REPORT OF THE JOINT COMMISSION ON HEALTH CARE

STUDY OF VIRGINIA'S CERTIFICATE OF PUBLIC NEED (COPN) PROGRAM PURSUANT TO HB 1302 OF 1996

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA



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Preface

The second enactment clause of House Bill (HB) 1302 of the 1996 Session of the General Assembly directed the Joint Commission on Health Care, with staff support from the Health Systems Agencies and the Virginia Department of Health, to study the appropriateness of Virginia's Certificate of Public Need (COPN) program with added emphasis on whether or not outpatient or ambulatory surgical centers should remain subject to this law.

The Virginia COPN program, which is authorized under Title 32.1 of the Code of Virginia, was established in 1973 with the objectives of: (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.

Based on our research and analysis, we concluded the following:

- There is little evidence of significant COPN impact on aggregate health expenditures, but there is evidence of savings for specific services covered by COPN.
- There is some evidence that COPN has contained resource supply, especially with high technology services.
- Growth in managed care and capitation payments reduces the incentives of health care providers to develop unneeded capacity and provide unnecessary services.
- There has been no relationship established between the level of managed care penetration nationally and the relative stringency of COPN.

- COPN has played a role in promoting better care outcomes by stressing the necessity for sufficient volume, especially high technology services.
- COPN has played a role in ensuring the delivery of health care services to the indigent and the uninsured by Virginia's regulated health care providers.
- The ability of Virginia's hospitals to cover the costs of care to the indigent and the uninsured is impacted by several factors, including: (i) greater competition in the marketplace; (ii) the development of new facilities which attract paying patients and which provide minimal care to the indigent and uninsured; and (iii) the evolution of managed care financing mechanisms. These trends could be hastened further by COPN repeal.
- Community-based health planning can and does serve a vital role in the Commonwealth, irrespective of the COPN program.
- The COPN program has not restricted the growth of outpatient surgery in Virginia.
- The COPN regulatory process favors hospital sponsored outpatient surgical hospital projects over outpatient surgical hospital projects of non-hospital sponsored investors.

A number of policy options were offered for consideration by the Joint Commission regarding the issues addressed in this report. These policy options are discussed on page 31.

Our review process on this topic included an initial staff briefing which was followed by a public comment period during which time interested parties forwarded written comments to us on the report. In many cases, the public comments provided additional insight into the various topics covered in this study. A summary of these public comments is provided in Appendix C.

Following a thorough review and discussion of this study, the Joint Commission introduced legislation (House Bill 2477) which was approved by the 1997 Session of the General Assembly and can be found in Appendix D.

The legislation directs the Commissioner of Health to report annually to the Governor and the General Assembly on the status of the COPN program. The report must include: (i) a summary of actions taken; (ii) a five-year schedule for analysis of the appropriateness of all COPN project categories; (iii) an analysis of health care market reform and the extent to which such reform obviates the need for COPN; (iv) an analysis of the accessibility by the indigent to care provided by regulated medical care facilities; and (v) an analysis of the relevance of COPN to the quality of care in regulated medical care facilities.

Jane N. Kusiak

Executive Director

June 20, 1997

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I. AUTHORITY FOR STUDY

House Bill 1302 (Appendix A) of the 1996 General Assembly included a second enactment clause which directed the Joint Commission on Health Care, with staff support from the Health Systems Agencies (HSAs) and the Virginia Department of Health (VDH), to study the appropriateness of Virginia's Certificate of Public Need Program (COPN) with added emphasis on whether or not outpatient or ambulatory surgical centers should remain subject to this law.

II. HISTORY OF VIRGINIA'S CERTIFICATE OF PUBLIC NEED PROGRAM

The Virginia COPN Program, which is authorized under Title 32.1 of the Code of Virginia, was established in 1973 with the objectives of: (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 (Preamble to 1973 Act).

COPN programs were initially adopted by states based upon the theory that excess hospital capacity and capital investment contributed substantially to escalating medical care costs. Social Security law amendments of 1972 allowed the federal government to withhold capital cost reimbursement under Medicare, Medicaid, and Child Health Programs of projects found to be inconsistent with the plans of designated state planning agencies.

Section 32.1-102 of the Code of Virginia requires existing medical care facilities and sponsors of proposed medical care facilities, as defined by this section, to receive a Certificate of Public Need from the Commonwealth of Virginia before expanding certain existing medical services, providing certain new medical services, or creating a new facility. The entire list of projects covered under this law can be found in Appendix B.

The Certificate Of Public Need Program Was Established in 1972 In An Attempt To Reduce The Rate Of Growth Of The Medicare And Medicaid Programs.

The genesis of the Certificate of Public Need program lies in amendments that were made to the Social Security Act in 1972, in an attempt to reduce the rate of growth of the Medicare and Medicaid Programs, which were established in 1964. The major provision, which spurred the development of COPN programs across the country, allowed for the denial of provider reimbursements under the Medicare, Medicaid, and Child Health Programs for the portion of any construction costs which were undertaken by a provider without state approval.

The National Health Planning and Resources Development Act of 1974 (NHPRDA) contained provisions which mandated all states to develop a COPN program by 1980. Federal appropriations were authorized to support regional and state level planning efforts.

Federal Role In Certificate Of Public Need Completely Eliminated In 1988.

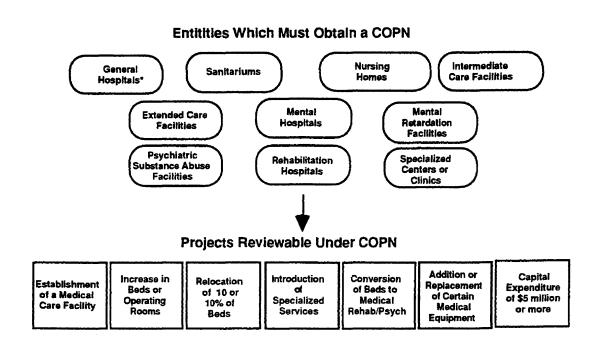
The federal role in COPN was completely eliminated in 1988, with the expiration of the NHPRDA. Since that time, the relative value of COPN has been debated in state capitals across the United States. Today, approximately 35 states and the District of Columbia currently have COPN programs.

III. DESCRIPTION OF VIRGINIA'S COPN PROGRAM

Figure 1 illustrates the types of entities which must obtain a COPN, along with the types of projects reviewable under the COPN program.

Figure 1

Health Care Entities Subject to COPN Review and Projects Reviewable Under COPN in Virginia



In 1988, Virginia Lifted Many Categories Of Services And Equipment For COPN Regulation. This Decision Was Reversed In 1992.

Source: Virginia Department of Health State Medical Facilities Plan

Virginia's approach to COPN regulation has undergone some major changes over the past several years. As Figure 2 identifies, coverage for the establishment of new facilities has remained under the COPN law since its inception, while there was a very brief period of deregulation between 1989 and 1992 for specialty services, non-hospital facilities, specialized medical equipment and other capital expenditures.

Figure 2

Major Changes in Regulation for COPN Reviewable
Facilities and Services: 1981 - 1996

	Hospital Facilities*	Nursing Home Beas	Specialty Services	Non-Hospital Facilities	Specialized Medical Equipment	Other Capital Expenditures
1981	Regulated	Moratorium	Regulated	Regulated	Regulated	Regulated
1983		Moratorium Lifted				
1988		Moratorium Reinstated				
1989		·	Deregulated**	Deregulated**	Deregulated	Deregulated
1992			Reregulated	Reregulated	Reregulated	Reregulated
1996		Moratorium ends/RFP Process Developed				Threshold increased \$1 million to \$5 million
Current Status	Regulated	AFP Process	Regulated	Regulated	Regulated	5 million Threshold

- Including Ambulatory Surgery Centers
- Four specialty services continued to be regulated under COPN in 1989 if introduced as new services by existing facilities; open heart surgery, psychiatric services, substance abuse treatment services, and medical rehabilitation. Additionally, the establishment of outpatient surgical hospitals continued to require COPN authorization.

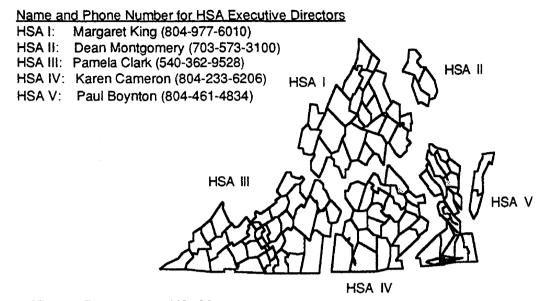
Source: Virginia Department of Health Division of Certificate of Public Need

Virginia's COPN Program Is Administered By VDH In Partnership With The Regionally Based HSAs.

The COPN program is administered by the Virginia Department of Health, in partnership with regional health planning agencies known as Health Systems Agencies (HSAs). Accordingly, each project is reviewed at the regional level but also is considered at the state level, with the Commissioner of Health making the final decision on each application. Figure 3 illustrates the regional health planning districts and identifies the Executive Director of each agency. All of these agencies are not-for-profit organizations with a board of directors, which is composed of providers and consumers. Most of these agencies are minimally staffed and receive most of their funding from state appropriations. While each agency's mission and scope of work is unique and reflects the interests and needs of each region, the review of COPN applications is the common function among all of the HSAs.

Figure 3

Location of Virginia's Five HSA Health Service Areas and Planning Districts



Source: Virginia Department of Health

Decision Making In The COPN Program Is Conducted At The Regional And State Levels.

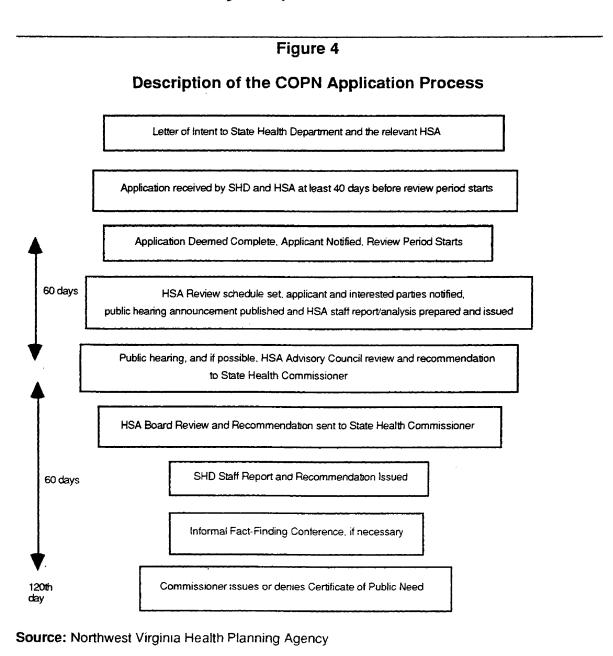
The decision making process under the COPN program is, for the most part, consistent throughout the Commonwealth. Appeals made to Commissioner's rulings must be made through the court system. Figure 4 highlights the major review processes for COPN applicants (see Appendix B for a complete description of the COPN review process). Regional health planning has been seen as an important component of the COPN approval process because it allows for the involvement of local consumers.

Proposed Projects Must Meet Relative Public Need Criteria.

COPN projects must meet relative public need criteria. The Commissioner of Health must consider 20 specified factors in evaluating COPN requests. The Board of Health establishes a State Medical Facilities Plan (SMFP), consisting of facility need projection methodologies and project review standards. Decisions to issue a COPN must be consistent with the SMFP or the Commissioner must find the SMFP to be inadequate, inaccurate, or outdated. If the latter, the Commissioner initiates amendments to the plan.

The Commissioner Of Health Has The Authority To Place Conditions Pertaining To The Provision Of Indigent Care And Primary Care.

A conditioning process was added to the COPN law in 1988, along with other changes mentioned in an earlier section of this report. The Commissioner may condition approvals on the provision of free or reduced rate care to indigents, the acceptance of patients with special needs, or the facilitation of primary care for underserved areas.



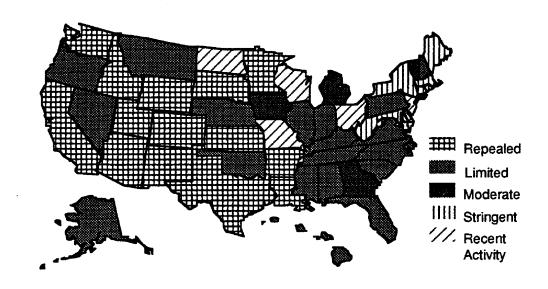
IV. APPROACHES TO COPN REGULATION IN OTHER STATES

Today, 35 States And The District Of Columbia Have COPN Laws.

Today, approximately 35 states and the District of Columbia currently have COPN programs. Lewin Associates recently completed a study for the Delaware Health Care Commission in which they clustered all states and the District of Columbia according to the stringency of their COPN regulation. As Figure 5 illustrates: 14 states do not have COPN programs, 23 states fell in the limited cluster including Virginia; 6 states fell in the moderate cluster and 8 states fell in the stringent cluster.

Figure 5

The Level of COPN Stringency by State as of May 1996



Source: 1996 Delaware Health Care Commission COPN Study

As Figure 5 illustrates, on the whole, states in the west and southwest either do not have a COPN program or have one with limited scope or coverage. States with the most stringent COPN laws are located in the

Northeast, with states in the Southeast maintaining a strong but limited role for its COPN programs.

Virginia And Its Surrounding States Have Very Similar COPN Programs.

As Figure 6 indicates, the texture of Virginia's COPN program and its surrounding states is very similar:

Scope of COPN Regulated Services for Virginia and Surrounding States

Figure 6

Project Categories	VA	MD	ку	WVA	TN
Hospital Beds	x	X	х	x	х
Ambulatory Surgical Centers	X		x	х	х
Nursing Home Beds	х	х	х	х	x
Specialty Services					
Neonatal Intensive Care	x	×	X	х	х
Obstetrical Services	х	х	х	х	
Open Heart Services	х	x	х	x	х
Organ Transplants	x	х	x	x	
Psychiatric Services	x	x	х	x	x
Medical Rehabilitation	Х	x	х	х	х
Substance Abuse Services	X	х	X	x	х

Source: October 1996 Joint Commission on Health Care Telephone Survey

For the most part, adding new beds and/or specialty services are covered by all of these programs. Two unique features of different programs are worthy of note:

- In Maryland, one operating room, multi-use, free standing ambulatory surgery centers or outpatient surgical hospitals can be developed without a COPN.
- In Tennessee, the development of new Obstetrical Services does not require a COPN but one must be obtained to discontinue these services. This provision was added as a way to ensure access to these services across the state.

Some States Have Significantly Altered Their Approach To COPN Regulation In Recent Years.

Some states have significantly altered their approach to COPN regulation in recent years. With the exception of the expansion of long-term care beds which most states continue to regulate, it appears that each state is charting its own course with most changes categorized as steps toward deregulation. What follows is a sampler of some unique approaches to COPN regulation:

OHIO-In 1995 this state decided to sunset its COPN Program on May 1, 1997 with the exception of long-term care beds and charted a course to replace this program with quality and safety standards as well as quality of care reporting requirements for previously reviewable health care services.

MISSOURI-In May of 1996, this state decided to phase out significant portions of its COPN program by December 31, 2001. Construction of new hospitals, nursing home and residential care beds will continue to be regulated.

NEW JERSEY-In 1995, this state created a pilot program to test the use of licensing as an alternative to COPN for regulating the number and locations of specialty services and equipment. In addition, reviews of some categories of projects which are deemed to be "low-risk health services" will be expedited by bypassing regional health planning agencies and conducting the entire review at the state level.

DELAWARE-In July of 1996, this state decided to phase out its COPN program by July 1999 with the intention of focusing on the extent to which hospitals cost shift to support indigent care financing and the development of consumer oriented information on the cost as well as the quality of health care services.

V. APPROPRIATENESS OF VIRGINIA'S COPN PROGRAM

Assessing the appropriateness of the Certificate of Public Need Program is a daunting task. Fortunately for Virginia, a few other states have recently completed very comprehensive reviews of COPN and summaries of these studies and related recommendations are described in Figure 7.

Figure 7
Summary of Recent COPN Studies Conducted Outside of Virginia

Study	Conclusions
Delaware Health Care Commission/Duke University COPN Study	Marketplace changes in the financing and delivery of health care offer sufficient potential for curbing costs while assuring a socially acceptable level of quality of care without a COPN regulatory structure.
May, 1996	No evidence exists to show that a spending surge would occur in Delaware as a result of COPN elimination.
State of Georgia/Lewin-VHI COPN Study December, 1995	High managed care penetration and stringent COPN co-exist in several states suggesting that COPN repeal is not mandatory if one wants to allow for the growth of managed care.
December, 1993	Little evidence was found which indicated that hospital bed supply and/or use rates are lower in states with more stringent COPN.
Alpha Center/Lewin-VHI COPN Study March, 1993	COPN programs do not appear to be a policy tool that, by itself, can achieve cost containment or improve access or quality. COPN programs have been more effective in controlling costs in the long term care sector
	COPN has some effect on maintaining access for underserved populations and promoting quality health care.
Campbell and Fournier COPN/ Indigent Care Study for Florida June, 1993	Implicit purpose of COPN program in Florida is to "cross-subsidize" to provide greater levels of indigent care.
	•

Overall, past Virginia based studies, as well as discussions with current administrators of the Virginia COPN program, are generally consistent with these findings.

The discussion which follows seeks to integrate these findings into a Virginia-specific context. This discussion will seek to answer the following questions related to COPN for health care facilities and services:*

- **Question 1:** Has the Certificate of Public Need Program contained health care costs or have other mechanisms been more effective in this area?
- **Question 2:** Has the Certificate of Public Need Program impacted the quality of health care delivered in the Commonwealth and does it have a future role to play in this area?
- Question 3: What role does the Certificate of Public Need Program play in the delivery of health care services to the indigent and uninsured and how will this role change in the future?
- **Question 4:** Should Ambulatory Surgery Centers (licensed in Virginia as Outpatient Surgical Hospitals) continue to be regulated by the Certificate of Public Need Program?
- * Please note that this discussion does not pertain to COPN for nursing home beds as this issue was recently addressed by the 1996 General Assembly. HB 1302 (1996) ended the COPN moratorium and replaced it with a Request for Applications (RFA) process for nursing home beds.

Question One: Has The Certificate Of Public Need Program
Contained Health Care Costs Or Have Other
Mechanisms Been More Effective In This Area?

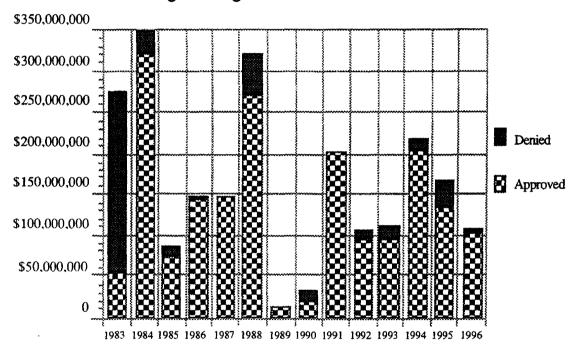
Data and studies on the affect of COPN on health care costs are inconclusive. COPN has not been shown to be linked to reductions in aggregate health care costs and charges, as both have risen over the years, but a recent report on the affect of COPN on the actual costs of specific medical technologies that are covered by the programs found tangible savings. The effectiveness of COPN on controlling total medical care costs has proven very difficult for researchers to study well because there are so many factors affecting total expenditures, with many of those factors not controlled by COPN. There is evidence, however, that COPN has had an effect on controlling costs for services that are covered under the program.

While it is impossible to draw any conclusions about the relationship between COPN denials for capital expenditures and the cost

of these services in the market, Figure 8 demonstrates that Virginia's COPN program has reviewed a significant amount of regulated capital expenditures. Over this 13 year period, denials averaged approximately 16% of the total capital expenditures reviewed.

Figure 8

Dollar Value (unadjusted) of Denied and Approved COPN Applications
Excluding Nursing Homes: Fiscal Year 1983 - 1996



Source: VDH Division of Certificate of Public Need

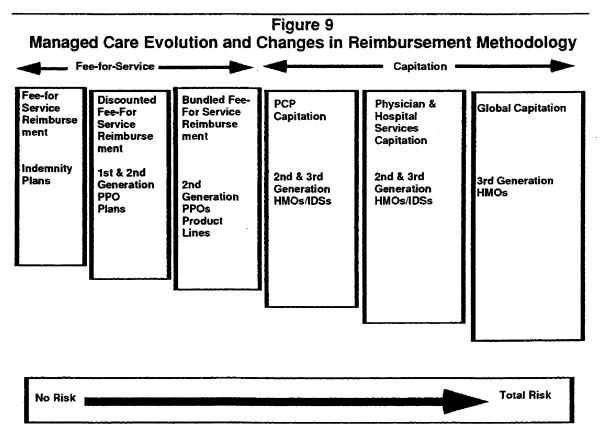
According to a report recently completed by the Alpha Center, states which have stringent enforcement of COPN regulations for new technology and services, such as organ transplantation, open heart surgery, CT scanners, MRI, and cardiac catheterization, have had tangible reductions in the diffusion of these services. The study suggested that the ability of COPN programs to control the diffusion of these services may have reduced hospital spending in the aggregate, although no direct link was made.

According to VDH's Division of Certificate of Public Need, Virginia saw a significant increase in expensive medical technology, such as CT scanners, lithotripsy, and MRIs after the deregulation of COPN in 1989,

and a significant reduction in the rate of increase of these services after reregulation of COPN in 1993.

Third Party Reimbursement Methodology Changes Are Seen By Many To Be The Most Effective Cost Containment Tool.

Much has changed in our nation's health care marketplace since the advent of the Certificate of Public Need process. Reimbursement policies have been changed to alter provider incentives. The most notable changes for hospitals came in the mid 1980s when Medicare adopted a new prospective reimbursement system which sets payment rates for each diagnostic related group (DRG).



Source: Jacque J. Sokolov, M.D. Advanced Health Plans, Inc.

Under this system providers are reimbursed a set amount for each patient based upon the patient's diagnosis, instead of cost-based reimbursement. Other reimbursement methodologies have emerged since that time under the rubric of "managed care" with the goal of limiting incentives for providers to perform inappropriate tests and services. Some

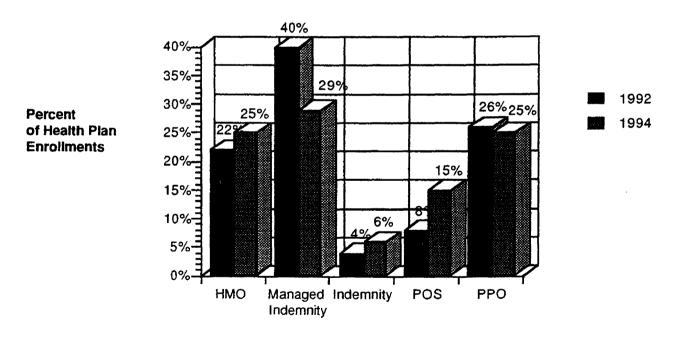
data indicate that managed care is most effective in controlling costs when combined with COPN. As Figure 9 illustrates, new phases of managed care evolution are most often categorized as changes in reimbursement methodologies employed in the marketplace.

Managed Care Reimbursement Strategies Significantly Alter Provider Incentives.

Today's health care marketplace is very competitive, with managed care companies claiming a greater percentage of the population each year. Figure 10 illustrates the rate of increase in managed care enrollment nationally as opposed to traditional indemnity enrollment from 1992 to 1994.

Figure 10

National Employer Health Plan Enrollments



Source: KPMG National Surveys of Employer Sponsored Health Plans 1992,1994

While the business community has clearly embraced managed care and shifted most of their covered lives into these products, the public payers are making this transition on a more gradual basis. This is a very important distinction. Although the majority of the population accesses care through an employee benefit plan, the major payer of care provided in hospitals, which is the primary target of COPN activity, is financed through Medicare.

Prospective provider reimbursement strategies such as Medicare "DRGs" began the shift towards a greater emphasis on altering provider behavior through reimbursement. Many would argue; however, that these strategies, which are targeted at one provider group or one episode of care, have led to much "gaming" in the system. When providers receive one sum for an episode of care, this episode can be altered by wrapping around additional services in an outpatient environment either before admission, or upon discharge. In the outpatient setting, reimbursement strategies which bundled certain services together for a set fee have been "unbundled" by providers to optimize provider reimbursement.

Managed care reimbursement strategies seek to alter provider financial incentives. Many providers are reimbursed on a risk-sharing basis which reduces or eliminates the incentive to provide unnecessary services. There are various risk sharing payment methods (e.g, fee withholds, capitation, etc.). Many view "capitation" as having the greatest impact on "realigning" providers' incentives.

Capitation is a method of payment for health services in which an individual or institutional provider is paid a fixed amount for each person served, without regard to the actual number or nature of services provided to each person in a set period of time. This reimbursement mechanism further refines earlier reimbursement reform by creating incentives for all providers to work together to keep covered lives healthy. Under this system, profitability lies in managing costs, not providing more services, as is the case under fee for service medicine. Capitation; however, is not used extensively in Virginia.

Managed Care is Expanding in Virginia.

In many states, managed care was established earlier and grew more quickly than in Virginia; however in recent years, there has been significant growth in managed care plans in the Commonwealth. In 1995 the HMO-PPO Digest, published by Hoescht Marion Roussel, Inc. indicated that Virginia's HMO enrollment increased 82% between 1993 and 1994. One in every six Virginians is enrolled in an HMO, with total 1995 HMO enrollments amounting to 1,083,683. The following table lists HMO enrollment in Virginia by region:

Figure 11
1995 HMO Enrollment in Virginia

Region	HMO Enrollment
Northern Virginia	562,041
Hampton Roads	245,696
Central Virginia	238,772
Blue Ridge	20,798
Roanoke Area	16,376
Southwest	0
Total Enrollment	1,083,683

Source: Virginia Association of HMOs

Other indicators of the recent growth in managed care in Virginia include the enrollment of all state employees in managed care since 1992 (89% enrolled in Point of Service Plan, 11% enrolled in HMOs) and enrollment of 59% of Medicaid recipients in managed care plans.

Question Two:

Has The Certificate Of Public Need Program Impacted The Quality Of Health Care Delivered In The Commonwealth And Does It Have A Future Role To Play In This Area?

Virginia's COPN Program Does Stress Volume And Capacity As Significant Indicators Of Whether A New Service Is Necessary Within A Given Marketplace.

Virginia's COPN program does stress volume and capacity as significant indicators of whether a new service is necessary within a given marketplace. It also regulates high cost, high risk services and technology such as organ transplant, open heart surgery, and neonatal intensive care. For the most part, outcomes for these highly specialized services are better when these programs are regional and the volumes of such programs are

high. In other words, rather than having two specialized services with low volume, it is in the best interest of the public for providers to cooperate and share limited capital and trained staff resources.

As the marketplace has become more competitive, institutional providers are seeking to develop internal capacity to provide services across the entire continuum of care rather than relying on referral relationships with other providers. This trend is challenging the basic foundation of the COPN program as it relates to review of these services.

Health planners argue that this type of competition among health care providers fosters the development of duplicative service capacity, which in turn increases the overall cost of health services to the consumer. These planners suggest that health care integration works to reduce inefficiency only when there is a net loss in overall system capacity.

The Most Significant Mechanisms Which The Commonwealth Employs To Monitor Quality Have Been The Licensure Process And Quality Measures.

Beyond COPN regulation, the Commonwealth has other tools such as facility licensure and certification requirements for Medicaid and Medicare. By far the most significant mechanisms which the Commonwealth employs to monitor quality has been the licensure process and quality measures. Licensure systems are gradually evolving to play a more significant role in quality review and the State Health Department is currently working with the Bureau of Insurance to strengthen the oversight of quality in the HMO industry.

The Commonwealth's teaching hospitals have continually shared concerns about the proliferation of high technology services. Some of these concerns focus upon outcomes while others are more related to protecting patient populations for teaching and revenue purposes.

Supporters of unbridled managed care favor developing more sophisticated mechanisms for publishing consumer information on more advanced services to offset any potential reduction in quality which may evolve from the duplication of advanced services and technology. They would argue that once capitation dominates the market as a reimbursement methodology that providers will focus more energy on prevention and primary care and will have the incentive to share resources when appropriate.

Another more subtle aspect of the COPN program which is impossible to quantify is the decision making process, both internally and with regional health planners, which providers go through in consideration of applying for a Certificate of Public Need. Informal discussions have many times led providers to abandon some plans and led others to shift the focus of the project.

Virginia Health Information, Inc., a not - for - profit entity which manages the patient level data base has recently published an obstetrical guide and has incorporated more studies on tertiary services in it's strategic plan.

Question Three: What Role Does COPN Play In The Delivery Of Health Care Services To The Indigent And Uninsured And How Will This Role Change In The Future?

The Baliles Certificate of Public Need Commission of 1987 recognized the inextricable link between the COPN program and the provision of indigent care. It found that the burden of uncompensated care fell unevenly among hospitals and that no mechanism was in place to relieve the excessive burden borne by certain facilities.

In response to these concerns, the 1988 General Assembly incorporated a conditioning process into the Certificate of Public Need Law and created the Indigent Health Care Trust Fund to equalize the burden of uncompensated care across private acute hospitals. Both of these programs, while still in place today, provide only minimal support for hospitals which provide high levels of uncompensated care.

The conditioning process authorizes the State Health Commissioner to condition approval of a certificate upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care. The VDH has established a conditioning standard which would set the provision of charity or reduced care at equivalent or greater than the median level of charity care for their planning district.

In a study conducted by Ellen Campbell and Gary Fournier in 1993 for the State of Florida, the authors assert that although the explicit purpose of COPN is to prevent hospitals from duplicating services and investing in costly excess capacity, the implicit purpose of COPN is to use the power of the state to issue licenses and restrict competition in order to

create an incentive for hospitals to provide high levels of care to the indigent.

The Larger Question At Hand Is Whether The Certificate Of Public Need Program Has A Role To Play In Protecting The Patient Base Of Providers Who Serve The Indigent.

As the market consolidates and providers who have traditionally provided a significant level of uncompensated care face growing competition for lives, the Certificate of Public Need Program is seen by some as a viable mechanism to limit a provider's entry into the market, if it is perceived that such an entity would skim off paying patients and not provide care for Medicaid and uninsured patients. The conversion of not-for-profit hospitals to for-profit hospitals is seen by some as having the potential for further straining providers who have traditionally served the indigent.

Question Four: Should Ambulatory Surgery Centers (Licensed in Virginia as Outpatient Surgical Hospitals) Continue To Be Regulated By The Certificate Of Public Need Program?

This section of the report was prepared to respond to a specific question which was raised within the study language directing the Joint Commission on Health Care to conduct this study. The following discussion outlines issues unique to this environment, but should not be considered in isolation of the more global questions posed in the previous section of this report.

ASCs can be either hospital sponsored or non-hospital sponsored, and vary according to governance, type of ownership or sponsorship, the types of services provided, and the comprehensiveness of services. ASCs are regulated under Virginia's COPN law as licensed outpatient surgical hospitals. Outpatient surgical hospitals are facilities at which surgical procedures are performed on outpatients. They constitute a medical environment exceeding the normal capability found in a physician's office. For the purpose of this issue brief, Ambulatory Surgery Centers will be referred to as outpatient surgical hospitals.

Virginia Currently Has 24 Licensed Outpatient Surgical Hospitals.

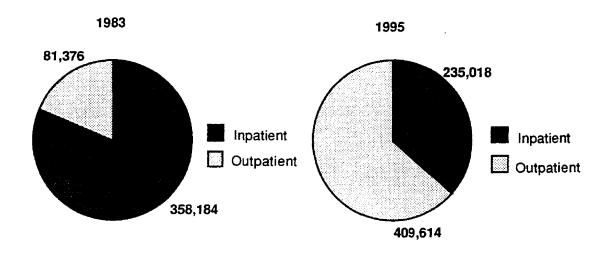
The first ASC was established in Phoenix, Arizona in 1970. Since that time the number of centers has grown significantly. Currently, there

are 24 licensed outpatient surgical hospitals in Virginia. Twelve of Virginia's 24 licensed outpatient surgical hospitals are wholly or partially owned by hospitals. Cosmetic surgery, minor surgery, and other minor invasive procedures are performed in physicians' offices that are not licensed and not regulated under COPN. Such facilities are not generally eligible for the payments provided by third party payers to general or outpatient hospitals.

As seen in Figure 12, there has been a dramatic shift from inpatient to outpatient surgeries over the past several years. This shift has occurred as the number of outpatient surgery procedures, performed in lieu of inpatient procedures, has grown in both community hospitals and in a growing number of freestanding ASCs.

Figure 12

Changes in the Volume of Inpatient versus Outpatient Surgery in Virginia: 1983 to 1995



Sources: Hospital Licensure Reports, State Medical Facilities Plans and Regional HSA data compiled by the Northern Virginia Health Planning Agency

The following three trends have contributed to the rapid growth in the types of procedures now done on an outpatient basis:

- New surgical techniques such as endoscopy and laser surgery which allow procedures to be done more quickly with less surgical trauma.
- New anesthetic agents, which allow a smooth, rapid recovery from anesthesia, with a much lower incidence of nausea and vomiting.
- Technological advances in monitoring equipment which increases the safety of all anesthetic techniques.

These trends, coupled with the lower costs of such surgeries, led to the development of payment policies which discourage hospital admission of surgical patients unless it is absolutely necessary.

Virginia ranks well above the national average in outpatient surgical facilities, and the number of freestanding outpatient surgical facilities has increased substantially over the last 10 years, more than keeping pace with national trends.

Charges For Surgical Procedures Performed In An Outpatient Setting Are Lower Than In An Inpatient Setting.

Surgical procedures commonly done on an outpatient basis may be done in general acute care hospitals and charged within the hospital's cost center or may be conducted in an outpatient surgical hospital which is separate from the hospital's cost structure, regardless of whether or not the facility is hospital sponsored.

The cost of similar surgical procedures performed in different settings varies, depending largely upon the fixed and variable cost structures of the facilities in which they are performed, but also upon the cost allocation policies and practices of the operators of the services and the complexity of the cases handled. Generally, allocated fixed costs are higher in inpatient settings than in outpatient settings because of cross-subsidization, higher inpatient indigent care burden, and related factors. Variable costs also may be higher because the more difficult cases are likely to be performed in inpatient settings. Figure 13 provides a comparison of reported charges for five high volume outpatient surgical procedures. It must be emphasized that these amounts reflect charges not costs, and are not the actual reimbursement (payment) received by the

facility. Reimbursement levels often vary significantly by facility and service.

Figure 13

1994 Average Gross Charges for the Top 5 Most Frequently Performed Outpatient Surgical Procedures for Virginia's Hospitals and Outpatient Surgical Hospitals as Reported to the Health Services Cost Review Council

	Hospitals	Outpatient Surgical Hospitals*
Cataract Removal	\$3,237.94	\$2,366.65
Removal of Colon Polyp	\$1,420.99	\$880.62
Myringotomy (ear tubes)	\$1,661.70	\$1,058.31
Breast Biopsy	\$2,085.85	\$1,406.98
Hernia Repair	\$3,369.11	\$1,790.77

Source: 1995 Annual Survey of Charges, Virginia Health Services Cost Review Council * Both hospital and non-hospital sponsored

On the other end of the spectrum, many physicians perform simple procedures in their offices and only receive a professional fee for such service. It is unclear to what extent deregulation of free-standing surgery centers would result in surgeons performing procedures in newly developed facilities that they otherwise would have performed in their private offices, and thus effectively receiving both a facility fee and a professional fee where, heretofore, they would have received only a professional fee from third party payers.

COPN Decisions Favor Hospital-Sponsored Facilities.

COPN decisions for the period 1992-1996 for free standing outpatient surgical hospitals indicate that hospital sponsored projects received more favorable decisions than did non hospital sponsored projects as illustrated in Figure 14.

Figure 14

COPN Decisions for Outpatient Surgical Hospitals As Reported by Virginia's Health Systems Agencies: 1992-1996

	Denied COPN	Received COPN		
Hospital-Related ASC Applicants	2	4		
Non-Hospital-Related ASC Applicants	5	1		

Source: Virginia's Regional Health Planning Agencies November, 1996

Because COPN regulations use the number of operating rooms available in a community as a basis for decision making and because most areas of the state have sufficient operating room capacity, hospital sponsored outpatient surgical hospital applicants can exchange an existing unused operating room for the new outpatient facility, without adding to capacity which is already deemed sufficient. This exchange of existing operating room capacity leads to hospital-sponsored applicants having greater success receiving a COPN application than non-hospital sponsored applicants.

General Acute Care Hospitals Provide A Greater Level Of Charity Care Than Outpatient Surgical Hospitals.

As can be seen in Figure 15, general acute care hospitals, the majority of which are not-for-profit facilities, provide a greater level of charity care than outpatient surgery centers, which include both non -

profit and for - profit entities. They provided approximately \$285 million in charity care in 1994, equivalent to an average of 3.2% gross revenue.

Figure 15

Charity Care/Bad Debt: Dollars and Percentage of Gross Patient Revenue: 1990-1994 (in thousands)

Acute Care Hospitals in Virginia

	Acute Care Hospitals in Virginia							
	1994	1993	1992	1991	1990	1990-94		
Gross Patient Revenue	\$8,958,416	\$8,512,070	\$7,876,626	\$6,909,991	\$6,114,489	\$38,371,592		
Charity Care	\$284,989	\$306,484	\$295,112	\$255,236	\$203,233	\$1,345,054		
(% of Gross)	3.2%	3.6%	3.7%	3.7%	3.3%	3.5%		
Bad Debt	\$267,789	\$258,819	\$271,849	\$259 <i>,</i> 790	\$262,443	\$1,320,690		
(% of Gross)	3.0%	3.0%	3.4%	3.7%	4.3%	3.4%		
Charity Care/ Bad Debt	\$552,778	\$565,303	\$566,961	\$515,026	\$465,676	\$2,665,744		
(% of Gross)	6.2%	6.6%	7.2%	7.4%	7.6%	6.9%		

Outpatient Surgical Hospitals in Virginia 1994 1992 1991 1990 1990-94 1993 Gross Patient \$112,779 \$61,141 \$49,024 \$39,648 \$32,661 \$295,253 Revenue **Charity Care** \$506 \$227 \$335 \$307 \$217 \$1,592 (% of Gross) 0.4% 0.4% 0.7% 0.8% 0.7% .5% **Bad Debt** \$2,467 \$776 \$492 \$5,480 \$1,103 \$642 (% of Gross) 1.8% 2.2% 1.8% 1.6% 1.6% 1.5% Charity Care/ \$2,973 \$949 \$709 \$7,072 \$1,330 \$1,111 **Bad Debt** (% of

Source: Virginia Health Services Cost Review Council, 1995 Hospital and Nursing Home Industry Trends

Bad Debt: A reduction in the accrued accounts receivable for non-payment of services after complete collection attempts have been exhausted.

2.3%

2.4%

2.2%

2.6%

2.4%

Gross)

<u>Charity Care</u>: Care for which no payment is received and which is provided to any persons whose gross family income is equal to or less than 100% of the federal non-farm poverty level.

Outpatient surgical hospitals provide much lower levels of charity care than general acute care hospitals. Outpatient surgical hospitals provided a total of \$506,000 in charity care in 1994, equivalent to .4% of gross revenue. Of this amount, 94% was provided by hospital sponsored facilities. In 1994, all of the nine non hospital-sponsored outpatient surgical hospitals were for profit entities. Seven reported no charity care.

Hospitals subsidize high cost services and care provided to the indigent and the uninsured with profits or excess revenue generated from surgical, as well as other procedures. Shifting outpatient surgery volume to non-hospital sponsored outpatient surgical facilities, many of which exclusively serve Medicare or commercially insured patients, reduces the ability of hospitals to cover these costs.

Non-hospital sponsored outpatient surgical facilities would argue that the issue of indigent care can be addressed more directly through means other than the COPN process.

VI. CONCLUSIONS

There Is Little Evidence Of Significant COPN Impact On Aggregate Health Expenditures; There Is Evidence Of Savings For Specific Services Covered By COPN.

Recent studies in Delaware, Georgia and Pennsylvania did not find any conclusive evidence of the effectiveness of COPN in containing aggregate health care costs in those states or nationally. Some studies have shown a relationship between lower costs and COPN for specific COPN regulated services. Recent COPN studies in Virginia were not designed to analyze the relationship between COPN regulation and aggregate health care costs in the Commonwealth, but the Virginia experience was a sharp increase in capital expenditures when services were deregulated and a sharp increase in expenditures when those services were re-regulated.

There Is Some Evidence That COPN Has Contained Resource Supply, Especially With High Technology Services.

Virginia's COPN program has contained health care resource supply for regulated health care expenditures to some extent, including high technology services, which make up the majority of COPN applications for the last several years, according to the VDH Division of Certificate of Public Need.

Growth In Managed Care And Capitation Payments Reduces The Incentives Of Health Care Providers To Develop Unneeded Capacity And Provide Unnecessary Services.

Managed care reimbursement strategies have reduced the incentives for health care providers to provide unnecessary services. The need to control health care supply will be increasingly less important, because health care providers under managed care will be incentivized to reduce unnecessary services instead of increasing the supply of services. In recent years, managed care has grown significantly in Virginia; however, Virginia's managed care market is still maturing.

There Has Been No Relationship Established Between The Level Of Managed Care Penetration Nationally And The Relative Stringency Of COPN.

Recent studies in Georgia and Delaware examined the relationship between COPN stringency and managed care penetration nationally. No relationship was established indicating that states with stringent COPN programs have lower levels of managed care penetration relative to states which have had repealed or limited COPN programs. The conclusions reached by these studies suggest that Virginia's COPN program, which is considered limited in relation to COPN programs in other states, has not hindered the growth of managed care and is unrelated to the level of managed care penetration in Virginia.

COPN Has Played A Role In Promoting Better Care Outcomes By Stressing The Necessity For Sufficient Volume, Especially High Technology Services.

Evidence suggests that higher volume facilities generally achieve better health outcomes. Because Virginia's COPN regulatory process stresses the necessity for sufficient volume when analyzing the relative need of high technology services, COPN can have an indirect effect in achieving higher quality for health care consumers in Virginia. The VDH Division of Certificate of Public Need requires COPN applicants to justify the need of new high technology equipment by requiring a sufficient volume of procedures within their service area. Virginia's COPN program, with its emphasis on the volume and quality of regulated health care capital expenditures, contributes to the assurance of higher quality services for Virginia's consumers.

COPN Has Played A Role In Ensuring The Delivery Of Health Care Services To The Indigent And The Uninsured By Virginia's Regulated Health Care Providers.

Through the process of indigent care conditioning, Virginia's COPN program can and has played a role in assuring greater levels of indigent care by regulated health care providers. Recent interviews of HSA directors and staff of the VDH Division of Certificate of Public Need do indicate significant levels of indigent care conditioning of applicants who have been granted Certificates of Public Need. The authority given in the Code of Virginia to condition COPN applicants on providing greater levels of indigent care has been widely utilized by the VDH Division of Certificate of Public Need.

The Ability Of Virginia's Hospitals To Cover The Costs Of Care To The Indigent And The Uninsured Is Impacted By Several Factors, Including: (i) Greater Competition In The Marketplace; (ii) The Development Of New Facilities Which Attract Paying Patients And Which Provide Minimal Care To The Indigent And Uninsured; And (iii) The Evolution Of Managed Care Financing Mechanisms. These trends could be hastened further by COPN repeal.

Evidence suggests nationally that managed care financing mechanisms, increased competition, and the development of specialized facilities which do not serve indigent and uninsured patients have reduced the ability of hospitals to cover the cost of care to the indigent and uninsured. The repeal of COPN could further increase the strain placed on Virginia's hospitals to fulfill their commitment to provide care to Virginia's uninsured and indigent patients.

Community-Based Health Planning Can And Does Serve A Vital Role In The Commonwealth, Irrespective Of The COPN Program.

Regional health planning offers local communities the opportunity to provide input on the types of health services provided by regulated health care providers. Virginia is one of the few states which has maintained a regional community-based health planning mechanism. Community-based health planning can and does offer local stakeholders the ability to require that regulated health providers offer necessary and assessable health care services to the citizens within their respective communities, including vulnerable populations.

The COPN Program Has Not Restricted The Growth Of Outpatient Surgery In Virginia.

Although the COPN program has denied COPN applications to Outpatient Surgical Hospital projects, there is no evidence that these denials have had an impact on the actual number of outpatient surgical procedures performed in Virginia. Existing outpatient surgical hospitals are not currently operating at capacity, which suggests that more outpatient surgeries could be performed in existing facilities. The demand for outpatient surgery is currently being met by Virginia's existing facilities based on the SMFP, and Virginia's outpatient surgery rate mirrors national trends.

The COPN Regulatory Process Favors Hospital Sponsored Outpatient Surgical Hospital Projects Over Outpatient Surgical Hospital Projects Of Non-Hospital Sponsored Investors.

Because of the overabundance of operating rooms in Virginia, as indicated by the SMFP, hospital sponsored outpatient surgical hospitals have greater success in receiving COPN applications because of the ability of the applicants to give up existing inpatient operating room capacity in exchange for new outpatient operating room capacity. Non-hospital sponsored applicants who wish to develop new outpatient surgical hospitals in Virginia may face denial because of their inability to eliminate existing operating rooms.

VII. POLICY OPTIONS

The following policy options are offered for consideration by the Joint Commission:

Option I: Maintain the Status Quo.

- Option II: Set a target date for eliminating the Certificate of Public Need Program at the year 2002, provided that the following conditions are met:
 - a. The development and implementation of a mechanism to reduce the number of uninsured Virginians. This mechanism would be developed by the Joint Commission through a study resolution introduced to the 1997 General Assembly.
 - b. The development of consumer friendly outcome data uniquely targeted to those tertiary services currently subject to the COPN program. Virginia Health Information, Inc. could be tasked to work with the Virginia Department of Health in accomplishing this task.
 - c. The level of covered lives under managed care capitation is sufficient to re-align provider incentives.
- Option III: Direct the Commissioner of Health to develop a more sophisticated methodology for conditioning COPN applications.
- Option IV: Direct the Commissioner of Health to change existing COPN need methodologies to allow for the development of new Outpatient Surgical Hospitals which do not have existing operating rooms.
- Option V: Repeal the COPN program immediately.

APPENDIX	<u>A</u>		
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CHAPTER 901

An Act to amend and reenact § 32.1-102.3:2 of the Code of Virginia, relating to certificates of public need for nursing home beds.

[H 1302] Approved April 10, 1996

Be it enacted by the General Assembly of Virginia:

- 1. That §32.1-102.3:2 of the Code of Virginia is amended and reenacted as follows:
- §32.1-102.3;2. Certificates of public need; applications for increases in nursing home bed supplies to be filed in response to Requests For Applications (RFAs).
- A. Except for applications for continuing care retirement community nursing home bed projects filed by continuing care providers registered with the State Corporation Commission pursuant to Chapter 49 (§38.2.4900 et seq.) of Title 38.2, the Commissioner of Health shall not only approve, authorize or accept applications for the issuance of any certificate of public need pursuant to this article for any project which would result in an increase in the number of beds in which nursing facility or extended care services are provided through June 30, 1996 when such applications are filed in response to Requests For Applications (RFAs).
- B. The Board of Health shall adopt regulations establishing standards for the approval and issuance of Requests for Applications by the Commissioner of Health. The standards shall include, but shall not be limited to, a requirement that determinations of need take into account any limitations on access to existing nursing home beds in the planning districts. The RFAs, which shall be published at least annually, shall be jointly developed by the Department of Health and the Department of Medical Assistance Services and based on analyses of the need, or lack thereof, for increases in the nursing home bed supply in each of the Commonwealth's planning districts in accordance with standards adopted by the Board of Health by regulation. The Commissioner shall only accept for review applications in response to such RFAs which conform with the geographic and bed need determinations of the specific RFA.
- C. Sixty days prior to the Commissioner's approval and issuance of any Request For Applications, the Board of Health shall publish the proposed RFA in the Virginia Register for public comment together with an explanation of (i) the regulatory basis for the planning district bed needs set forth in the RFA and (ii) the rationale for the RFA's planning district designations. Any person objecting to the contents of the proposed RFA may notify, within fourteen days of the publication, the Board and the Commissioner of his objection and the objection's regulatory basis. The Commissioner shall prepare, and deliver by registered mail, a written response to each such objection within two weeks of the date of receiving the objection. The objector may file a rebuttal to the Commissioner's response in writing within five days of receiving the Commissioner's response. If objections are received, the Board shall, after considering the provisions of the RFA, any objections, the Commissioner's responses, and if filed, any written rebuttals of the Commissioner's responses, hold a public hearing to receive comments on the specific RFA. Prior to making a decision on the Request for Applications, the Commissioner shall consider any recommendations made by the Board. However, the Commissioner may approve or authorize:
- 1. The issuance of a certificate of public need for a project for the (i) renevation or replacement on site of an existing facility or any part thereof or (ii) replacement off site of an existing facility at a location within the same city or county and within reasonable proximity to the current site when replacement on the current site is proven infeasible, in accordance with the law, when a capital expenditure is required to comply with life cafety codes, licensure, certification or accreditation standards. Under no circumstances shall the State Health Commissioner approve, authorize, or accept an application for the issuance of a certificate for any project which would result in the continued use of the facility replaced as a nursing facility.
- 2. The issuance of a certificate of public need for any project for the conversion on site of existing licensed beds to beds certified for skilled nursing services (SNF) when (i) the total number of beds to be converted does not exceed the lesser of twenty beds or ten percent of the beds in the facility; (ii) the facility has demonstrated that the SNF beds are needed specifically to serve a specialty heavy care patient population, such as ventilator dependent and AIDS patients and that such patients otherwise will not have reasonable access to such services in existing or approved facilities; and (iii) the facility further commits to admit such patients on a priority basis once the SNF unit is certified and operational.
- 3. The issuance of a certificate of public need for any project for the conversion on site of existing beds in an adult care residence licensed pursuant to Chapter 9 (§62.1.172 et seq.) of Title 63.1 as of March 1, 1990, to beds certified as nursing facility beds when (i) the total number of beds to be converted does not exceed the lesser of thirty beds or twenty five percent of the beds in the adult care residence; (ii) the adult care residence has demonstrated that nursing facility beds are needed specifically to serve a patient population of AIDS, or ventilator dependent, or head and spinal cord injured patients, or any combination of the three, and that such patients otherwise will not have reasonable access to such services in existing or

approved nursing facilities; (iii) the adult care residence further commits to admit such patients once the nursing facility bods are certified and operational; and (iv) the licensed adult care residence otherwise meets the standards for nursing facility bods as set forth in the regulations of the Board of Health. Notwithstanding the conditions required by this exception related to serving specific patient populations, an adult care residence which has obtained by January 1, 1991, a certificate of public need for a project for conversion on site of existing bods in its facility licensed pursuant to Chapter 9 of Title 63.1 as of March 1, 1990, to bods certified as nursing facility bods may use the bods converted to nursing facility bods pursuant to this exception for patient populations requiring specialized care of at least the same intensity which meet the criteria for the establishment of a specialized care nursing facility contract with the Department of Medical Assistance Services.

- 4. The issuance of a certificate of public need for a project in an existing nursing facility owned and operated by the governing body of a county when (i) the total number of new bods to be added by construction does not exceed the lesser of thirty bods or twenty five percent of the existing nursing facility bods in the facility; (ii) the facility has demonstrated that the nursing facility bods are needed specifically to serve a specialty heavy care patient population, such as demonstrated that the ventilator dependent, and AIDS patients; and (iii) the facility has executed an agreement with a state supported medical college to provide training in geriatric nursing.
- 5. The issuance of a certificate of public need for a nursing facility project located in the City of Staunton when (i) the total number of new beds to be constructed does not exceed thirty beds: (ii) the facility is owned by and will be operated as a nonprofit entity; and (iii) the project is proposed as part of a retirement community that is a continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 (§38.2.4900 et seq.) of Title 38.2.
- 6. The issuance of a certificate of public need for any project for an increase in the number of beds in which nursing home or extended care services are provided, or the creation of new beds in which such services are to be provided, by any continuing care provider registered with the State Corporation Commission pursuant to Chapter 49 of Title 38.2, if (i) the total number of new or additional nursing home beds plus any existing nursing home beds operated by the provider does not exceed twenty percent of the continuing care provider's total existing or planned independent living and adult care residence population when the beds are to be added by new construction, or twenty five beds when the beds are to be added by conversion on site of existing beds in an adult care residence licensed pursuant to Chapter 9 of Title 63.1; (ii) such beds are necessary to meet existing or reasonably anticipated obligations to provide care to present or prospective residents of the continuing care facility pursuant to continuing care contracts meeting the requirements of § 38.2 4905; (iii) the provider agrees in writing not to seek certification for the use of such new or additional beds by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security. Act: (iv) the provider agrees in writing to obtain, prior to admission of every resident of the continuing care facility, the resident's written acknowledgement that the provider does not serve recipients of medical assistance services and that, in the event such resident becomes a medical assistance services recipient who is eligible for nursing facility placement, such resident shall not be eligible for placement in the provider's nursing facility unit; and (v) the provider agrees in writing that only continuing care contract holders will be admitted to the nursing home beds after the first three years of operation.

Further, if a certificate is approved pursuant to this subdivision, admissions to such new or additional beds shall be restricted for the first three years of operation to patients for whose care, pursuant to an agreement between the facility and the individual financially responsible for the patient, private payment will be made or persons who have entered into an agreement with the facility for continuing care contracts meeting the requirements of \$38.2.4905.

- 7. The issuance of a certificate of public need for a nursing facility project associated with a continuing care provider which did not operate a nursing home on January 1, 1993, and was registered as of January 1, 1993, with the State Corporation Commission pursuant to Chapter 49 of Title 38.2. if (i) the total number of new beds to be constructed does not exceed sixty beds; (ii) the facility is owned by and will be operated as a nonprofit entity; (iii) after the first three years of operation, the facility will admit only retired officers of the United States uniformed forces and their surviving spouses; (iv) the provider agrees in writing not to seek certification for the use of such beds by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security Act; and (v) the provider agrees in writing to obtain, prior to admission of every resident of the continuing care facility, the written acknowledgement that the provider does not serve recipients of medical assistance services and that, in the event such resident becomes a medical assistance services recipient who is eligible for nursing facility placement, such resident shall not be eligible for placement in the provider's nursing facility unit. Further, if a certificate is approved, pursuant to this subdivision, admissions to such beds shall be restricted to persons for whose care, pursuant to an agreement with the facility, private payment will be made or persons who have entered into an agreement with the facility for continuing care contracts meeting the requirements of § 38.2-1905.
- 8. The issuance of a certificate of public need for a nursing facility project located in the City of Norfolk if (i) the total number of beds to be constructed does not exceed 120 beds; (ii) the facility will replace an existing facility in the City of Chesapeake; (iii) the construction of the facility has been delayed by environmental contamination caused by leaking underground storage tanks; and (iv) the total capital costs of the facility will not exceed \$4,387,000.
- 9. The issuance of a sertificate of public need for a project in an existing nonprofit nursing facility located in the City of

Lynchburg if (i) the current facility consists of four nursing units, with the two nursing units constructed in 1969 to be retained; (ii) forty of the newly constructed beds will replace existing eighteen two bed and twenty two bed units, built before 1915; (iii) the total number of beds to be constructed does not exceed sixty beds, including forty existing and twenty new beds; (iv) the area around the construction site has been identified by the local governing body for major renovation and revitalization; and (v) the project is the subject of a memorandum of agreement between the local governing body and the applicant, pursuant to which, the local governing body agrees to make certain improvements to the area of the project's location.

- 10. The issuance of a certificate of public need for an increase in the number of beds in which nursing facility or extended care services are provided or the creation of new beds in which such services are to be provided in the City of Virginia Be by an association described in \$55,45% created in connection with a real estate cooperative for which an application for registration was filed as required by \$55, 497 prior to January 1, 1994, which offers a level of nursing services to its residents consistent with the definition of continuing care in §38.2-4900 if (i) the total number of new or additional nursing care beds plus any existing nursing care beds operated by the association does not exceed twenty percent of the number of total existing or planned cooperative units when beds are to be added by new construction or by conversion on site of existing bods in a licensed adult care residence; (ii) such bods are necessary to meet existing or reasonably anticipated obligations to provide nursing care to present or prospective residents of the cooperative units pursuant to a written agreement with the association: (iii) the association agrees in writing not to seek certification for the use of any such beds by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security Act; (iv) the association agrees in writing to obtain, prior to each resident's occupancy of a cooperative unit, the resident's written acknowledgment that the association does not serve recipients of medical assistance services and that in the event such resident becomes a medical assistance services recipient who is eligible for nursing facility placement such resident shall not be eligible for placement in the association's nursing facility unit; (v) the association agrees in writing that only residents of cooperative units will be admitted to the nursing care beds after the first three years of operation as a nursing care facility; and (vi) the association complies with the disclosure requirements for continuing care providers pursuant to Chapter 49 of Title
- 11. The issuance of a certificate of public need for a nursing facility project located in the City of Charlottesville if (i) the total number of beds to be converted from hospital to nursing facility use does not exceed thirty beds; (ii) the facility will provide nursing services to patients committed to, transferred to, or discharged from facilities owned by the Department of Mental Health, Mental Retardation and Substance Abuse Services and from any psychiatric hospital located in the City of Charlottesville or Albemarle County; and (iii) the facility has executed an agreement with the Department of Mental Health, Mental Retardation and Substance Abuse Services to provide such services.
- 12. The issuance of a certificate of public need for a nursing facility project located in Montgomery County if (i) the total number of beds to be constructed does not exceed sixty beds; (ii) the facility has entered into a partnership with several-public institutions of higher education to establish a gerentelogy center for the conduct of research and the education of professionals; and (iii) the nursing facility beds will be an integral part of an existing health care institution which has a mission of providing a continuum of care as recorded in its 100 year plan.
- 13. The issuance of a certificate of public need for a nursing facility project located in the Town of Colonial Beach if (i) the total number of beds to be converted from adult care residence to nursing facility use does not exceed seven; (ii) the facility is owned by a nonprofit health care center located in Fredericksburg; and (iii) the total number of new or additional beds plus existing nursing facility beds operated by the facility will not exceed sixty.
- 14. The issuance of a certificate of public need to a nursing facility in Ashland, Virginia, currently operating at ninety nine percent occupancy to convert ten private rooms to semiprivate, thereby adding ten bods to an existing fifty bed wing to promote efficiency of operations and improve access for area residents if the total capital expenditures will not exceed \$15,000.
- 15. The issuance of a certificate of public need for a nursing facility project located in an existing facility which currently contains 325 "independent living" units with home health services available, seventy five assisted living units, and thirty one nursing facility beds, only five of which are certified for use by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security Act if (i) the total number of beds to be constructed does not exceed thirty beds, (ii) the facility agrees in writing not to seek certification for the use of any such beds by persons eligible to receive medical assistance services pursuant to Title XIX of the United States Social Security Act, (iii) such beds are necessary to meet existing or reasonably anticipated obligations to provide nursing care to present or prospective residents of this retirement community, and (iv) the retirement community agrees in writing that only residents of the retirement community will be admitted to such nursing facility beds after the first three years of operation.
- 16. The issuance of a certificate of public need for a project in an existing facility located in Scott County for the conversion on site of existing bods in an adult care residence licensed pursuant to Chapter 9 (§ 63.1-172 et seq.) of Title 63.1 as of October 1, 1994, to bods certified as nursing facility beds when (i) the total number of beds to be converted does not exceed

the lesser of thirty bods or twenty five percent of the bods in the adult care residence; (ii) the adult care residence has demonstrated that nursing facility bods are needed specifically to serve a population of patients having Alzheimer's Disease or related disorders and that such patients will not otherwise have reasonable access to such services in existing or approved nursing facilities; (iii) the adult care residence will restrict admissions to such patients once the nursing facility bods are certified and operational; and (iv) the licensed adult care residence otherwise meets the standards for nursing facility bods as set forth in the regulations of the Board of Health.

- 17. The issuance of a certificate of public need in an existing nursing facility project if (i) the facility's total number of beds will not exceed sixty-beds, including existing beds and those proposed; (ii) the space in the existing nursing facility in which the proposed additional beds will be located has never been occupied by any licensed beds; and (iii) the total direct capital costs associated with the proposed project will not exceed \$10,000.
- 18. The issuance of a certificate of public need to a nonprofit nursing facility project located in Henrico County that is designed to provide a continuum of care for patients with Alzheimer's Disease and related disorders if (i) the project was under construction January 1, 1995, and will be ready for occupancy no later than June 1, 1996; (ii) not less than thirty of the newly constructed beds will be designated and retained as private pay beds; and (iii) the total number of beds to be constructed does not exceed sixty beds.

Notwithstanding the foregoing and other provisions of Article 1.1 (§ 32.1-102.1 et seq.) of Chapter 4 of this title, the state home for aged and infirm veterans authorized by Chapter 668, 1989 Acts of Assembly, shall be exempt from all the 1993 certificates of public need review requirements as a medical care facility.

- 2. That the Commissioner of Health, in cooperation with the Director of the Department of Medical Assistance Services and other affected public and private stakeholders, shall evaluate the need for and appropriateness of requiring adult care residences providing assisted living and intensive assisted living levels of care to be subject to the Commonwealth's Certificate of Public Need regulations and the requirements established pursuant to this article or a similar and parallel program for determining need and preventing redundant capitalization. The Commissioner shall provide to the Secretary of Health and Human Resources and the Joint Commission on Health Care an interim report by October 1, 1996, and a final report of his findings and recommendations by June 1, 1997.
- 3. That the Joint Commission on Health Care shall study the appropriateness of the Commonwealth's Certificate of Public Need regulations and requirements, including, but not limited to, the need for and appropriateness of requiring outpatient or ambulatory surgical centers to be subject to the Commonwealth's Certificate of Public Need regulations and requirements pursuant to this act. The Department of Health and the health-system agencies shall provide staff support and technical assistance for the study. The Joint Commission on Health Care shall complete its work in time to submit its findings and recommendations to the 1997 Session of the General Assembly.

APPENDIX B

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Telephone (804) 977-6010, Fax (804) 977-0748



Virginia Medical Care Facilities

Certificate of Public Need (COPN) Program

A Summary

This summary is based on the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations of the Board of Health, Commonwealth of Virginia, Amendment #8P, effective June 16, 1994. It is designed to provide a general overview. COPN applicants and anyone else who might need definitive information on the program should consult the COPN Rules and Regulations themselves and, if necessary, request a ruling from the State Health Department on their applicability to a particular project.

October 1994

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Abbreviations Used: CT computed tomography	

MRI magnetic resonance imaging

MSI magnetic source imaging

positron emission tomography, PET

single photon emission computed tomography SPECT

What Is a Certificate of Public Need (COPN)?

A COPN is a document issued by the Commissioner of Health of the Commonwealth of Virginia to authorize legally a medical care facility project.

What Entities Must Obtain a COPN?

- Existing medical care facilities if a project is to be initiated
- Sponsors of a new medical care facility or medical care facility project (or service)

Medical care facilities subject to review under the regulations:

- General hospitals
- Sanitariums
- Nursing homes
- Intermediate care facilities
- Extended care facilities
- Mental hospitals
- Mental retardation facilities
- Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of alcoholics or drug addicts
- Rehabilitation hospitals
- Specialized centers or clinics or that portion of a physician's office developed for the provision of:
 - outpatient or ambulatory surgery
 - cardiac catheterization
 - computed tomographic (CT) scanning
 - gamma knife surgery, or stereotactic radiosurgery
 - lithotripsy
 - magnetic resonance imaging (MRI)
 - magnetic source imaging (MSI)
 - positron emission tomographic (PET) scanning
 - radiation therapy
 - single photon emission computed tomography (SPECT) scanning
 - such other specialty services as may be designated by regulation

Medical care facilities not subject to review:

 Any facility of the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS)

- Any non-hospital substance abuse residential treatment program operated by or contracted primarily for the use of a community services board under the DMHMRSAS Comprehensive Plan
- Any physician's office, except that portion developed for the provision of specialized services described above

What Is a Reviewable Project under the COPN Program?

- The establishment of a medical care facility (see page 1, above)
- An increase in the total number of beds or operating rooms in an existing or authorized medical care facility
- Relocation of 10 beds or 10 percent of the beds, whichever is less, from one existing physical facility to another in any 2-year period (except that a hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing home beds for a maximum of 30 days for any one patient, i.e., as swing beds)
- Introduction into any existing medical care facility of:
 - Any new nursing home service, such as intermediate care, extended care, or skilled care facility services except when such medical care facility is an existing nursing home
 - Any new cardiac catheterization, CT, gamma knife surgery, lithotripsy, MRI, MSI,
 medical rehabilitation, neonatal special care services, obstetrical services, open heart
 surgery, PET scanning, organ or tissue transplant service, radiation therapy, SPECT,
 psychiatric, substance abuse treatment, or such other specialty clinical services as may
 be designated by regulation, which the facility has never provided or has not provided
 in the previous 12 months
- The conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds
- The addition or replacement by an existing medical care facility of any medical equipment
 for cardiac catheterization, CT, gamma knife surgery, lithotripsy, MRI, MSI, open heart
 surgery, PET scanning, radiation therapy, SPECT, or other specialized services designated
 by regulation, except for the replacement of any medical equipment determined by the
 Commissioner to be an emergency (see below)
- Any capital expenditure of \$1 million or more by or on behalf of a medical care facility not
 defined as reviewable under the 6 categories listed above, except capital expenditures
 registered with the Commissioner of less than \$2 million that do not involve the expansion
 of any space in which patient care services are provided (see page 12, below)

Moratorium on Increases in Nursing Facility Beds - and Exceptions

No application for a COPN for a medical care facility project which would increase the number of beds in which nursing facility or extended care services are provided shall be approved, authorized

or accepted through June 30, 1995. There are 10 specifically defined exceptions. The exceptions include projects involving:

- Renovation or replacement on site of a nursing home, intermediate care or extended care
 facility or any portion thereof -- or replacement off-site of an existing facility at a location
 within the same city or county and within reasonable proximity to the current site when
 replacement on the current site is proven unfeasible -- when a capital expenditure is
 required to comply with life safety codes, licensure, certification or accreditation
 standards.
- The conversion on site of existing licensed beds of a medical care facility other than a nursing facility or nursing home, extended care, or intermediate care facility to beds certified for skilled nursing services (SNF) when: (1) the total number of beds to be converted does not exceed the lesser of 20 beds or 10 percent of the beds in the facility: (2) the facility has demonstrated that the SNF beds are needed specifically to serve a specialty heavy care patient population (such as ventilator-dependent and AIDS patients) and that such patients otherwise will not have reasonable access to such services in existing or approved facilities; and (3) the facility commits to admit such patients on a priority basis.
- The conversion on site of existing beds in a licensed adult care residence to beds certified as nursing facility beds when: (1) the total of beds to be converted does not exceed the lesser of 30 beds or 25 percent of the beds in the adult care residence; (2) the adult care residence has demonstrated that nursing facility beds are needed specifically to serve a patient population of AIDS, ventilator-dependent, and/or head and spinal cord injured patients, and that such patients otherwise will not have reasonable access to such services in existing or approved nursing facilities; (3) the adult care residence commits to admit such patients; and (4) the adult care residence otherwise meets standards for nursing facility beds.
- An increase in the number of beds in which nursing facility or extended care services are provided, or the creation of new beds in which such services are to be provided, by a continuing care provider registered as of 1/15/91 with the State Corporation Commission (under Code Title 38.2, Chapter 49), if: (1) the total number of new or additional beds does not exceed 32 when added by new construction or 25 when added by conversion on site of existing adult care residence beds licensed as of 1/15/91; (2) such beds are necessary to meet existing or reasonably anticipated obligations to provide care to present or prospective residents of the continuing care facility pursuant to continuing care contracts; and (3) if the applicant had an existing complement of beds as of 1/15/91, the applicant has agreed not to seek Medicaid certification for new or additional beds; admissions to these beds, if approved, must be restricted to persons who have entered into continuing care contracts.

There is an exception similar to this last for projects of continuing care providers registered with the State Corporation Commission at any time that allows admission to the beds during the first 3 years of their operation to patients who are not continuing care contract holders but for whose care private payment is made. The provider must have agreed to obtain in writing, prior to admission, each resident's acknowledgment that, since the provider does not serve Medicaid recipients, he or she would not be eligible to receive care in the provider's nursing facility with Medicaid assistance if he or she should become eligible for such assistance.

Another very limited exception is for the development of a nursing facility project in the City of Staunton with up to 30 beds. The facility must be owned by and will be operated as a nonprofit entity, and the projects must be proposed as part of a retirement community that is a continuing care provider registered as such with the State Corporation Commission

Who Has a Role in the COPN Process?

An individual, corporation, partnership, association, or any other legal entity, whether governmental or private, may play a role in the COPN process. The principal participants are:

- The applicant for a COPN.
- The regional health planning agency for the health planning region in which the proposed project is to be located.
- Any resident of, or any person who regularly uses health care facilities in, the geographic area served or to be served by the applicant.
- Any facility or HMO located in the health planning region in which the project is proposed which provides services similar to those of the project under review.
- Third-party payors.
- Agencies reviewing or establishing rates for health care facilities.
- The State Health Department's Office of Resources Development.
- The State Health Commissioner, who approves or disapproves issuance of COPNs.

Any person affected by a proposed project under review may submit written opinion, data, and other information to the appropriate regional health planning agency and the Commissioner for consideration prior to their final action on the project. Views may also be presented at a public hearing conducted on a project by the regional health planning agency. All meetings and hearings at which a COPN application is considered are open to the public in accordance with the Virginia Freedom of Information Act.

On What Basis Is Public Need Determined?

In determining whether a public need exists for a proposed project, factors which must be taken into account (when applicable) include:

• Recommendation -- and the reasons for it -- of the appropriate regional health planning agency.

- Relationship of the project to the applicable plans of the regional health planning agency, the Virginia Health Planning Board, and the State Board of Health.
- Relationship of the project to the long-range development plan, if any, of the applicant.
- Need that the population served or to be served by the project has for the project.
- Extent to which the project will be accessible to all residents of the area proposed to be served.
- Area, population, topography, highway facilities and availability of the services to be
 provided by the project in the particular part of the health planning region in which the
 project is proposed.
- Less costly or more effective alternate methods of reasonably meeting identified health service needs.
- Immediate and long-term financial feasibility of the project.
- Relationship of the project to the existing health care system of the area in which the project is proposed.
- Availability of resources for the project.
- Organizational relationship of the project to necessary ancillary and support services.
- Relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.
- Special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center, or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health planning region in which the project is to be located.
- Need and availability in the health planning region for osteopathic and allopathic services
 and facilities and the impact on existing and proposed institutional training programs for
 doctors of osteopathy and medicine at the student, internship, and residency training
 levels.
- Special needs and circumstances of health maintenance organizations.
- Special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.
- Costs and benefits of the construction associated with the proposed project.
- Probable impact of the project on the costs of and charges for providing health services by the applicant and on the costs and charges to the public for providing health services by other persons in the area.
- Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.
- The efficiency and appropriateness of the use of existing services and facilities in the area similar to the health services or facilities proposed.

What Is the Schedule and Procedure for Review of a COPN Application?

COPN applications are reviewed in batches, by type of project and, for nursing facility projects, by the Planning District (PD) in which the project is to be located (see schedule, below). There is one review period per year for nursing facility projects and 2 such periods, starting 6 months apart, for other types of projects. The State Health Commissioner may, at least 120 days prior to the first day of a review period for a type of project, issue a request for applications that address a specific need for services identified in the State Medical Facilities Plan by publishing a notice in a newspaper in the area where the need has been identified.

BATCH GROUP	TYPE OF PROJECT	LETTER OF INTENT DUE	APPLI- CATION DUE	REVIEW PERIOD BEGINS	HSA REC- COMMEND- ATION DUE	REVIEW PERIOD ENDS
A	General Hospitals, Obstetrical Services, Neonatal Special Care Services	Dec 2 Jun 1	Jan 1 Jui 1	Feb 10 Aug 10	Apr 11 Oct 9	June 10 Dec 8
В	Open Heart Surgery, Cardiac Catheterization, Ambulatory Surgery Centers, Operating Room Additions, Transplant Services	Dec 30 Jul 2	Jan 29 Aug 1	Mar 10 Sep 10	May 9 Nov 9	Jul 8 Jan 8
С	Psychiatric Facilities, Substance Abuse Treatment, Mental Retardation Facilities	Jan 30 Aug 1	Mar 1 Aug 31	Apr 10 Oct 10	June 9 Dec 9	Aug 8 Feb 7
D	Diagnostic Imaging Facilities, Services	Mar 1 Sept 1	Mar 31 Oct 1	May 10 Nov 10	July 9 Jan 9	Sep 7 Mar 10
E	Medical Rehabilitation Facilities, Services	Apr 1 Oct 1	May 1 Oct 31	June 10 Dec 10	Aug 9 Feb 8	Oct 8 Apr 9
F	Selected Therapeutic Facilities, Services	May 1 Nov 1	May 31 Dec 1	July 10 Jan 10	Sept 8 Mar 1	Nov 7 May 9
G	Nursing Home Beds, Services	Nov 1	Dec 1	Jan 10	Mar 11	May 10
		Dec 30	Jan 29	Mar 10	May 9	July 8
		Mar 1	Mar 31	May 10	July 9	Sept 7
		May 1	May 31	Jul 10	Sept 8	Nov 7
		July 2	Aug 1	Sep 10	Nov 9	Jan 8
		Sept 1	Oct 1	Nov 10	Jan 9	Mar 10

An applicant must submit to the Commissioner (with a copy to the appropriate regional health planning agency) a letter of intent to file an application, identifying the type of project, its proposed scope or size, its location, and the owner, at least 30 days prior to the submission of the application (or 10 days after the first letter of intent is filed for another project of the same type that would be reviewed in the same time period and be located in the same planning district or medical service area). Within 7 days of receipt of this letter, the State Health Department sends the appropriate application forms to the applicant. These forms are to be filled out and submitted

to the Department, with a copy to the regional health planning agency, at least 40 days prior to the first day of the period in which the application is to be reviewed. The applicant must be notified within 15 days of receipt of the application if additional information is required or if the application is considered complete as submitted. Any additional information requested must be submitted at least 5 days before the review period is to begin. An application fee -- 1.0% of the proposed capital expenditure for the project or \$10,000, whichever is less -- must also be paid.

The review period is 120 days, starting on the 10th day of the month, unless that day falls on a weekend or holiday, in which case the review period starts on the next work day.

During the first 60 days of the review period, the regional health planning agency must:

- send notification of its review schedule to the applicant and to other health care providers and identifiable consumer groups who may be affected by the proposed project;
- make arrangements for a public hearing to receive comment in support of or in opposition to the project, giving notice, at least 9 days before the hearing is to be held, in a newspaper of general circulation in the city or county in which the project is proposed;
- hold, and keep a verbatim record of, the public hearing, in the city or county in which the
 project is proposed or a contiguous city or county;
- hold no more than 2 meetings to review the project, one of which must be for the public hearing;
- provide the applicant with an opportunity, prior to any vote on a recommendation, to
 respond to any comments made about the project by its staff, any information in a staff
 report, or comments by those voting; and
- complete its review and submit its recommendation to the Commissioner.

By the 70th day, review by the State Health Department's Office of Resources Development is to be completed and a report with the staff recommendation sent to the applicant.

There may be an informal, fact-finding conference before the Commissioner's decision on the application is rendered. Such conferences are generally held when there is opposition to or a recommendation for denial of an application or competing applications on the part of the public, the regional health planning agency, State Health Department staff, third-party payors, and/or interested parties seeking to demonstrate "good cause" at the conference. "Good cause" for this purpose means: there is significant relevant information not previously presented at and not available at the time of the public hearing; there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing; or there is a substantial material mistake of fact or law in the State Health Department staff's report on the application or in the report submitted by the regional health planning agency. Any person seeking to show good cause must give written notification, stating the grounds, at least 7 days prior to the conference, sending it to the Commissioner, the applicant and any competing applicant, and the regional health planning agency.

The Commissioner's decision on the application is due by the 120th day, unless the applicant and, when applicable, the parties to any informal fact-finding conference held have agreed to an extension of the review schedule.

How Is the State Health Commissioner's Decision Issued?

The Commissioner sends a letter to the applicant stating his decision to approve or deny the application and giving the reasons for that decision. If the application has been approved, the COPN will be enclosed with the letter.

A decision to approve issuance of a COPN must be consistent with the most recent applicable provisions of the State Medical Facilities Plan unless the Commissioner finds, on the basis of evidence presented, that those provisions are inaccurate, outdated, inadequate, or otherwise inapplicable. The Commissioner may approve a portion of a project if the applicant has been consulted and agrees to that portion.

The Commissioner may condition the approval of an application for a project on the agreement by the applicant to provide an accceptable level of free care or care at a reduced rate to indigents, to provide care to persons with special needs, or to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area. The terms of such agreements must be specified in writing prior to the Commissioner's decision to approve the project. A civil penalty of \$100 per violation per day may be levied for willful refusal, failure, or neglect to honor such an agreement.

The certificate issued is not transferable from the holder to any other legal entity regardless of the relationship, under any circumstances.

Is There Provision for Emergencies or Expedited Review?

When there is a documented emergency, the State Health Commissioner may waive the requirements for review of projects in batch groups in 120-day scheduled review periods, e.g., allowing a project to be reviewed in the period set for another type of project.

Emergency replacement of medical equipment identified above (page 2) as subject to COPN review is not a "project" of a medical care facility requiring a COPN. It does, however, require authorization by the Commissioner of Health. To request such authorization, the owner of the equipment must submit information to the Commissioner to demonstrate that:

- the equipment is inoperable as a result of a mechanical failure, Act of God, or other reason which may not be attributed to the owner and the repair of the equipment is not practical or feasible; or
- the immediate replacement of the medical equipment is necessary to maintain an essential clinical health service or to assure the safety of patients or staff.

The owner will be notified by letter of the Commissioner's decision to deny or authorize the emergency replacement of the equipment within 15 days of receipt of such a request.

There is a also an expedited review process, established for:

- Relocation at the same site of 10 beds or 10 percent of the beds, whichever is less, from
 one existing physical facility to another when the cost of such relocation is less than \$1
 million.
- The replacement at the same site by an existing medical care facility of any medical
 equipment for the provision of cardiac catheterization, CT, lithotripsy, MRI, open heart
 surgery, PET scanning, radiation therapy, or SPECT when the medical care facility meets
 applicable State Medical Facilities Plan standards for replacement of such medical
 equipment.
- The introduction into a medical care facility of any new SPECT service when the medical care facility currently provides non-SPECT nuclear medicine imaging services and meets the applicable State Medical Facilities Plan standards for establishment of SPECT services.

Application forms for expedited review are sent by the State Health Department to an applicant within 7 days of receipt of a written request that identifies the owner, the type, and location of the project. (A copy must also be submitted to the appropriate regional health planning agency.) The review period starts when the application form has been received by the Department and the regional health planning agency and has been deemed complete, and the application fee (the lesser of 1.0 percent of the proposed capital expenditure for the project or \$10,000) has been paid. Department staff and the regional health planning agency shall each review the application and forward a recommendation to the Commissioner within 40 days, and the Commissioner's decision on the application is to be made within 45 days. Any person directly affected by review of the project under the expedited review process may submit written opinions, data, and other information to the regional health planning agency and to the Commissioner before their final action.

The Commissioner shall approve and issue a COPN for a project determined to meet the criteria for expedited review specified above. If the Commissioner determines that a project does not meet these criteria, the applicant will be sent forms to use for filing an application for review of the project in the appropriate 120-day review period. Such an applicant will be exempted from the requirements to submit a letter of intent to submit an application and for an application fee.

May the Commissioner's Decision on a COPN Application Be Appealed?

The decision of the Commissioner to approve or disapprove issuance of a COPN may be appealed to a circuit court under applicable provisions of the Administrative Process Act. Those who may appeal are: the applicant; a third-party payor providing health care insurance or prepaid coverage to 5% or more of the patients in the applicant's service area; the regional health planning agency operating in that area; or any person showing "good cause" (see page 7, above). Court review must be requested within 30 days after the decision is issued. The court may affirm, vacate, or modify the decision.

For How Long Is a COPN Valid? How and on What Basis May It Be Extended?

A certificate of public need is valid for 12 months, but extensions for additional time periods may be approved. An extension is generally for 12 months. An extension for an indefinite period is considered when satisfactory completion of the project has been demonstrated (with "completion" defined as "conclusion of construction activities necessary for substantial performance of the contract").

A request for extension must be submitted to the Commissioner in writing, with a copy to the appropriate regional health planning agency, at least 30 days prior to the expiration date of the COPN or of an approved extension period. The review period for an extension request is 35 days, beginning on the date of receipt at the State Health Department and the appropriate regional health planning agency. The regional health planning agency must complete its review and forward its recommendations to the Commissioner within 30 days. Failure to notify the Commissioner within that time frame constitutes a recommendation of approval by the regional agency. Action by the Commissioner is to be taken by the 35th day.

The basis for approval for an extension depends on how far beyond the date of issuance the time period of the extension would be:

- Within 24 months beyond the expiration date of the certificate, that is, for a second year, demonstration that progress is being made on the authorized project is required.
- Beyond 24 months, substantial and continuing progress towards the development of the
 project must be being made towards development of the project, a schedule for
 completion must have been provided and found to be reasonable, and any delays caused by
 events beyond the control of the owner and/or substantial delays not attributable to the
 owner are to be considered.
- Beyond 3 years (or beyond the time period for completion originally approved, if that was longer) must be considered as a significant change (see below).

Progress made towards the implementation of an authorized project must be demonstrated in accordance with the schedule of development included in the COPN application. Progress reports are required as follows in extension requests:

- 12 months following issuance of the COPN, documentation showing:
 - ownership or control of the site;
 - the site meets all zoning and land use requirements;
 - architectural planning has been initiated;
 - preliminary architectural drawings and working drawings have been submitted to appropriate state reviewing agencies and the State Fire Marshal;
 - construction financing has been completed or will be completed within 2 months; and
 - purchase orders or lease agreements exist for equipment and new service projects.

- 24 months following issuance, documentation showing:
 - all required financing is completed;
 - pre-construction site work has been initiated;
 - construction bids have been advertised, the contractor has been selected, and the construction contract has been awarded; and
 - construction has been initiated.

On completion of the project, any documentation not previously provided is required which shows the final costs of the project, method(s) of financing, and completion of the project in accordance with the application submitted or any subsequently approved changes.

What Happens in the Case of a Significant Change or Changes in a Project?

Prior written approval from the Commissioner of Health is required for any significant change in a project for which a COPN has been issued. A significant change means any alteration, modification, or adjustment to a reviewable project for which a COPN has been issued (or for which a COPN has been requested and the public hearing has already been held) which:

- changes the site;
- increases the capital expenditure amount authorized by the Commissioner on the COPN issued for the project by 10% or more;
- changes the service(s) proposed to be offered; or
- extends the schedule for completion of the project beyond 3 years from the date of
 certificate issuance or beyond the time period approved by the Commissioner at the date
 of certificate issuance, whichever is greater.

The review period is 35 days, starting when a written request for approval of the significant change has been received by the State Health Department and a copy has been received by the appropriate regional health planning agency. The nature and purpose of the changes are to be identified in the request, and an application fee -- \$10,000 or 1.0% of the proposed capital expenditure, whichever is less -- must have been paid to the Department before review begins. The Commissioner may require a public hearing, which is conducted by the regional health planning agency within the first 30 days of the review period and with the same requirements for notice as apply to public hearings on COPN applications. The regional health planning agency must complete its review of the proposed change and notify the Commissioner of its recommendation by the 30th day, with failure to do so constituting a recommendation of approval. The Commissioner's decision must be made by the 35th day.

The Commissioner cannot approve:

• a significant change in cost for a project which exceeds the authorized capital expenditure by more than 20%; or

extension of the schedule for completion of a project beyond the 3 years defined as
requiring significant change review (see above) except when delays in completion of a
project have been caused by events beyond the control of the owner, and the owner has
made substantial and continuing progress toward completion of the project.

Type of Review COPN Application	Review Period
Standard Procedure	120 days
Expedited Process	4 5 days
Certificate Extension	35 days
Significant Change	35 days

On What Basis Might a COPN Be Revoked?

- Lack of progress
- Failure to report progress
- Unapproved changes
- Failure to initiate construction
- Misrepresentation
- Non-compliance with assurances

Other Requirements: Registration and Acquisition

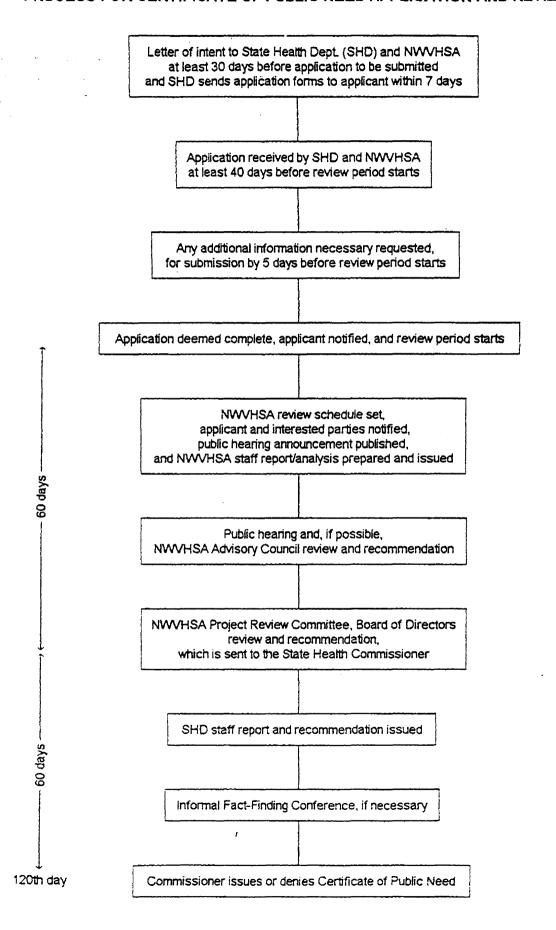
At least 30 days before any person contracts to make or is otherwise legally obligated to make a capital expenditure by on or behalf of the facility of \$1 million or more but less than \$2 million for nurse call systems, materials handling and management information systems, parking lots and garages, child care centers, laundry systems or other undertaking that does not involve the expansion of any space in which patient care services are provided, that expenditure must be registered with the State Health Commissioner. Information to be provided in registering includes the purpose of the expenditure and the projected impact that the expenditure will have on charges for services.

At least 30 days before anyone is contractually obligated to acquire an existing medical care facility, the cost of which is \$600,000 or more, that person must give written notification to the Commissioner and the appropriate regional health planning agency. The facility's name, the current and proposed owner, the cost of acquisition, the services to be added or deleted, the number of beds to be added or deleted, and the projected impact that the acquisition will have on

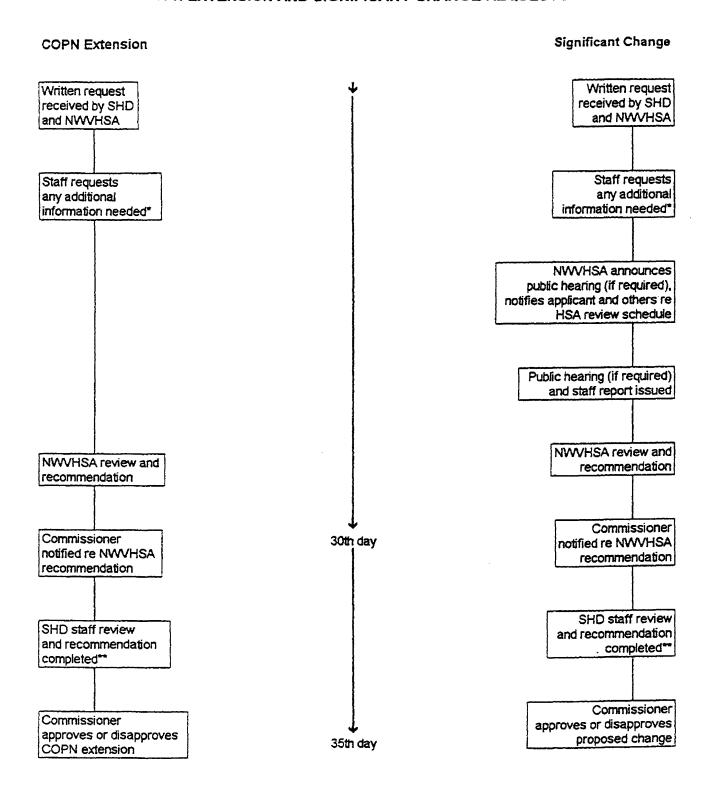
the charges for services to be provided are to be identified in the notification. The Commissioner will acknowledge receipt of this notification within 30 days. If it has been determined that a reviewable clinical health service or beds are to be added as a result of the acquisition, the Commissioner may require the proposed new owner to obtain a COPN prior to the acquisition, in which case the appropriate batch group for the project will be identified in the acknowledgment.

mpk-10/27/94

PROCESS FOR CERTIFICATE OF PUBLIC NEED APPLICATION AND REVIEW



NWVHSA PROCESS FOR REVIEW OF COPN EXTENSION AND SIGNIFICANT CHANGE REQUESTS



- * If a significant amount of additional information is needed before the request could be considered substantially complete, the beginning of the review period will be delayed until that information has been submitted.
- ** An informal fact-finding conference may at this point be found to be needed, in which case the Commissioner's decision is likely to be delayed.

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	APPENDIX C		

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Joint Commission on Health Care

Summary of Public Comments on Draft Issue Brief 6: Study of Virginia's Certificate of Public Need (COPN) Program

Comments regarding the Study of Virginia's Certificate of Public Need Program Issue Brief were received from the following 14 interested parties:

Carilion Health System
Chesapeake General Hospital
INOVA Health System
Medical Society of Virginia
Physicians Surgical Alliance
William M. Reid, Jr., M.D.
H. W. Trieshmann, Jr., M.D.
Connell J. Trimber, M.D.
Virginia Association of Non-Profit Homes for the Aging
Virginia Association of Regional Health Planning Agencies
Virginia Department of Health
Virginia Health Care Association
Virginia Hospital & Healthcare Association
Virginia Poverty Law Center

Policy Options Presented in Issue Brief

The following policy options were offered for consideration by the Joint Commission:

Option I: Maintain the Status Quo.

- Option II: Set a target date for eliminating the Certificate of Public Need Program at the year 2002, provided that the following conditions are met:
 - a. The development and implementation of a mechanism to reduce the number of uninsured Virginians. This mechanism would be developed by the Joint Commission through a study resolution introduced to the 1997 General Assembly.
 - b. The development of consumer friendly outcome data uniquely targeted to those tertiary services currently subject to the COPN program. Virginia Health Information, Inc. could be tasked to work with the Virginia Department of Health in accomplishing this task.
 - c. The level of covered lives under managed care capitation is sufficient to re-align provider incentives.
- Option III: Direct the Commissioner of Health to develop a more sophisticated methodology for conditioning COPN applications.
- Option IV: Direct the Commissioner of Health to change existing COPN need methodologies to allow for the development of new Outpatient Surgical Hospitals which do not have existing operating rooms.
- Option V: Repeal the COPN program immediately.

Summary of Individual Public Comments

Carilion Health System

Robert B. Manetta commented in support of Option II.

Chesapeake General Hospital

Donald S. Buckley stated that they supported the Virginia Hospital and Healthcare Association's position for Option I until the problem of health care for the uninsured is resolved. He also expressed strong support of hospital sponsored ambulatory surgery centers.

INOVA Health System

Donald L. Harris expressed strong support for the continuation of the COPN program and stated that Inova feels strongly that the Certificate of Public Need program has served the citizens of the Commonwealth very well since its inception in the 1970's.

He also indicated support for Option III but expressed opposition to Option IV stating that the Commissioner today has the flexibility to approve such applications if other circumstances dictate the need for such facilities. He also supported the development of consumer friendly outcome data regardless of COPN considerations.

Medical Society of Virginia (MSV)

Madeline I. Wade stated that the MSV opposes Option I and Option III and while they do not object in principle to Option II, MSV would prefer Option V which would provide for the repeal of the COPN law. She indicated MSV believes that COPN has not held down costs as originally intended and it instead eliminates competition. She stated that MSV believes that competition represents an important source of innovation, efficiency and increased productivity which will benefit our health care system. Further she stated that COPN legislation arose as a mechanism to address cost, quality and access issues under a reimbursement methodology which has become largely obsolete. While those problems may continue, COPN can no longer realistically be expected to be the cure, and its adverse side-effects far outweigh any modest benefit it may continue to supply.

Physicians Surgical Alliance

John T. Brennan, Jr., representing the Physicians Surgical Alliance, expressed strong support for Option V. He described his experience in working with his client Dr. Allen to open an outpatient surgical facility in Northern Virginia, and how his client's experience is representative of the institutional bias the COPN program has established against new, physician-owned health care services. He further stated that he believes this bias has been created through the political and economic power which existing hospital providers have been able to bring to bear in the process.

He stated that although the draft study concludes that access to care for the indigent remains a high policy priority, these access issues can and should be resolved through other means.

He concurred that the COPN program has not restricted the growth of outpatient surgery in Virginia; however, he stated that such capacity has grown through a system that permits only existing hospitals to participate in this growth, and which effectively prohibits new competitors from doing so. He believed that no new outpatient surgical services sponsored by non-hospital providers will be approved in Virginia under the current COPN system because the system has been erected and operates to protect this from occurring.

William M. Reid, Jr., MD.

Dr. Reid expressed strong support for Option V and provided extensive feedback on the report.

Dr. Reid stated that there is no evidence to support a conclusion that high volume ASCs do better work than low volume ASCs because of COPN. He also pointed out that to suggest that COPN plays a role in providing for indigent care is a gross exaggeration. He described examples of how hospitals have established mechanisms for avoiding the provision of elective indigent care and felt a more correct statement would be that the Virginia COPN law keeps the indigent from getting any elective care by promoting high prices for surgery. He also recommended that cost shifting should be replaced with direct allocation of state funds to reduce the cost of caring for the indigent and uninsured.

He stated that his direct experience with his local HSA leads him to the conclusion that they are simply a trade association of the local non-profit

hospitals designed to keep out competition. They are a waste of time and money and suffer from unenlightened leadership. With or without COPN, the HSA serves very little useful function in a competitive market based health care system.

In summary, he stated that the conditions which spawned the development of COPN no longer exist, if they ever did. He stated that government bureaucrats who insist on maintaining antiquated laws based upon discredited ideas don't have to face the voting public and he doesevery day. He stated that immediate deregulation of ASCs is mandatory and elimination of the COPN program entirely would be even better.

H.W. Treishman, Jr. MD-Newport News

Dr. Treishman strongly supported deregulation of ambulatory surgery centers as he felt the practice of medicine and the financing of health care has changed over the last 15 years as has the effect of government regulation on health care financing. Dr. Treishman made specific reference to his specialty (orthopaedics), and the lower costs associated with outpatient procedures. He also indicated that not only is there adequate capacity of outpatient surgical suites in Virginia, but that the factors driving the growth in ambulatory surgery function are independent of the COPN program. He also indicated that he and his partners provide \$10,000 per month of care to the uninsured and underinsured and that this policy would not be affected by any change to the COPN law.

Connell J. Trimber M. D.-Alexandria

Dr. Trimber voiced strong support for Option V calling for the elimination of the COPN program. He also stated that because the draft does not really define who the indigents are, we are at a loss to really evaluate what we are talking about. He made reference to the financial positions of Northern Virginia hospitals and having to send indigent patients over to Washington Hospital Center for treatment.

${f Virginia}$ Association of Non-Profit Homes for the Aging

Marcia A. Melton expressed support for Option II and noted that with a changing delivery system, consideration should also be extended to a continual evaluation of the "Request for Application Process" which seeks to limit the growth of nursing home beds.

Virginia Association of Health Planning Agencies

Dean Montgomery expressed strong support for Option I not only based upon the recognition of COPN's role in quality of care and indigent care but also based upon the impact that COPN has had on resource supply. He raised several concerns relating to policy statements in the report as well as technical aspects of the report. He voiced disagreement with points raised within the report pertaining to whether the COPN program has had an impact on health care costs. Specific reference was drawn to Virginia's experience during a three -year period (1989-1992) of partial repeal of COPN when hundreds of millions of dollars were spent to renovate and expand hospitals. He further stated that these costs are still being passed on to patients and payors.

Criticism was made of the study conclusions of other state reports relative to the COPN role in containing costs. He stated that these studies are flawed because they look very broadly at total acute spending per state without taking into account the effects of factors such as managed care that may also be affecting expenditures. The shift toward managed care at the same time as repeal of Certificate of Public Need may mask the cost impact of such an action.

In relation to the ambulatory surgery center portion of the report, he offered a comparison between Maryland and Virginia in the level of surgeries done in each state.

Virginia Department of Health

In general, Randolph L. Gordon, M.D., M.P.H., Commissioner, stated that VDH felt the report presents a reasonable exposition of the issues particularly as it relates to the role of this program in health care quality and provision of indigent care. VDH also felt that containment of medical costs is not a documentable achievement of this program. VDH supported gradual deregulation of this program and provided a discussion of gastroenterological endoscopy as a possible starting point for a fundamental rethinking of the program.

Virginia Health Care Association

Mary Lynne Bailey stated that VHCA had no position relative to the specific issue of COPN for ambulatory surgery centers, but opposition to Option V which called for the immediate repeal of COPN. She further stated that VHCA supported the competitive procedure for needed nursing facility beds.

Virginia Hospital and Healthcare Association

Katharine M. Webb concurred with the conclusions of the report as outlined in the revised issue brief and stated that the crux of the issue with respect to COPN continuation in Virginia lies with the resolution of financing of care for the uninsured. VHHA supported the continuation of COPN in its current form and scope.

Virginia Poverty Law Center

Jill A. Hanken expressed support for Option I because the health planning aspect of COPN and the role of HSA's are vitally important, and the COPN program offers one way for Virginia to address the problem of indigent care and care for the uninsured.

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APPENDIX	X D	

CHAPTER 462

An Act to amend the Code of Virginia by adding in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.12, relating to certificates of public need.

[H 2477] Approved March 16, 1997

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 1.1 of Chapter 4 of Title 32.1 a section numbered 32.1-102.12 as follows:

§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 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;
- 5. 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; and
- 6. An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article.

JOINT COMMISSION ON HEALTH CARE

Director

Jane Norwood Kusiak

Senior Health Policy Analyst

Patrick W. Finnerty

Office Manager

Mamie V. White

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Joint Commission on Health Care Old City Hall, Suite 115 1001 East Broad Street Richmond, Virginia 23219 (804) 786-5445 (804) 786-5538 (FAX)

E-Mail: jchc@leg.state.va.us

Internet Address:

http://legis.state.va.us/jchc/jchchome.htm