 or more to Expand and Renovate the Hospital	6	VA-	04256	06/08/2010	3.0% indigent / primary care

Appendix I

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

(As of June 30, 2010 for reports due during FY 2010)

COPNs With		
Conditions Reported Met	No Report Submitted	
1	0	Alliance Imaging
2	0	Augusta Hospital Corporation
2	0	Association of Alexandria Radiologists
1	0	Bath County Community Hospital
17	1	Bon Secours Virginia
5	1	Carilion
3	0	Chesapeake General
0	1	Commonwealth Imaging LLC
2	0	Community Health Systems
1	0	Community Memorial Health Center
1	0	Community Radiology of Virginia, Inc.
2	0	Culpeper Regional Hospital
1	0	Cumberland Hospital for Children and Adolescents
1	0	Drs. Mark & Christine Rauch
1	0	Eye Surgery Limited, LLC
1	0	Fairfax Radiological Consultants, P.C.
1	0	Falls Church Lithotripsy Associates, L.L.C.
1	0	Fauquier Health
1	0	First Meridian Medical Corporation / MRI & CT Diagnostics
1	0	Halifax Regional Hospital, Inc.
1	0	Hampton Roads Orthopaedics & Sports Medicine
24	0	HCA
2	0	HealthSouth
12	3	Inova
1	0	Institute for Women's Imaging
1	0	Kindred Hospitals East
2	0	Lifepoint
6	0	Martha Jefferson Hospital
10	0	Mary Washigton Healthcare (formerly Medicorp)
1	0	Mid-Rivers Cancer Center
0	1	Mountain States Health Alliance
2	0	MRI & Imaging of Virginia (MedQuest)
1	0	Northern Virginia Eye Surgery Center
3	0	Novant
1	0	Orthopaedic Center of Central Virginia
1	0	Orthopaedic Surgery & Sports Medicine Specialists

1	0	Osteopathic Surgical Centers, LLC
1	0	Radiology Consultants of Lynchburg
4	0	Radiology Imaging Associates
1	0	Reston Radiology Consultants
7	0	Riverside
1	0	Roanoke Ambulatory Surgery Center, LLC
1	0	Roanoke Valley Center for Sight
20	1	Sentara Healthcare
0	1	Shore Health Services
1	0	The Center for Cosmetic Laser & Dermatologic Surgery
1	0	The Skin Cancer Surgery Center
1	1	Tidewater Orthopaedic Associates
1	0	Tidewater Physicians Multispecialty Group
1	0	Tuckahoe Orthopaedic Associates, LTD
1	0	Twin County Regional Hospital
2	0	UVa Medical Center
6	1	Valley Health
1	0	Virginia Beach Eye Center
1	0	Virginia Cancer Institute, Inc.
1	0	Virginia Cardiovascular Specialists (Intercardia)
6	0	Virginia Hospital Center
0	1	Virginia Medical Imaging
2	0	Virginia Physicians
0	1	Virginia Surgery Center
0	3	Virginia Urology
1	0	Washington Radiology Associates, P.C.
1	0	Wellmont Health System
1	0	West End Orthopedics
1	0	Winchester Eye Surgery Center, LLC