



COMMONWEALTH of VIRGINIA

Office of the Governor

William A. Hazel, Jr., MD
Secretary of Health and Human Resources

December 4, 2015

The Honorable Charles J. Colgan, Sr.
Co-Chairman, Senate Finance Committee
10677 Aviation Lane
Manassas, VA 20110-2701

The Honorable Walter A. Stosch
Co-Chairman, Senate Finance Committee
4551 Cox Road, Ste. 110
Glen Allen, VA 23060-6740

The Honorable Stephen H. Martin
Chairman, Senate Education and Health Committee
P.O. Box 700
Chesterfield, VA 23832

The Honorable S. Chris Jones
Chairman, House Appropriations Committee
P.O. Box 5059
Suffolk, VA 23435-0059

The Honorable Robert D. Orrock, Sr.
Chairman, House Health, Welfare and Institutions Committee
P.O. Box 458
Thornburg, VA 22565

Dear Senator Colgan, Senator Stosch, Senator Martin, Delegate Jones and Delegate Orrock:

Pursuant to Item 278D of the 2015 Appropriation Act, I am providing you with a copy of the final report of the Certificate of Public Need (COPN) Workgroup, which I convened. Item 278D directed the Secretary of Health and Human Resources to convene a workgroup of key stakeholders in order to “review the current certificate of public need process and the impact of such process on health care services in the Commonwealth, and the need for changes to the

current certificate of public need process.” The workgroup met five times between July and November of this year.

Through its discussions and deliberations, the workgroup focused in particular on the following issues and topics:

- Purpose and Objectives of the COPN Program,
- Review and Update of the State Medical Facilities Plan,
- Process for Submission and Review of COPN Applications,
- Conditioning of Certificates,
- Transparency of the Program,
- Process for Evaluating Whether Certain Facilities and Projects Should Remain Subject to COPN Requirements, and
- Resources to Administer the Program.

The workgroup received numerous informational presentations and received extensive written and verbal comments throughout the study process.

The report contains 34 recommendations focused on making the COPN program more timely, predictable and transparent. The report also includes recommendations which, if implemented, would reduce the number of projects that are subject to COPN requirements. In addition, the report calls for further review in conjunction with stakeholders, of certain issues raised during the study, including those related to the provision of charity care.

I look forward to working with the members of the General Assembly during the 2016 Session to implement the recommendations contained in this report.

Sincerely,

A handwritten signature in black ink, appearing to read "William A. Hazel, Jr.", written in a cursive style.

William A. Hazel, Jr., M.D.

Certificate of Public Need Workgroup – Final Report

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Certificate of Public Need Workgroup Members

Eva Hardy – Retired Executive Vice President, Dominion Resources, Inc, and former Secretary of Health and Human Resources, *Chair*

Carol Armstrong – Manager of Benefits Administration, Southern States Cooperative

J. Abbott Byrd, III, MD – Orthopaedic Surgeon, Atlantic Orthopaedic Specialists

Karen Cameron – Director, Virginia Consumer Voices for Health Care

Robert Cramer – Former Manager of HR Services, Norfolk Southern Corporation

Richard M. Hamrick, III, MD – Chief Medical Officer, HCA Virginia Health System

William A. Hazel, Jr, MD – Secretary of Health and Human Resources, Commonwealth of Virginia, *ex officio*

Kim Horn – President, Kaiser Foundation Health Plan of Mid-Atlantic States

Brian Keefe – CFO of Capitol Market, Aetna, Inc

C. Burke King – President, Anthem Blue Cross & Blue Shield Virginia

Jill Lobb - Corporate Director of Benefits, Huntington Ingalls Industries

Mary Mannix – President & CEO, Augusta Health

Jamie Baskerville Martin – Attorney, McCandlish Holton, *non-voting advisor*

Deborah Oswalt – Executive Director, Virginia Health Care Foundation

Douglas Suddreth – Vice President of Development, Autumn Corporation

Pamela Sutton-Wallace – CEO, UVA Medical Center

Richard A. Szucs, MD – Radiologist, Commonwealth Radiology PC

David H. Trump, MD, MPH – Chief Deputy Commissioner, Virginia Department of Health

Staff

Erik Bodin – Director, Office of Licensure and Certification, Virginia Department of Health

Peter Boswell – Director, Division of Certificate of Public Need, Virginia Department of Health

Doug Harris – Adjudication Officer, Virginia Department of Health

Joseph Hilbert – Director of Governmental and Regulatory Affairs, Virginia Department of Health

Susan Puglisi – Policy Analyst, Office of Licensure and Certification, Virginia Department of Health

EXECUTIVE SUMMARY

In order for certain types of medical facilities to be built, the Commonwealth of Virginia has utilized the Certificate of Public Need (COPN) program to review, analyze and determine what services and facilities are authorized. This program, which Virginia adopted in 1973, has been studied extensively in the past by Governors, the Virginia General Assembly including the Joint Commission on Health Care, and the Virginia Department of Health (VDH). While health care has changed dramatically in the last two decades, the COPN program, though serving a purpose in terms of the establishment and siting of hospitals and services, has remained largely unchanged. The charge of the workgroup appointed by the Secretary of Health and Human Resources has been to review and make recommendations for immediate improvements to the COPN process, and to carefully plan for future significant long term changes that would improve access to healthcare services while establishing strong guidelines for indigent care.

The provisions of Virginia's COPN program, and the process by which it is administered, are set forth in statute and regulation. The COPN program is administered by VDH. A key component of the program is development and maintenance of the State Medical Facilities Plan (SMFP). A total of 35 states administer COPN programs.

The 2015 General Assembly directed the Secretary of Health and Human Resources to convene a workgroup of key stakeholders in order to "review the current certificate of public need process and the impact of such process on health care services in the Commonwealth, and the need for changes to the current certificate of public need process." There have been prior efforts to substantially eliminate the program, but those prior efforts were not fully implemented. Programs in other states have been subject to various studies and evaluations, over a period of many years, concerning their impact and effect.

The workgroup met five times between July and November of 2015. The workgroup received numerous informational presentations and received extensive written and verbal comments. Through its discussions and deliberations, the workgroup focused in particular on the following issues and topics within the context of the study mandate:

- Purpose and Objectives of the Program,
- Review and Update of the SMFP,
- Process for Submission and Review of Applications,
- Conditioning of Certificates,
- Transparency of the Program,
- Process for Evaluating Whether Certain Facilities and Projects Should Remain Subject to COPN Requirements, and
- VDH Resources to Administer the Program.

Purpose and Objectives. The program does not have a statement of purpose in either statute or regulation. The following recommendation is made:

1. The Code of Virginia should be amended to establish a statement of purpose for COPN that reflects the components of the Institute for Healthcare Improvement's Triple Aim (patient experience of care, population health and cost), and that is also reflective of promoting access to care.

Review and Update of the SMFP. The process by which the SMFP is reviewed and updated needs to be more timely and rigorous. The following recommendations are made:

- 2a The SMFP should be reviewed and updated in a timely and rigorous manner.
- 2b The SMFP task force should be convened to review SMFP and propose restructuring of plan, consider additional criteria, and recommend other changes.
- 2c VDH should determine the type and amount of any additional required resources necessary to comply with statutory requirements for review and update of the SMFP.
- 2d The SMFP should be aligned with the goals and metrics of the State Health Improvement Plan and be renamed the State Health Services Plan.
- 2e The Code of Virginia should be amended to establish statutory requirements for the process by which the SMFP is reviewed and updated.
- 2f The Code of Virginia should be amended to exempt the SMFP from the provisions of the Administrative Process Act, subject to requirements that a Notice of Intended Regulatory Action be published, and a public comment period including a public hearing be held prior to the effective date of the revised SMFP.
- 2g VDH should adopt the practice of preparing and submitting all future amendments to the SMFP as Fast Track Regulatory Actions.
- 2h The Code of Virginia should be amended to require annual review of the SMFP and an update of the SMFP every 2 years
- 2i The State Health Commissioner should assess the current organization and composition of the SMFP Task Force and make recommendations to the State Board of Health if any changes in the organization, composition or manner of appointment are deemed advisable. The assessment should also address any need for a defined quorum for meetings of the SMFP Task Force.

Process for Submission and Review of Applications. The process for application submission and review needs to be more efficient and streamlined. The following recommendations are made:

- 3a The process for submission and review of COPN applications should be streamlined.
- 3b VDH should evaluate COPN application forms to ensure that only data necessary for review of an application is required to be submitted and that the forms reflect statutory requirements. VDH should make all necessary revisions to the forms.
- 3c The Code of Virginia and the COPN regulations should be amended to require that a COPN application be substantially complete at the time of submission.
- 3d VDH should develop recommendations to reduce the standard review process to not more than 120 days from the receipt of the letter of intent. VDH shall consider changes in the current process to effect such a reduction in the length of the review process, including but not limited to changes reflected in other study recommendations as well as: elimination or reduction of the "completeness" period between the submittal of an application and its acceptance as "complete," reduction of the current 70-day period for DCOPN review of an application, and earlier scheduling of a public hearing.
- 3e VDH should: i) assess projects that may be appropriate for a 45-day expedited review process, which may include projects that are generally non-contested and/or raise

comparatively few health planning concerns; ii) develop a process for reviewing such applications in a 45-day review period and identify the conditions under which such applications would require transition to a standard review cycle, and; iii) establish requirements for COPNs issued pursuant to a 45-day expedited review process, including conditions for indigent care and quality assurance. The analytical framework described in Recommendation 6b should be applied to determine whether any project type should be eligible for expedited review.

- 3f The role of the SMFP in COPN decisions should be clarified to allow the Division of Certificate of Public Need (DCOPN) to recommend approval of an application that is in general agreement with the SMFP.
- 3g VDH should work with Virginia Health Information (VHI) to develop a process for the collection of data, as part of required utilization reporting, concerning the specific type of equipment utilized.
- 3h The filing timeline for good cause petitions should be clarified to resolve the discrepancy between the statutory and regulatory requirement.

Conditioning of Certificates. The manner in which conditions are determined, and the process by which compliance with conditions is enforced, needs to be clarified and standardized. The following recommendations are made:

- 4a Rules regarding the conditioning of COPNs, including the process for defining and calculating charity care, should be clarified, standardized and enforced.
- 4b The Secretary of Health and Human Resources and VDH should study and review charity care services delivered throughout the Commonwealth and recommend changes to the definition of charity care imposed across providers. A report shall be submitted to the General Assembly prior to the 2017 Session.
- 4c The Secretary of Health and Human Resources should convene stakeholders to explore appropriate authority for the Commissioner to impose additional conditions on COPNs consistent with the SMFP and the Virginia State Population Health Plan.
- 4d VDH should assess the capacity of DCOPN to monitor compliance with conditions imposed on COPNs. Based on that assessment, VDH should determine if additional resources are needed to support administration of this function.

Transparency of the Program. A wide range of program-related information needs to be made more readily available to the public. The following recommendations are made:

- 5a The transparency of the COPN program to the public should be increased.
- 5b A real-time automated/electronic tracking and posting mechanism for Letter of Intent (LOI) filings should be implemented to make LOIs available to the public as soon as they are received.
- 5c An online library should be created where all relevant COPN information and documents are posted and easily available to the public.
- 5d The collection of COPN-relevant data and the availability of such data should be improved and standardized by:
 - Clarifying rules for reporting utilization of operating rooms and procedure rooms.

- Expediting publication of VHI reports.
 - Maintaining an accessible inventory of all COPN-authorized (operational and not yet operational) providers/beds/units for all COPN-reviewable services.
- 5e VDH should assess the cost of implementing 1) a real-time automated/electronic tracking and posting mechanism for LOI filings, 2) creating an online library of all relevant COPN applications and documents, 3) maintaining an accessible inventory of all COPN authorized providers/beds/units and 4) on-line publishing of charity care conditions, compliance reporting status, details on the exact amount provided and/or contributed, and to whom. Based on that assessment, VDH should determine if additional resources are needed to fund the cost of implementation.

Process for Evaluating Whether Certain Facilities and Projects Should Remain Subject to COPN Requirements. The workgroup discussed the extent to which certain medical facilities and projects should continue to remain subject to COPN requirements. The workgroup's discussions revealed the absence of an adequate data-driven, analytical framework to support the development of specific recommendations for the elimination of COPN requirements for certain types of facilities and projects. Prior to 2012, a semblance of such a framework existed at the state level in the form of the COPN Annual Report required by the Code of Virginia. Those reports, prepared by the VDH, contained recommendations concerning the continued appropriateness of COPN requirements for various types of medical facilities and projects. The following recommendations are made:

- 6a The General Assembly should consider amending the definition of "Project" to no longer include the following: lithotripsy, obstetrical services, magnetic source imaging, nuclear medicine imaging services, and replacement of a medical facility within the same primary service area.
- 6b The Virginia Department of Health should develop an analytical framework that incorporates review of the SMFP to support development of recommendations concerning the appropriateness of continuing to impose COPN requirements on specific medical facilities and projects or whether such projects should be subject to expedited review. The analytical framework should be aligned with the goals and metrics of Virginia's State Health Improvement Plan. The analytical framework should also take into consideration components of the approach utilized prior to 2012 in development of the COPN Annual Report. The analytical framework should include a recurrent three-year schedule for analysis of all COPN project categories, with procedures for analysis of at least three project categories per year. The recurrent three-year schedule should be developed such that COPN projects that are of relatively low complexity and low cost are analyzed first, and projects that are of relatively high complexity and high cost are analyzed subsequently. VDH should develop recommendations based on the results of its analysis and transmit those recommendations to the General Assembly, Governor and Secretary of Health and Human Resources. The analytical framework should also include appropriate metrics to evaluate the impact of introducing a more competitive health care framework that could reduce costs and increase access to health care services. The analytical

framework will include a process for stakeholder involvement in review and public comment on any recommendations.

- 6c Providers of services that are no longer required to obtain a COPN should be required to provide a specified level of charity care in services or funds that matches the average percentage of indigent care provided in the appropriate health planning region and to participate in Medicaid.
- 6d Providers of services that are no longer required to obtain a COPN, along with all prospective COPN holders, should be required to obtain accreditation from a nationally-recognized accrediting organization for the purposes of quality assurance, as approved by the Virginia Department of Health.
- 6e VDH should provide a status report on implementation and impact of workgroup's recommended reforms to the Governor and General Assembly by December 1, 2017.

VDH Resources to Administer the Program. The program is funded solely by application fees. There are no general funds authorized or appropriated for the COPN program. DCOPN's fee-based funding varies year-to-year based on the number and types of COPN projects. The following recommendations are made:

- 7a VDH should have adequate resources to administer the COPN program in cost-effective manner.
- 7b VDH should assess the amount of funding required to administer the statutory and regulatory requirements of the COPN program in a cost-effective manner. This assessment should take into account the need for timely and rigorous updates of the SMFP, monitoring of compliance with COPN conditions, and use of technology to support the submission and processing of applications. Based on that assessment, VDH should determine if additional resources are needed for cost-effective administration. If additional resources are determined to be necessary, COPN application fees should be increased in order to provide additional funding to support cost effective administration of the program.

INTRODUCTION

The Virginia COPN program is a regulatory program administered by VDH pursuant to legislation enacted in 1973 by the General Assembly. In order for certain types of “medical facilities” to implement certain types of “projects”, permission must first be obtained from the Commonwealth in the form of a COPN issued by the Health Commissioner. A total of 35 states administer certificate of need programs. The standards and criteria by which VDH reviews COPN applications are contained within the SMFP. Virginia’s COPN program has been subject to several studies since its original enactment. Similar programs in other states have been subject to various studies and evaluations, over a period of many years, concerning their impact and effect.

Study Mandate

The General Assembly, in Item 278D of the 2015 Appropriation Act, directed the Secretary of Health and Human Resources to convene a workgroup of key stakeholders in order to “review the current certificate of public need process and the impact of such process on health care services in the Commonwealth, and the need for changes to the current certificate of public need process.” (Appendix A.) The study mandate directed the workgroup to conduct a comprehensive review of the program by examining several different topics related to the COPN program including the application review and decisionmaking process, application fees, impact of the program on establishment of new health care services and on charity care, regional health planning agencies, and the SMFP. According to the mandate, the workgroup is to include recommendations for the process to be introduced during the 2016 General Assembly Session, as well as any additional changes that may require further study or review.

Workgroup Activities

In response to the legislative mandate, the Secretary of Health and Human Resources, Dr. William Hazel, convened an 18-member workgroup representing a broad range of perspective and expertise (Appendix B). The workgroup held 5 meetings during 2015: on July 1, August 19, September 28, October 27, and November 16.

July 1 Meeting. Secretary Hazel opened the meeting by providing initial remarks. The Secretary said that, during its deliberations, the workgroup should focus on 1) What is the public good? 2) Is COPN working? 3) If not, what needs to be fixed? and 4) How do we define public good if COPN is to be kept? The Secretary also asked the workgroup to focus on whether COPN procedures are fair, open, and transparent. In his remarks to the workgroup, the Secretary described the many ways in which Virginia’s health care environment is changing, including changes in the commercial health insurance market as well as expanded coverage through the federal health insurance exchange and other changes related to implementation of the Affordable Care Act.

Peter Boswell, Director of VDH’s DCOPN, provided an overview of the statutes and regulations governing COPN and the SMFP in Virginia, as well the policies and process by which those requirements are administered. DCOPN also provided the workgroup with information concerning its workload, staffing and funding.

Susan Puglisi, Policy Analyst in the VDH Office of Licensure and Certification provided an overview of COPN requirements in other states. This presentation included information on the specific types of facilities and services that require a COPN in each state, as well as the length of application review periods and the amount of each state's application fee.

Finally, Patrick Finnerty of PWF Consulting briefed the workgroup on the provisions of the COPN Deregulation Plan developed in 2000 by Virginia's Joint Commission on Health Care. This plan, prepared in compliance with legislation enacted by the 2000 General Assembly, was never implemented as enabling legislation was not enacted by the 2001 General Assembly.

The meeting agenda included a public comment period but no members of the public signed up to speak. The minutes from the July 1, 2015 meeting are attached as Appendix C.

August 19th Meeting. The State Health Commissioner, Dr. Marissa Levine, provided the workgroup with a status report on development of Virginia's State Health Improvement Plan, referred to as Virginia's Plan for Well-Being. During the presentation, there were questions concerning and discussion of the potential role of COPN and SMFP in population health improvement planning.

The Director of the VDH Office of Licensure and Certification, Erik Bodin, provided the workgroup with an additional, detailed explanation of the statutory and regulatory provisions governing COPN and the SMFP in Virginia. This included a description of the 11 categories of "medical care facilities" that are subject to COPN, the seven categories of "projects" within medical care facilities that require COPN approval, the eight statutory considerations that must be taken into account during the review of a COPN application, and the five guiding principles of the SMFP. Mr. Bodin described the COPN review process, including the review standards and criteria contained within the SMFP. Mr. Bodin also described the process that DCOPN uses to recommend conditions to be attached to certain COPNs, and the monitoring of compliance with those conditions.

Follow-up information concerning COPN in other states was provided by Joe Hilbert, VDH Director of Governmental and Regulatory Affairs. This presentation included information concerning the experience of three states following their decision to repeal COPN, as well as the activities of seven other states that undertook comprehensive reviews of their COPN programs.

Finally, Koren Wong-Ervin, Attorney-Advisor with the U.S. Federal Trade Commission (FTC), provided the workgroup with comments concerning the FTC's perspective on COPN. The meeting agenda included a public comment period but no members of the public signed up to speak. The minutes from the August 19th meeting are attached as Appendix D.

September 28th Meeting. Erik Bodin provided information to the workgroup, including description of a case study, concerning how, why, and how often VDH denies COPN applications. The case study summarized how one particular application was evaluated in relation to the eight statutory considerations for COPN review.

Richard Thomas, Ph.D., with the American Health Planning Association (AHPA), provided the workgroup with comments concerning AHPA's perspective on COPN. Stephen Weiss, Senior Policy Analyst with the Joint Commission on Health Care (JCHC), briefed the

workgroup on the results of his analysis of certain health-care system characteristics in states with and without COPN.

Finally, the workgroup reviewed and discussed a framework of potential ideas for recommendations. Three potential scenarios were considered: 1) Retain COPN as is, 2) Retain COPN but with modifications that could range from minor to significant, and 3) Eliminate COPN. As part of potential scenario 2, several ideas for modifications were discussed. These included: 1) Updating the SMFP, 2) Improving the processing of COPN applications, 3) Making revisions to the conditioning of COPN applications, 4) Strengthening post-COPN approval compliance monitoring, 5) Promoting greater transparency in the COPN program, and 6) Eliminating certain facilities and services from the need to obtain COPN approval.

The meeting agenda included a public comment period but no members of the public signed up to speak. The minutes from the September 28th meeting are attached as Appendix E.

October 27th Meeting. The workgroup heard testimony from 12 individuals, representing range of stakeholders, during a public comment period:

- Charlotte Tyson- Lewis Gale Medical Center
- Dr. Michael Fabrizio - Urology of Virginia/Eastern Virginia Medical School
- John Duval - Virginia Commonwealth University Health System
- Don Adam - Adeptus Health
- Jim Dunn - BonSecours
- Dr. Paul Matherne – University of Virginia Health System
- Dr. Alan Matsumoto – University of Virginia Health System
- Don Harris- Inova Health System
- Dr. Jamil H. Khan- Childrens Hospital of the King’s Daughters
- Brent Rawlings-Virginia Hospital and Healthcare Association
- Paul Speidell-Sentara Health System
- Doug Gray- Virginia Association of Health Plans

The workgroup also discussed draft Recommendations and Policy Options. The minutes from the October 27th meeting are attached as Appendix F.

November 16th Meeting. The workgroup heard testimony from the following individuals during a public comment period:

- Bruce Kupper – Medarva Healthcare
- Jill Hanken – Virginia Poverty Law Center.

The workgroup also discussed and approved recommendations for the final report.

Report Outline

Following the discussion of the study mandate and COPN workgroup activities, the report provides an overview of the COPN program in Virginia. This includes a brief history of the program, including a summary of prior studies conducted by the Executive and Legislative branches. The report also describes the statutory and regulatory provisions governing COPN and the SMFP. The policies and processes used by VDH to administer the COPN program are reviewed, and staffing and funding of the VDH DCOPN are described.

A description of COPN programs in other states, including information concerning the number and types of facilities and services subject to COPN, is included in the report. Over the past ten to 20 years, a considerable body of literature has developed examining the impact of COPN programs across the country, as measured by a range of variables. Taken as a whole, there is a significant variation and discrepancy in the methodologies, findings and conclusions of many of these studies. The FTC and AHPA are examples of organizations that have examined and considered the impact of COPN. Additional information concerning COPN program in other states is included in the report.

In order to begin the process of developing recommendations for reforming Virginia's COPN program, the workgroup first established a Framework of Potential Ideas for Recommendations. Following a discussion of the Framework document, members of the workgroup and stakeholders were given the opportunity to submit written comments. Those written comments are summarized in Appendix G. The workgroup used the written comments, as well as additional comments received from stakeholders and further discussion, to develop a set of recommendations and policy options discussed in the report.

The Virginia Hospital and Healthcare Association (VHHA) established a COPN Task Force in order to conduct its own review of the COPN process and develop specific recommendations corresponding to each item in the study mandate. VHHA issued an initial report of findings and recommendations in June 2015. This report references the VHHA report in various sections.

CERTIFICATE OF PUBLIC NEED IN VIRGINIA

The provisions of Virginia's COPN program, and the process by which it is administered, are set forth in statute and regulation. Virginia's program has been the subject of numerous studies by both the Executive and Legislative branches since its initial enactment. Furthermore, there have been prior efforts to substantially eliminate the program, but those prior efforts were not fully implemented. The program is administered by VDH's DCOPN.

Prior Studies of Virginia's COPN Program

The history of COPN in Virginia stretches back more than 40 years, to the enactment of Virginia's COPN statute in 1973, approximately one year before the National Health Planning and Resources Development Act of 1974 was passed, requiring all states to operate certificate of need programs as a condition for receiving certain federal funding. Congress subsequently repealed the federal certificate of need requirement effective on January 1, 1987. In Virginia, this action stimulated several studies of COPN in the 1980's and subsequent years, generating various recommendations.

Baliles Commission. During his Administration, former-Governor Baliles appointed a COPN study commission that issued several recommendations. One of those recommendations led to legislation enacted by the 1989 General Assembly which eliminated COPN requirements for certain types of equipment and capital expenditures, and codified a moratorium on new nursing home beds. The 1989 legislation also provided for the elimination—with a delayed effective date—of COPN requirements for hospitals and ambulatory surgery centers. However, legislation enacted by the 1991 General Assembly postponed elimination of those COPN

requirements and the 1992 General Assembly repealed the elimination. The legislation enacted in 1992 not only repealed the planned elimination of COPN requirements for hospitals and ambulatory surgery centers, but it also increased the numbers of facilities and services subject to COPN. The legislation added construction of new facilities, addition of new beds, initiation of certain new services, and purchase of new or replacement major medical equipment, to the list of projects requiring COPN approval.

Joint Commission on Health Care Study. In 1996, the Joint Commission on Health Care (JCHC) was directed by the General Assembly to study the appropriateness of COPN regulations and requirements, including the need for or appropriateness of requiring ambulatory surgery centers to be subject to COPN. The JCHC developed five policy options as a result of its study:

- I: Maintain the Status Quo.
- II: Set a target date for eliminating the COPN 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 VDH in accomplishing this task. c. The level of covered lives under managed care capitation is sufficient to re-align provider incentives
- III: Direct the Commissioner of Health to develop a more sophisticated methodology for conditioning COPN applications.
- 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.
- V: Repeal the COPN program immediately.

In 1996, the General Assembly replaced the moratorium on new nursing home beds with a Request for Applications process administered by VDH. In 1997 the General Assembly enacted legislation requiring VDH to provide a detailed annual report on the COPN program.

Special Joint Subcommittee. In 1998, a special joint subcommittee of the General Assembly initiated a two-year study of COPN. In 1999, the General Assembly enacted legislation recommended by the joint subcommittee to eliminate COPN requirements for replacement of any equipment, registration of equipment purchases, and revision of the administrative procedures for review of COPN applications.

Joint Commission on Health Care Deregulation Plan. The 2000 General Assembly directed the JCHC to develop a “transition plan” to eliminate the COPN program, with the transition to begin on July 1, 2001, and be completed by July 1, 2004. The plan was developed through extensive stakeholder engagement and with the assistance of a professional facilitator. Key provisions of plan included:

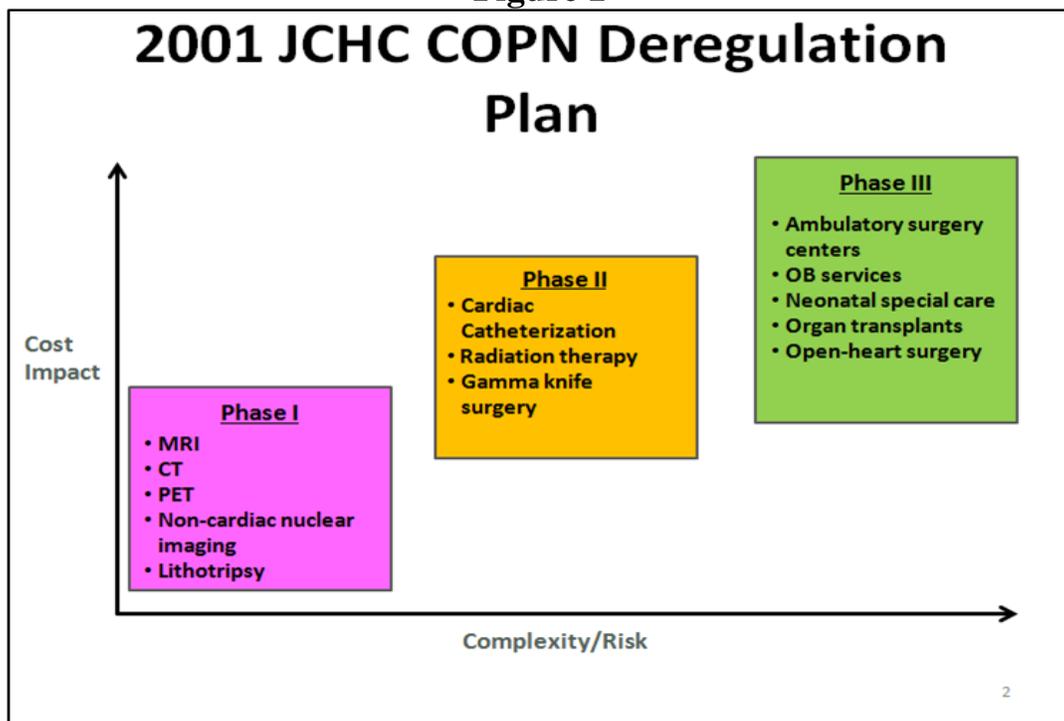
- Meeting health care needs of indigent and uninsured populations;
- Establishing licensure standards and providing adequate oversight for deregulated services;
- Determining effect of deregulation on academic health centers, long-term care facilities, rural hospitals; and
- Monitoring effect of deregulation during and after transition period.

COPN would have been retained for Nursing Homes, Hospital beds, Mental Health and Substance Use Disorder Facilities. Figure 1 summarizes the three phases of the plan. The JCHC plan had a significant estimated fiscal impact of \$40.5M (Phase 1), \$56.5M (Phase II), \$38 M (Phase III). Legislation introduced during the 2001 Session to implement the plan was not enacted.

Provisions of Virginia’s COPN Statute

Prior to establishing certain types of medical facilities, or beginning certain types of projects, the Commissioner is required to determine if a public need for the facility or project exists. If a public need is determined, a certificate is issued by the Commissioner. The standards and criteria used to determine if a public need exists are contained in the COPN law and the SMFP. Those standards and criteria are developed in accordance with five guiding principles established in regulation.

Figure 1



While reviewing applications for COPNs, VDH and the Commissioner are required to take eight considerations, defined in statute, into account in making a determination of public need.

Projects. Section 32.1-102.3 of the Code of Virginia states that no person shall commence any project without first obtaining a certificate of public need issued by the Commissioner. Seven different types of “projects” require a COPN:

1. Establishment of a medical care facility;
2. An increase in the total number of beds or operating rooms in an existing medical care facility;
3. Relocation of beds from one existing facility to another, provided that "project" does not include the relocation of up to 10 beds or 10 percent of the beds, whichever is less,

- ...a hospital shall not be required to obtain a certificate for the use of 10 percent of its beds as nursing home beds as provided in § 32.1-132;
4. Introduction into an existing medical care facility of any new nursing home service, such as intermediate care facility services, extended care facility services, or skilled nursing facility services, regardless of the type of medical care facility in which those services are provided;
 5. Introduction into an existing medical care facility of any following new services (which the facility has never provided or has not provided in the previous 12 months;)
 - cardiac catheterization,
 - computed tomographic (CT) scanning,
 - stereotactic radiosurgery,
 - lithotripsy,
 - magnetic resonance imaging (MRI),
 - magnetic source imaging (MSI),
 - medical rehabilitation,
 - neonatal special care,
 - obstetrical,
 - open heart surgery,
 - positron emission tomographic (PET) scanning,
 - psychiatric,
 - organ or tissue transplant service,
 - radiation therapy,
 - stereotactic radiotherapy,
 - proton beam therapy,
 - nuclear medicine imaging,
 - substance abuse treatment.
 - or such other specialty clinical services as may be designated by the Board of Health.
 6. Conversion of beds in an existing medical care facility to medical rehabilitation beds or psychiatric beds;
 7. The addition by an existing medical care facility of any medical equipment for the provision of;
 - cardiac catheterization,
 - CT scanning,
 - stereotactic radiosurgery,
 - lithotripsy,
 - MRI,
 - MSI,
 - open heart surgery,
 - PET scanning,
 - radiation therapy,
 - stereotactic radiotherapy,
 - proton beam therapy, or
 - other specialized service designated by the Board by regulation.

Replacement of existing equipment shall not require a COPN.

Medical Care Facilities. According to § 32.1-102.1 of the Code of Virginia, only the following types of medical care facilities shall be subject to COPN review:

1. General hospitals.
2. Sanitariums.
3. Nursing homes.
4. Intermediate care facilities, except those established for individuals with intellectual disability that have no more than 12 beds and are in an area identified as in need of residential services for individuals with intellectual disability in any plan of the Department of Behavioral Health and Developmental Services.
5. Extended care facilities.
6. Mental hospitals.
7. Facilities for individuals with intellectual disability.
8. Psychiatric hospitals and intermediate care facilities established primarily for the medical, psychiatric or psychological treatment and rehabilitation of individuals with substance abuse.
9. Specialized centers or clinics or that portion of a physician's office developed for the provision of:
 - outpatient or ambulatory surgery,
 - cardiac catheterization,
 - computed tomographic scanning,
 - stereotactic radiosurgery,
 - lithotripsy,
 - magnetic resonance imaging,
 - magnetic source imaging,
 - positron emission tomographic scanning,
 - radiation therapy,
 - stereotactic radiotherapy,
 - proton beam therapy,
 - Non-cardiac nuclear medicine imaging, or
 - Other specialty services designated by the Board of Health by regulation.

Required Considerations During COPN Review. In determining whether a public need for a project has been demonstrated, the Commissioner shall consider:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care;
2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:
 - (i) the level of community support for the project;
 - (ii) the availability of reasonable alternatives to the proposed service or facility;
 - (iii) any recommendation or report of the regional health planning agency;
 - (iv) Any costs and benefits of the project;
 - (v) the financial accessibility of the project; and
 - (vi) at the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project;
3. The extent to which the application is consistent with the State Medical Facilities Plan;

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served;
5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities;
6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital;
7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by:
 - (ii) the potential for provision of services on an outpatient basis;
 - (iii) any cooperative efforts to meet regional health care needs; and
 - (iv) at the discretion of the Commissioner, any other factors as may be appropriate; and
8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be served,
 - (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and
 - (ii) any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Consideration number 4, concerning institutional competition, was added to the statute in 2008. In 2009, the General Assembly enacted legislation which consolidated 21 considerations into the current eight.

State Medical Facilities Plan. The Code of Virginia defines the SMFP to mean the planning document adopted by the Board of Health which shall include, but not be limited to, (i) methodologies for projecting need for medical care facility beds and services; (ii) statistical information on the availability of medical care facilities and services; and (iii) procedures, criteria and standards for review of applications for projects for medical care facilities and services. The SMFP is contained in regulation (12VAC5-230), which specifies five Guiding Principles in the Development of Project Review Criteria and Standards:

1. The COPN program is based on the understanding that excess capacity or underutilization of medical facilities are detrimental to both cost effectiveness and quality of medical services in Virginia.
2. The COPN program seeks the geographical distribution of medical facilities and to promote the availability and accessibility of proven technologies.
3. The COPN program seeks to promote the development and maintenance of services and access to those services by every person who needs them without respect to their ability to pay.
4. The COPN program seeks to encourage the conversion of facilities to new and efficient uses and the reallocation of resources to meet evolving community needs.
5. The COPN program discourages the proliferation of services that would undermine the ability of essential community providers to maintain their financial viability.

The review standards and criteria contained in the SMFP are typically based on measures of service utilization (e.g. procedure volume or bed occupancy) and access to the service by the population within a region or planning district. The criteria also typically distinguish between

the need to establish a new facility or service, and the need to expand an existing facility or service. For example, the following review criteria are contained in the SMFP for Computed Tomography (CT) services – a type of diagnostic imaging:

- CT services should be within 30 minutes driving time one way under normal conditions of 95% of the population of the health planning district using a mapping software as determined by the commissioner.
- No new fixed site or mobile CT service should be approved unless fixed site CT services in the health planning district performed an average of 7,400 procedures per existing and approved CT scanner during the relevant reporting period and the proposed new service would not significantly reduce the utilization of existing providers in the health planning district.
- Proposals to expand an existing medical care facility's CT service through the addition of a CT scanner should be approved when the existing services performed an average of 7,400 procedures per scanner for the relevant reporting period. The commissioner may authorize placement of a new unit at the applicant's existing medical care facility or at a separate location within the applicant's primary service area for CT services, provided the proposed expansion is not likely to significantly reduce the utilization of existing providers in the health planning district.
- CT services should be under the direction or supervision of one or more qualified physicians.

Section 32.1-102.2:1 requires the State Board of Health to appoint and convene an SMFP task force of no fewer than 15 individuals to meet at least once every two years. The task force shall consist of representatives from VDH and the DCOPN, representatives of regional health planning agencies, representatives of the health care provider community, representatives of the academic medical community, experts in advanced medical technology, and health insurers. The task force shall complete a review of the SMFP updating or validating existing criteria in the SMFP at least every four years.

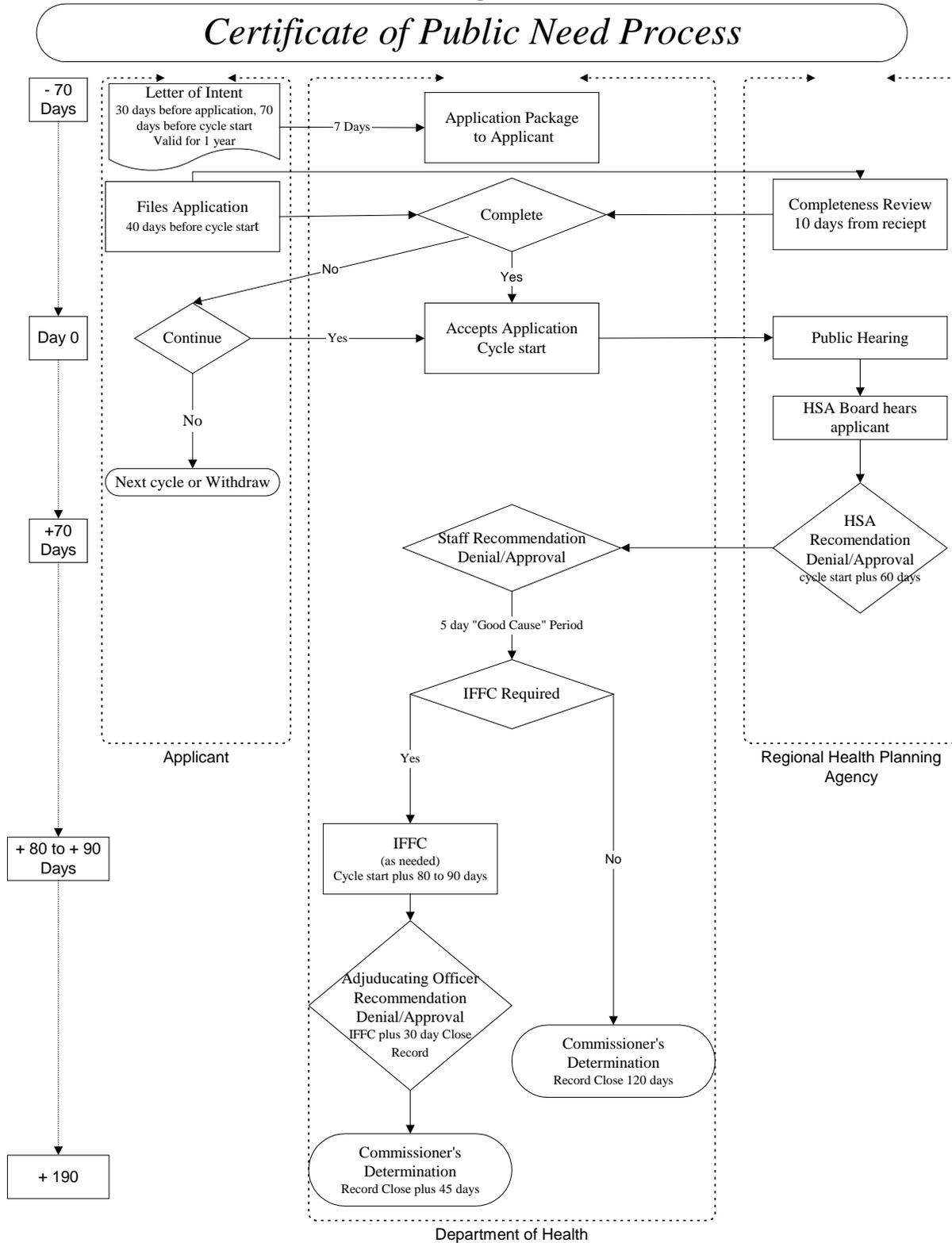
COPN Application Review Process and Decisionmaking

The components and required timeframes of the application review process are specified in statute and regulation. There is a pre-application phase, which includes submission of a letter of intent, and subsequent submission of an application. COPN applications are submitted in batches according to the type of project, as specified in regulation:

- A. General Hospitals/Obstetrical Services/Neonatal Special Care Services
- B. Open Heart Surgery/Cardiac Catheterization/Ambulatory Surgery Centers/Operating Room Additions/Transplant Services
- C. Psychiatric Facilities/Substance Abuse Treatment/Mental Retardation Facilities
- D. Diagnostic Imaging Facilities/Services, Selected Therapeutic Facilities/Services
- E. Medical Rehabilitation Beds/Services
- F. Selected Therapeutic Facilities/Services, Diagnostic Imaging Facilities/Services
- G. Nursing Home Beds at Retirement Communities/Bed Relocations/Miscellaneous Expenditures by Nursing Homes

Figure 2 illustrates the key steps and timelines in the COPN application review process.

Figure 2



Source: Virginia Department of Health

The applications are reviewed, and decisions made, during a 190-calendar day review cycle. A public hearing is held on each application, and an Informal Fact Finding Conference (IFFC) is sometimes necessary as part of the decision making process.

Letter of Intent and Application. The COPN Regulations require that a letter of intent must be submitted by the later of:

- 30 days prior to the submission of an application for a project included within a particular batch group or
- 10 days after the first letter of intent is filed for a project within a particular batch group for the same or similar services and facilities for the same area.

Applications must be submitted at least 40 days prior to the first day of a scheduled review cycle to be considered for review in the same cycle. VDH and the appropriate regional health planning agency, if a regional health planning agency has been designated, shall determine whether the application is complete or not. VDH is required to notify the applicant, if the application is not complete, of the information needed to complete the application.

Regional Health Planning Agency Review. Section 32.1-102.6 of the Code of Virginia states that the appropriate regional health planning agency shall

- review each completed application within 60 calendar days of beginning of the batch review cycle and
- hold one public hearing on each application in a location in the county or city in which the project is proposed or a contiguous county or city.

The regional health planning agency shall submit its recommendations on each application and its reasons therefore to VDH within 10 calendar days after the completion of its 60-calendar-day review.

Prior to 2009, each of Virginia's five health planning regions (Central, Northern, Eastern, Northwest and Southwest) had a regional health planning agency designated by the Board of Health. However, in 2009, four of the five regional health planning agencies suspended operations and dissolved, due to a lack of funding. Northern Virginia is currently the only health planning region with a regional health planning agency. The Code of Virginia has since been amended to require DCOPN to conduct the required public hearing if the application is from a region of the state without a designated regional health planning agency.

VDH Review. The VDH DCOPN is required to complete its review of the application, which includes a recommendation to the Commissioner concerning approval or denial of the application, by the 70th day of the review cycle. By the 75th day of the review cycle, VDH must determine whether an IFFC is necessary as part of the review process. An IFFC is required if either the regional health planning agency or DCOPN has recommended denial of the application, or if there are competing applications. VDH establishes a date between the 80th and 90th calendar days within the 190-calendar-day review period for holding an IFFC, which is conducted by the VDH Adjudication Officer.

At this point, it is possible for a non-applicant to seek to be made a party to the case. This is done through the filing of a "good cause" petition. Any person seeking to be made a party to the case for good cause shall notify VDH of his request on or before the 80th calendar day following the beginning of the batch review cycle. According to the statute, "good cause"

means that (i) there is significant relevant information not previously presented at and not available at the time of the public hearing, (ii) there have been significant changes in factors or circumstances relating to the application subsequent to the public hearing, or (iii) there is a substantial material mistake of fact or law in the Department staff's report on the application or in the report submitted by the health planning agency.

In any case in which an IFFC is held, a date shall be established for the closing of the record which shall not be more than 30 calendar days after the date of the IFFC. In any case in which IFFC is not held, the record shall be closed on the earlier of (i) the date established for holding the informal fact-finding conference or (ii) the date that VDH determines an IFFC is not necessary.

Commissioner's Decision. The Commissioner is required to make a decision on the application within 45 calendar days of the closing of the record. If a decision is not made within 45 days of the closing of the record, the Commissioner shall, give notice to the applicant(s) and any persons seeking to show good cause, that the application(s) shall be deemed approved 25 calendar days after expiration of the 45-day period, unless a decision is made within that 25-day period. In any case when a determination whether a public need exists for a project is not made by the Commissioner within 70 calendar days after the closing of the record, the application shall be deemed to be approved and the certificate shall be granted. The Code of Virginia states that the applicants, and only the applicants, shall have the authority to extend any of the time periods. If all applicants consent to extending any time period, the Adjudication Officer, with the concurrence of the applicants, shall establish a new schedule for the remaining time periods.

Process for Nursing Home Projects

Except for applications for continuing care retirement community nursing home bed projects the Commissioner shall only approve, authorize or accept applications for the issuance of any COPN only in response to Requests for Applications (RFAs) for any project which would result in an increase in the number of nursing facility beds in a planning district. The RFAs, which are required to be published at least annually, are jointly developed by VDH and the Department of Medical Assistance Services. RFAs are 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.

Need for New Service. A health planning district should be considered to have a need for additional nursing facility beds when:

1. The bed need forecast exceeds the current inventory of beds for the health planning district; and
2. The average annual occupancy of all existing and authorized Medicaid-certified nursing facility beds in the health planning district was at least 93%, excluding the bed inventory and utilization of the Virginia Veterans Care Centers.

No health planning district should be considered in need of additional beds if there are unconstructed beds designated as Medicaid-certified. This presumption of 'no need' for additional beds extends for three years from the issuance date of the certificate.

Exception to the RFA Process. The Commissioner may approve applications for the transfer of nursing facility beds from one planning district to another when no RFA has been issued in cases in which the applicant can demonstrate:

- (i) there is a shortage of nursing facility beds in the planning district to which beds are proposed to be transferred,
- (ii) the number of nursing facility beds in the planning district from which beds are proposed to be moved exceeds the need for such beds,
- (iii) the proposed transfer of nursing facility beds would not result in creation of a need for additional beds in the planning district from which the beds are proposed to be transferred, and
- (iv) the nursing facility beds proposed to be transferred will be made available to individuals in need of nursing facility services in the planning district to which they are proposed to be transferred without regard to the source of payment for such services.

Continuing Care Retirement Communities. Applications for continuing care retirement community (CCRC) nursing home bed projects can only be accepted if:

- the facility is registered with the State Corporation Commission as a continuing care provider,
- the number of new nursing home beds does not exceed the lesser of 20% of the CCRC's total number of non-nursing home beds or 60 beds,
- the number of new nursing home beds requested in any subsequent application does not cause the CCRC's total number of nursing home beds to exceed 20 percent of its total number of non-nursing home beds, and
- the CCRC has established a qualified resident assistance policy.

COPN Conditioning

Section 32.1-102.4 states that the Commissioner may condition the approval of a COPN (i) upon the agreement of the applicant to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care or (ii) upon the agreement of the applicant to facilitate the development and operation of primary medical care services in designated medically underserved areas of the applicant's service area, (iii) or both.

The certificate holder is required to provide documentation to VDH demonstrating that the certificate holder has satisfied the conditions of the certificate. VDH is allowed to approve alternative methods to satisfy the conditions pursuant to a plan of compliance. The plan of correction shall identify a timeframe within which the certificate holder will satisfy the conditions of the certificate, and identify how the certificate holder will satisfy the conditions of the certificate, which may include

- (i) making direct payments to an organization authorized under a memorandum of understanding with VDH to receive contributions satisfying conditions of a certificate,
- (ii) making direct payments to a private nonprofit foundation that funds basic insurance coverage for indigents authorized under a memorandum of understanding with VDH to receive contributions satisfying conditions of a certificate, or
- (iii) other documented efforts or initiatives to provide primary or specialized care to underserved populations.

Only contributions made over and above the amount that an applicant had been making prior to COPN approval count toward satisfying the condition. Any person willfully refusing, failing, or neglecting to honor such agreement shall be subject to a civil penalty of up to \$100 per violation per day until the date of compliance.

COPN Monitoring

A COPN is issued with a schedule for the completion of the project and a maximum capital expenditure amount. The schedule may not be extended and the maximum capital expenditure may not be exceeded without the approval of the Commissioner in accordance with regulations.

VDH DCOPN monitors each project for which a certificate is issued to determine its progress and compliance with the schedule and with the maximum capital expenditure. DCOPN also monitors all CCRCs for which a certificate is issued authorizing the establishment of a nursing home facility. Any willful violation of a provision of § 32.1-102.3:2 or conditions of a certificate of public need granted under the provisions of § 32.1-102.3:2 is subject to a civil penalty of up to \$100 per violation per day until the date the Commissioner determines that such facility is in compliance.

CERTIFICATE OF PUBLIC NEED IN OTHER STATES

Most states still have Certificate of Need programs, although specific requirements vary across the country. Virginia's COPN program is relatively comprehensive in nature. Attempts to evaluate the impact of CON programs in various states, while numerous, have been largely inconclusive.

35 States Have Certificate of Need Programs

More than two-thirds of the states still have some form of COPN program, although, unlike Virginia's program, most other states refer to their programs as Certificate of Need (CON) programs. Figure 3, compiled by the National Conference of State Legislatures, indicates that three states – Arizona, Minnesota and Wisconsin, have “variations” on Certificate of Need programs in their respective states. There can be considerable variation from one state to the next – particularly in terms of the scope of the program. Relative to other states, Virginia has a fairly comprehensive CON program in terms of the number of different type of facilities and services that are included (Figure 4).

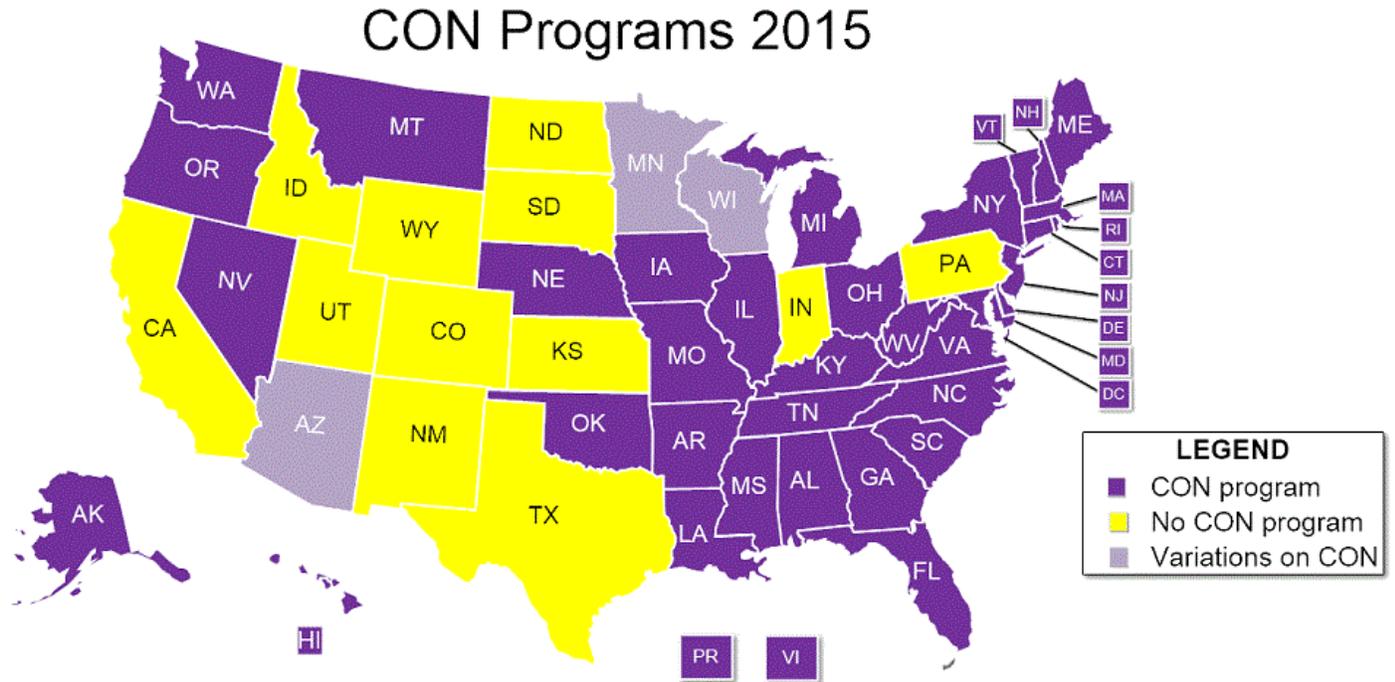
Attempts to Evaluate Impact of CON Programs Have Been Largely Inconclusive

The Workgroup compiled a wide range of studies that reported various findings concerning the impact, effectiveness or utility of CON programs across the country. Those studies have all been posted to the Workgroup's website. www.vdh.virginia.gov/Administration/COPN.htm

There are numerous challenges inherent in evaluating the impact of COPN programs. These include:

- Circumstances are different in every state (and among CON programs)

Figure 3



Notes: Wisconsin - The term "Certificate of Need" is not used in the relevant statutes, however the state maintains an approval process for nursing homes. Arizona - Applies only to ambulance services and ambulances. Minnesota - Conducts a "Public Interest Review" prior to determining whether to approve construction of a new hospital or an increase in the number of beds in an existing hospital.

Source: National Conference of State Legislatures.

Figure 4

Facilities and Services Subject to CON in Other States

Regulated Services	Number of States
Nursing Home Beds/Long Term Care Beds	35 + DC (including VA)
Acute Hospital Beds	28 (including VA)
Ambulatory Surgical Centers	27 (including VA)
Long Term Acute Care	26 + DC (including VA)
Cardiac Catheterization	26 (including VA)

Figure 4 (continued)
Facilities and Services Subject to CON in Other States

Regulated Services	Number of States
Psychiatric Services	26 (including VA)
Rehabilitation	25 (including VA)
Open Heart Surgery	25 (including VA)
Radiation Therapy	23 (including VA)
Neo-Natal Intensive Care	23 (including VA)
Source: VDH Staff Analysis.	

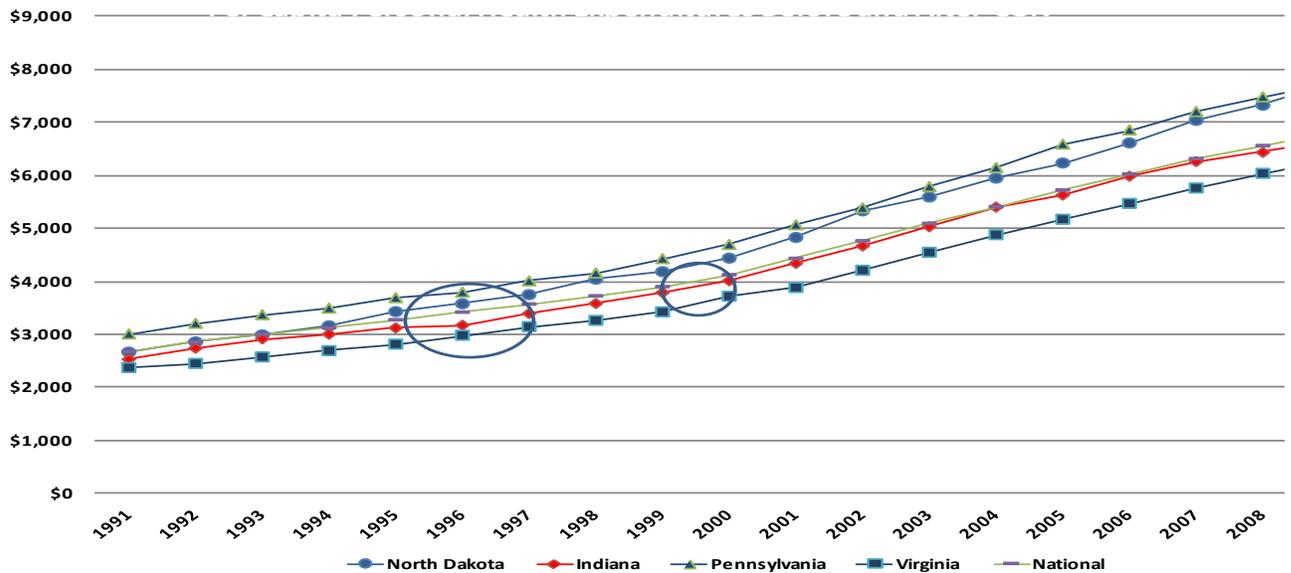
- Difficult to measure the relevant variables (e.g., quality, access, costs) or to even track the utilization of services
- Many difficult to measure factors affect the operation of the system and its attributes
- Very difficult to isolate, much less assess, the effect of CON regulation

Joint Commission on Health Care Analysis. Staff from the JCHC presented the results of analysis which looked at certain health care characteristics in states with and without CON. The results of the analysis provides an example of the difficulty in drawing conclusions about the impact of ending CON in a state., Figure 5 summarizes the results of JCHC’s analysis of per capita health care expenditures before and after CON was repealed in North Dakota, Indiana and Pennsylvania. These three states are among the most recent states to repeal CON.

JCHC found that both North Dakota’s (1995) and Pennsylvania’s (1996) per capita health expenditures were above the national average at the time they ended their CON programs and there was no marked change in the growth or decline rates of the per capita expenditures after the CON programs were eliminated. Indiana’s per capita health expenditures mirror the national per capita health expenditure trend line. JCHC staff told the workgroup that it is difficult to draw any conclusions about what happens when a CON program is ended in a state.

National Conference of State Legislatures Analysis. The National Conference of State Legislatures (NCSL) has conducted an extensive review of studies that have been cited, in some

Figure 5
North Dakota, Indiana and Pennsylvania
per capita health expenditures before and after the CON programs were eliminated



3

Source: Joint Commission on Health Care.

cases, by opponents of CON and, in other cases, by supporters of CON. NCSL’s summary of the opposing viewpoints is contained in Figure 6.

Federal Trade Commission Comments. A representative of the FTC told the workgroup that CON laws:

- Create or increase barriers to entry and expansion to the detriment of health care competition and consumers;
- Undercut consumer choice, stifle innovation, and weaken the market’s ability to contain health care costs; and
- Appear to have generally failed in their intended purposes of controlling growing health care costs, increasing quality of health care, and ensuring access to care for uninsured and underinsured in urban and rural areas.

American Health Planning Association Comments. A representative of the AHPA told the workgroup that many “questionable” assertions concerning COPN have been raised, including that its primary purpose is to:

- “Control” healthcare costs,
- Limit entry into the market,
- Protect existing providers, and
- Limit the expansion of services.

According to the AHPA, the following types of benefits are derived from COPN

- Improves access to care (especially for the underserved),
- Supports safety net hospitals,
- Supports rural hospitals,

Figure 6

C.O.N. SUPPORTERS' VIEWS	C.O.N. OPPONENTS' VIEWS
<p>Health care cannot be considered as a “typical” economic product. Many “market forces” do not obey the same rules for health care services as they do for other products. This makes hospital, lab and other services insensitive to market effects on price, and suggests a regulatory approach based on public interest. CONs can promote appropriate competition while maintaining lower costs for treatment services. By controlling construction and purchasing, state governments can oversee what expenditures are necessary and where funds will be used most effectively. A <u>study</u> conducted by the "big-three" automakers claims lower health care costs in CON states than in non-CON states. CONs have a valuable impact on the quality of care. When facilities and equipment are monitored, hospitals and other treatment centers can acknowledge what sort of services are in demand and how effectively patients are being taken care of. The CON process can call attention to areas in need because planners can track and evaluate the requests of hospitals, doctors and citizens and see which areas are underserved or need to be improved and developed.</p>	<p>"It is not clear that these state-sponsored programs actually controlled health care costs." In 2004 the Federal Trade Commission (FTC) and the Department of Justice both claimed that CON programs actually <i>contribute</i> to rising prices because they inhibit competitive markets that should be able to control the costs of care and guarantee quality and access to treatment and services.</p> <p>CON programs are not consistently administered. A 'flexible' program could allow development, to the dismay of competitors. A 'restrictive' program could limit competition, with the same effect. Many argued that health facility development should be left to the economics of each institution, in light of its own market analysis, rather than being subject to political influence.</p> <p>In theory, Certificates of Need are granted based on objective analysis of community need, rather than the economic self-interest of any single facility. However, opponents of CON programs claim that the programs have not worked this way. They cite examples in which CONs were apparently granted on the basis of political influence, institutional prestige or other factors apart from the interests of the community.</p>

Source: VDH Staff Analysis of Information Compiled by National Conference of State Legislatures.

- Assures availability of services to the community,
- Assures the provision of charity care,
- Establishes standards for the provision of services,
- Prevents unqualified entities from providing certain services,
- Limits excess bed capacity,
- Discourages unnecessary growth/expansion,
- Standardizes processes for service and facility development, and
- Creates a forum for public involvement and discussion.

FRAMEWORK OF ISSUES DEVELOPED BY WORKGROUP

At its September 28, 2015 meeting, the Workgroup reviewed and discussed a draft framework of potential ideas for recommendations. Following the September 28th meeting, workgroup members submitted written comment concerning the draft framework (Appendix G).

Based on the written comments and subsequent discussion, the workgroup focused on the following issue and topics within the context of the study mandate:

- Purpose and Objectives of Virginia’s COPN Program,
- Review and Update of the State Medical Facilities Plan,
- Process for Submission and Review of COPN Applications,
- Conditioning of COPNs,
- Transparency of the COPN Program,
- Process for Evaluating Whether Certain Facilities and Projects Should Remain Subject to COPN Requirements, and
- Virginia Department of Health Resources to Administer the COPN Program.

Purpose and Objectives of Virginia’s COPN Program

When the COPN statute was first enacted in 1973, it contained a statement of purpose. The statement of purpose said, in part, “The purpose of this chapter is to promote comprehensive health planning in order to help meet the health needs of the public; to assist in promoting the highest quality of health care at the lowest possible cost; to avoid unnecessary duplication by ensuring that only those medical care facilities which are needed will be constructed; and to provide an orderly administrative procedure for resolving questions concerning the necessity of construction or modification of medical care facilities.” The statement of purpose was repealed in 1979 as part of a re-codification of the statute.

There was consensus within the workgroup that the COPN program should have a clear statement of purpose. Several workgroup members suggested that the Institute for Healthcare Improvement’s (IHI) Triple Aim serve as the basis for a statement of purpose. The Triple Aim is a framework developed by IHI that describes an approach to optimizing health system performance. It is IHI’s belief that new designs must be developed to simultaneously pursue three dimensions:

- Improving the patient experience of care (including quality and satisfaction);
- Improving the health of all people in Virginia; and
- Reducing the per capita cost of health care.

Recommendation:

1. The Code of Virginia should be amended to establish a statement of purpose for COPN that reflects the components of the IHI’s Triple Aim (patient experience of care, population health and cost), and that is also reflective of promoting access to care.

Review and Update of the State Medical Facilities Plan

The workgroup had extensive discussions concerning the frequency and process by which the SMFP is reviewed and updated. The provisions of the SMFP, contained in the Virginia Administrative Code (12VAC5-230), have not been updated via regulatory amendment since 2009. The report of the VHHA COPN Task Force states that “The lack of regular reviews and revisions to the SMFP dilutes the SMFP’s relevance and undermines the effectiveness of the COPN law.” The VHHA report also states:

If the SMFP provisions are outdated and not in line with current practice, then project analysts, the Hearing Officer and the Commissioner cannot rely on them when making their COPN recommendations and decisions. This leads to greater

discretion and variation in decision making and can lead to less consistency in decisions overall.

A Notice of Intended Regulatory Action (NOIRA) was published on June 29, 2015 to implement recommendations issued by the SMFP Task Force on October 30, 2013. The intent of this regulatory action is to correct several definitions in relation to cardiac catheterization as well as the occupancy standard utilized for determining the need for new nursing home beds. The public comment period for the NOIRA ended on July 31, 2015. VDH has prepared draft proposed amendments to the SMFP, but has not yet submitted them pending finalization of the COPN Workgroup's recommendations.

The SMFP Task Force last met on July 29, 2015 to review provisions concerning mental health services. Two subcommittees were established, one for need methodology and one for travel time criteria. The subcommittees met on October 28, 2015. Recommendations have not yet been issued.

The workgroup discussed potential options for enabling more timely review and update of the SMFP. The State regulatory process prescribed by the Virginia Administrative Process Act, which typically requires 18-24 months to complete the standard three-stages of NOIRA, proposed and final amendments, can be an obstacle to timely updates to the SMFP following completion of review by SMFP Task Force. State law does allow for an expedited "Fast Track" process for regulatory actions that are considered to be non-controversial. However, if ten or more individuals object to a Fast Track regulatory action – either due to the substance of the action or the fact that it is being expedited – the Fast Track action automatically reverts to a NOIRA. VDH believes that, to the extent that the SMFP Task Force follows a process that leads to consensus recommendations reflective of views of the broader community of stakeholders, the Fast Track process can be used to update the SMFP.

Another potential way to expedite updates to the SMFP would be to remove it from regulation by repealing 12VAC5-230, and having the State Board of Health approve the SMFP as a non-regulatory health planning document. However, the Office of the Attorney General has advised VDH that, since the SMFP clearly affects COPN applications and because it has provisions that envision compliance, it has the force of law and must be promulgated as a regulation. While the SMFP must remain in regulation, consideration could be given to exempting the SMFP from many of the requirements of the Administrative Process Act (APA), while still requiring a public comment period and public hearing on any proposed amendments. The State Air Pollution Control Board and the Board of Housing and Community Development currently have this type of exemption from the APA.

Another obstacle to the timely review and update of the SMFP is the limited number of staff within the DCOPN. Staffing within DCOPN has been reduced from 7.5 full-time equivalent (FTE) positions in FY10 to 5 FTE in FY15. The same staff responsible for review of COPN applications are responsible for making revisions to the SMFP. Unlike some other states (e.g., North Carolina and Georgia) DCOPN does not have dedicated staff for the SMFP.

The workgroup also discussed the need to create a robust SMFP that is more objective and data-driven, with more specific definitions and formulas for determining need and service expansion requirements, and that relies upon verifiable, well-sourced utilization data. Along these lines, the workgroup had discussions concerning how the SMFP should relate to and be

aligned with broader health planning and health policy data and issues. A State Health Improvement Plan—with a focus of improving population health—is currently under development by VDH in conjunction with a wide range of public and private sector stakeholders. The framework for the plan is based on the foundation of a healthy, connected community which supports a strong start for children. Two of the pillars of the framework are quality healthcare and preventive actions, both of which support physical and emotional wellness and aging well. The VHHA report states:

Facilities, health care services, and medical equipment planning, which is the purpose of the SMFP, should be part of any statewide health plan. Similarly, the SMFP should be integrated with, or at least take into consideration, the state plan for population health. By understanding how facilities, health care services, and medical equipment planning fits into the Commissioner's overall plan, hospitals and other medical care facilities can better plan for changes and updates to their individual facility plans.

The workgroup discussed that the VHI patient level database could potentially be used to help inform decisions about population health needs and the appropriate placement of regulated facilities and services.

Section 32.1-122.03 of the Code of Virginia authorizes, but does not require, the State Board of Health to develop a State Health Plan:

A. The Board may develop, and revise as it deems necessary, the State Health Plan with the support of the Department and the assistance of the regional health planning agencies. Following review and comment by interested parties, including appropriate state agencies, the Board may develop and approve the State Health Plan. The State Health Plan shall be developed in accordance with components and methodologies that take into account special needs or circumstances of local areas. The Plan shall reflect data and analyses provided by the regional health planning agencies and include regional differences where appropriate. The Board, in preparation of the State Health Plan and to avoid unnecessary duplication, may consider and utilize all relevant and formally adopted plans of agencies, councils, and boards of the Commonwealth.

B. In order to develop and approve the State Health Plan, the Board may conduct such studies as may be necessary of critical health issues as identified by the Governor, General Assembly, Secretary or by the Board. Such studies may include, but not be limited to: (i) collection of data and statistics; (ii) analyses of information with subsequent recommendations for policy development, decision making and implementation; and (iii) analyses and evaluation of alternative health planning proposals and initiatives.

VDH has not developed or published such a plan for approval by the Board of Health in many years. However, development of the State Health Improvement Plan would be consistent with and responsive to this statutory authority.

Recommendations:

- 2a. The SMFP should be reviewed and updated in a timely and rigorous manner.
- 2b. The SMFP task force should be convened to review the SMFP and propose restructuring of the plan, consider additional criteria, and recommend other changes.
- 2c. VDH should determine the type and amount of any additional required resources necessary to comply with statutory requirements for review and update of the SMFP.

- 2d. The SMFP should be aligned with the goals and metrics of the State Health Improvement Plan and be renamed the State Health Services Plan.
- 2e. The Code of Virginia should be amended to establish statutory requirements for the process by which the SMFP is reviewed and updated.
- 2f. The Code of Virginia should be amended to exempt the SMFP from the provisions of the Administrative Process Act, subject to requirements that a Notice of Intended Regulatory Action be published, and a public comment period including a public hearing be held prior to the effective date of the revised SMFP.
- 2g. VDH should prepare and submit all future amendments to the SMFP as Fast Track Regulatory Actions.
- 2h. The Code of Virginia should be amended to require annual review of the SMFP and an update of the SMFP every 2 years.
- 2i. The State Health Commissioner should assess the current organization and composition of the SMFP Task Force and make recommendations to the State Board of Health if any changes in the organization, composition or manner of appointment are deemed advisable. The assessment should also address any need for a defined quorum for meetings of the SMFP Task Force.

Process for Submission and Review of COPN Applications

The workgroup engaged in extensive discussions concerning numerous aspects of the process for submission and review of COPN applications. Much of that discussion focused on the type and amount of information required by VDH to review an application, the amount of time required for review, as well as the standards and criteria by which decisions are made.

The VHHA report states that COPN application forms do not reflect current COPN review requirements and should be updated to reflect current information needs.

For example, the nursing home application form requires submission of substantial information such as staffing by shift, hours per staff member, pro forma data by payer mix, and bed complement by type of unit, which is not relevant to evaluation of the Eight Statutory Considerations or SMFP requirements. Additionally, the nursing home application requires a copy of the state licensing survey, which is available to DCOPN through the Office of Licensure and Certification; so it is unclear why it is requested as part of the COPN application process.

Section 32.1-102.6 of the Code of Virginia requires VDH to notify an applicant if the application is not complete, and the information needed to complete the application. The VDH DCOPN informed the workgroup that it experiences the submission of substantially incomplete applications, even blank forms with just a title page and signature page completed. Establishment of minimum acceptability thresholds for application submittal could reduce the burden on DCOPN staff to ask for materials, and potentially reduce the amount of time between the application deadline and the completeness response deadline.

The COPN Regulations could be amended to actually define a complete application. Regulatory amendments could specify that:

- An application will be considered complete when all relevant sections of the application form have substantive responses.
- The applicant should be satisfied that they have provided sufficient information to make their case that a public need for the requested project exists without the addition of supplemental or supporting material at a later date.
- VDH may seek, at its discretion, additional information from the applicant or other sources.

The length of the standard COPN review cycle is 190 days, although the review of applications does not take that long in every instance. The workgroup discussed potential options to reduce the length of the standard review cycle. These discussions revealed that the authority of VDH to conduct expedited reviews of applications is currently limited by statute to review of projects as defined in 32.1-102.1(8):

Any capital expenditure of \$15 million or more, not defined as reviewable in subdivisions 1 through 7 of this definition, by or on behalf of a medical care facility other than a general hospital.

According to DCOPN, rarely if ever would a medical facility other than a general hospital have a \$15 million dollar capital expenditure that was not otherwise reviewable as a COPN project. Consequently, VDH's current statutory authority to conduct expedited reviews of projects is virtually non-existent.

COPN regulations (12VAC5-220-310) currently establish a 45-day review cycle for any application submitted for expedited review. The workgroup, in conjunction with DCOPN, identified potential approaches to greater use of expedited review. In the event that greater use of expedited review occurs within the COPN program, the full 190-day review cycle would be retained in order to accommodate applications for projects that are of such magnitude, complexity and controversy as to require all of the time allotted.

45-Day Abbreviated Review. This type of review – which would require statutory and regulatory amendment - could be used for those types of projects that are generally non-contested and/or raise comparatively few health planning concerns. VDH would need to develop a process for reviewing applications in a 45-day period and identifying the conditions under which such applications would require transition to a standard review cycle and establish requirements for COPNs issued pursuant to a 45-day abbreviated review process, including conditions for indigent care and quality assurance. The analytical framework described in Recommendation 6b should be applied to determine whether any project type should be eligible for abbreviated review.

Reducing the Standard Review Cycle and Increasing the Number of Annual Batch Review Cycles. The workgroup also considered potential approaches to shortening the application review process that, rather than utilizing expedited review as an exception to the standard 190-day cycle, shortened the standard cycle itself and increased the number of annual review cycles beyond the current two. In order to have three annual batch review cycles, each annual cycle – from initial application to Commissioner's decision - would be 120 days:

- Proportional to the 190-cycle, a 90-day cycle would result in 44 days (instead of the current 70) for DCOPN review, conduct of a public hearing and recommendation.

- A 120-day cycle would result in 76 days (instead of the current 120) for review by the VDH Adjudication Officer and the Commissioner's decision.

More frequent cycles would also require more complete and robust submissions from the applicants as the opportunity for asking questions of the applicant, collecting and accessing public comment, and conducting independent investigation by DCOPN analysts would be significantly reduced.

The workgroup also discussed the possibility of revising public hearing requirements in order to potentially expedite the COPN application review and decision making process. According to DCOPN, at many of the public hearings the only attendees are DCOPN staff and the applicant. There is a cost, in terms of both money and time, both for both VDH and the applicant, in advertising and holding the public hearing. The opportunity to submit written comments has always existed. Written comments can be accepted any time up to when the decision is made. However, the workgroup concluded that the public hearing is an important part of the process and should not be eliminated. There were additional suggestions from the workgroup that VDH explore alternative means of obtaining public comment.

A member of the Workgroup commented that greater clarity and guidance is needed in COPN review. For example, the role of the SMFP in COPN decisions could be clarified to allow DCOPN to recommend approval of an application, and the Commissioner to authorize a project, that is "in general agreement with" the SMFP, even if not strictly compliant with it.

The workgroup discussed the possibility of repealing the requirement for registration of replacement medical equipment. This requirement is found at § 32.1-102.1:1 of the Code of Virginia. The only reason for registration is that so DCOPN can determine if the replacement costs exceed the capital threshold requiring a new COPN. Given the current amount of the capital threshold (\$18 million), this never occurs. However, several members of the workgroup expressed concern with repealing this requirement, as registration provides information which can indicate if equipment originally obtained pursuant to a COPN was subsequently replaced (without need for a COPN) with an inferior version. The suggestion was made to collect additional information concerning the specific type of equipment as part of required utilization reporting to Virginia Health Information (VHI.) According to VHI, this type of additional information can be collected.

The workgroup identified a discrepancy between statutory and regulatory requirements for filing of good cause petitions. The COPN statute requires that a petition for good cause be filed "on or before the eightieth calendar day following the day which begins the appropriate batch review cycle." However, the COPN regulation states that a petition for good cause shall be filed "no later than four days after the department has completed its review and recommendation of an application and has transmitted the same to the applicants and to persons who have prior to the issuance of the report requested a copy in writing." The dates can vary by several days depending on whether the statutory or regulatory deadline is used, adding uncertainty to the process.

Recommendations:

- 3a. The process for submission and review of COPN applications should be streamlined.
- 3b. VDH should evaluate COPN application forms to ensure that only data necessary for review of an application is required to be submitted and that the forms reflect

- statutory requirements. The Virginia Department of Health should make all necessary revisions to the forms.
- 3c. The Code of Virginia and the COPN regulations should be amended to require that a COPN application be substantially complete at the time of submission.
 - 3d. VDH should develop recommendations to reduce the standard review process to not more than 120 days from the receipt of the letter of intent. VDH shall consider changes in the current process to effect such a reduction in the length of the review process, including but not limited to changes reflected in other study recommendations as well as: elimination or reduction of the "completeness" period between the submittal of an application and its acceptance as "complete," reduction of the current 70-day period for DCOPN review of an application, and earlier scheduling of a public hearing.
 - 3e. VDH should: i) assess projects that may be appropriate for a 45-day expedited review process, which may include projects that are generally non-contested and/or raise comparatively few health planning concerns; ii) develop a process for reviewing such applications in a 45-day review period and identify the conditions under which such applications would require transition to a standard review cycle, and; iii) establish requirements for COPNs issued pursuant to a 45-day expedited review process, including conditions for indigent care and quality assurance. The analytical framework described in Recommendation 6b should be applied to determine whether any project type should be eligible for expedited review.
 - 3f. The role of the SMFP in COPN decisions should be clarified to allow DCOPN to recommend approval of an application that is in general agreement with the SMFP.
 - 3g. VDH should work with VHI to develop a process for the collection of data, as part of required utilization reporting, concerning the specific type of equipment utilized.
 - 3h. The filing timeline for good cause petitions should be clarified to resolve the discrepancy between the statutory and regulatory requirement.

Conditioning of COPNs

The workgroup discussed conditioning with a focus on how charity care is defined and calculated for purposes of establishing conditions of COPN. The workgroup observed that differing definitions at the state level tends to create confusion among stakeholders and policymakers in assessing the role of COPN in helping to assure provision of charity care. The workgroup also focused on the process by which VDH DCOPN monitors the compliance of COPN holders in satisfying the conditions. There was general consensus among the workgroup members that the VDH monitoring process needs to be strengthened.

Definition of Charity Care. There is no definition of charity care in statute or regulation. Prior to the repeal of the Indigent Health Care Trust Fund in 2009, § 32.1-332 of the Code of Virginia defined charity care as “hospital care for which no payment is received and which is provided to any person whose family income is less than 100 percent of the federal poverty level.” VDH issued a Guidance Document in March 2004 titled “Compliance with Conditions of Certificates of Public Need.” The guidance document contains the following definitions:

- *Charity care* means health care services delivered for which it was determined at the time of service provision that no payment was expected.
- *Indigent* means any person whose gross annual family income is equal to or less than 200 percent of the Federal Non-Farm Poverty Level as published for the then current year in the Code of Federal Regulations. This equates to individuals whose household income is at income levels A through E as defined in the Virginia Administrative Code at 12 VAC5-200-10.
- *Indigent Care* means health care services delivered as charity care to patients who are indigent.

Inpatient Hospitals, Outpatient Surgical Hospitals and other licensed health care facilities are required by law to report charity care information to VHI. This information is reported to VHI as part of the Efficiency and Productivity Information Collection System (EPICS.) The following definitions are utilized by VHI:

- *Charity care* - Total established full charges for services to indigent patients at 100%, between 100% and 200% and in excess of 200% of the federal non-farm poverty level as well as any charity care for which partial payment is received. Charity care expense is reduced by the amount of disproportionate share allocated to state teaching hospitals (currently UVA and VCU).”
- *Charity care at 100% of the poverty level* - care for which no payment is received and that is provided to any person whose gross annual family income is equal to or less than 100% of the federal non-farm poverty level as published for the then current year in the Code of Federal Regulations.
- *Charity Care for which partial payment is received* - persons who qualify for discounted payments in accordance with the hospital’s or health system’s charity care policy. This category may include persons who are uninsured or insured. It may also include persons at 100%, at 200% or over 200% of the FPL for which partial payment is received OR who qualify for discounted payments due to the hospital or health system’s policy regarding medically indigent or catastrophic cases.

VDH Compliance Monitoring. Reports of indigent and primary care provided in compliance with COPN conditions are reported annually to DCOPN based on either the COPN holder’s fiscal year or the calendar year. The specific time period is selected by the COPN holder, and reports are due within 90 days of the end of the reporting period. The amounts of care provided are reported on the basis of provider charges. The reports received by VDH are hard-copy, paper documents. Historically, due to lack of staff resources, DCOPN has not attempted to verify the data concerning the amount of provided that is self-reported by COPN holders. This was considered to be a significant shortcoming by the workgroup. One possible method of verification would be to compare the information reported to VDH with the data maintained by VHI. However, since VDH and VHI define charity care somewhat differently, the utility of such a comparison could be limited. DCOPN is supportive of revising its definition of charity care so that it is in better alignment with the VHI definition.

Several workgroup members commented concerning perceived deficiencies in how charity care is currently calculated and reported. This included statements that many health care providers have no way of knowing the income level of their patients. Other workgroup members expressed dissatisfaction with the use of self-reported provider charges as the basis for reporting. Some workgroup members suggested that the COPN program should focus on measurement of charity care by a provider’s Relative Value Units (RVUs) multiplied by either a Medicaid or

Medicare conversion factor, rather than being based on provider charges. There was also discussion concerning the extent to which “uncompensated care” should include deductibles, co-insurance, contractual allowances or bad debt. In addition, there was discussion as to whether charity care contributions in response to COPN conditions should be made to the Virginia Health Care Fund (§ 32.1-67). According to the VHHA report, “charity care:”

should be defined in statute or by regulation and that definition should be used consistently in COPN application forms, DCOPN guidance documents, EPICS and in the application of the Eight Statutory Considerations.

The workgroup determined that further review, in conjunction with stakeholders, was required in order to determine the most appropriate definition of charity care for purposes of the COPN program.

Expansion of Commissioner’s Authority to Condition. The authority of the Commissioner to impose conditions on COPNs is specified in statute. The workgroup discussed whether and how the current statutory authority to condition could be expanded. Possibilities mentioned include authority to condition for services agreeing to reach nationally-recognized standards of care, or for agreeing to achieve specified objectives related to population health-consistent with the State Health Improvement Plan. The workgroup determined that further review was required to determine the appropriateness of expanding the Commissioner’s authority to condition COPNs.

Recommendations:

- 4a. Rules regarding the conditioning of COPNs, including the process for defining and calculating charity care, should be clarified, standardized and enforced.
- 4b. The Secretary of Health and Human Resources and VDH should study and review charity care services delivered throughout the Commonwealth and recommend changes to the definition of charity care imposed across providers. A report shall be submitted to the General Assembly prior to the 2017 Session.
- 4c. The Secretary of Health and Human Resources should convene stakeholders to explore appropriate authority for the Commissioner to impose additional conditions on COPNs consistent with the SMFP and the Virginia State Population Health Plan.
- 4d. VDH should assess the capacity of DCOPN to monitor compliance with conditions imposed on COPNs. Based on that assessment, VDH should determine if additional resources are needed to support administration of this function.

Transparency of the COPN Program

During the workgroup’s deliberations, there was considerable discussion and a general consensus that VDH needed to do a much better job in making COPN information readily available to the public. According to the VHHA report greater transparency is needed in public records pertaining to COPN applications and review process:

DCOPN retains public records pertaining to COPN applications and the COPN review process, including, but not limited to LOI filings, applications, DCOPN and RHPA staff reports and recommendations, IFFC transcripts and exhibits, Adjudication Officer’s recommended decisions, and Commissioner decisions. Access to this information is necessary to evaluate whether and when COPN

applications should be filed, whether a COPN application is likely to be approved or denied, how the Commissioner has rendered decisions on similar projects in the past, and other information critical to assessing the COPN review process. In order for any public citizen to access such information, it is necessary to request the information by telephone or in writing from DCOPN staff or in some instances to file a Freedom of Information Act (“FOIA”) request.

The ability to have prompt access to LOI filings is particularly important. Because of the way the COPN process is structured, the timing and filing of LOIs affect the ability to file competing applications within a review cycle. Without prompt access to information on LOI filings, potential applicants are forced to continually query DCOPN for information on the status of LOIs that have been filed.

Additional types of documents and information that could potentially be made available include completeness responses, public hearing scheduling information, commentary from opponents and interested parties, and good cause petitions. It could also include extension and significant change requests and decisions; applicability determinations; and updated capital expenditure thresholds for registration and COPN authorization.

Some workgroup members commented that utilization data reporting requirements are not clear and the availability of reports is significantly delayed. For example, the prior year’s utilization is not available from VHI until November of the following year. That time lag means that a diagnostic imaging application reviewed in early 2016 will rely on 2014 data. The timeline for data reporting to VHI is governed by state regulations, Methodology to Measure Efficiency and Productivity of Health Care Institutions (12-VAC5-216):

Each health care institution...will submit an annual historical performance filing as prescribed in § 32.1-276.7 of the Code of Virginia...[which] will be used to collect audited financial information and other information for all of the categories listed in 12VAC5-216-40. It will provide the basis for the evaluation by the board. The annual historical performance filing shall be received by the board within 120 days after the close of the health care institution's fiscal year.

VHI policies allow facilities to request a single 30-day extension or, if the facility has long-term care unit, a single 45-day extension for the filing due date.

Recommendations:

- 5a. The transparency of the COPN program to the public should be increased.
- 5b. A real-time automated/electronic tracking and posting mechanism for Letter of Intent (LOI) filings should be implemented to make LOIs available to the public as soon as they are received.
- 5c. An online library should be created where all relevant COPN information and documents are posted and easily available to the public.
- 5d. The collection of COPN-relevant data and the availability of such data should be improved and standardized by:
 - Clarifying rules for reporting utilization of operating rooms and procedure rooms.
 - Expediting publication of VHI reports.

- Maintaining an accessible inventory of all COPN-authorized (operational and not yet operational) providers/beds/units for all COPN-reviewable services.
- 5e. VDH should assess the cost of implementing 1) a real-time automated/electronic tracking and posting mechanism for LOI filings, 2) creating an online library of all relevant COPN applications and documents, and 3) maintaining an accessible inventory of all COPN authorized providers/beds/units, and 4) on-line publishing of charity care conditions, compliance reporting status, details on the exact amount provided and/or contributed, and to whom. Based on that assessment, VDH should determine if additional resources are needed to fund the cost of implementation.

Process for Evaluating Whether Certain Facilities and Projects Should Remain Subject to COPN Requirements

The workgroup discussed whether the study mandate authorized the workgroup to consider whether or not certain types of medical facilities and projects should continue to remain subject to COPN requirements. The workgroup's discussions revealed differences of opinion and a lack of consensus concerning the appropriateness of continued COPN regulation for many different types of projects. The discussions further revealed the absence of an adequate data-driven, analytical framework to support the development of specific recommendations for the elimination of COPN requirements for certain types of facilities and projects. Prior to 2012, a semblance of such a framework, albeit in somewhat limited form, existed at the state level in the form of the COPN Annual Report.

COPN Annual Report Formerly Prepared by VDH. In 1997, the General Assembly enacted § 32.1-102.12 of the Code of Virginia. This statute required the State Health Commissioner to report annually to the Governor and the General Assembly on the status of the COPN program. The report was required to include:

1. A summary of the Commissioner's COPN actions during the prior fiscal year;
2. A five-year schedule for analysis of all project categories which provides for analysis of at least three project categories per year;
3. An analysis of the appropriateness of continuing the certificate of public need program for at least three project categories in accordance with the five-year schedule for analysis of all project categories;
4. An analysis of the effectiveness of the application review procedures used by the regional health planning agencies, if any, and the Department required by § 32.1-102.6 which details the review time required during the past year for various project categories, the number of contested or opposed applications and the project categories of these contested or opposed projects, the number of applications upon which the regional health planning agencies have failed to act in accordance with required timelines, the number of applications reviewed in health planning regions for which no regional health planning agency was designated, and the number of deemed approvals from VDH because of its failure to comply with required timelines, and any other data determined by the Commissioner to be relevant to the efficient operation of the program;
5. An analysis of health care market reform in the Commonwealth and the extent, if any, to which such reform obviates the need for the certificate of public need program;
6. An analysis of the accessibility by the indigent to care provided by the medical care facilities regulated pursuant to this article and the relevance of this article to such access;

7. An analysis of the relevance of this article to the quality of care provided by medical care facilities regulated pursuant to this article; and
 8. An analysis of required equipment registrations, including the type of equipment, whether an addition or replacement, and the equipment costs.
- VDH prepared and submitted annual reports pursuant to this requirement through 2011.

VDH established a five-year schedule for analysis of all project categories within the current scope of COPN regulation that provided for analysis of at least three project categories per year. Although there was some variation over the years depending on the type of project being analyzed, the VDH analysis tended to focus on volume of COPN applications, extent to which applications were approved, and service utilization. Many of the recommendations in these annual reports called for the continuation of COPN requirements. However, there were also recommendations to remove COPN requirements for certain types of services (i.e., lithotripsy, obstetrical beds, and nuclear medicine imaging services), and to expand the use of a Request for Applications Process for other types of services. In addition, many of the recommendations either envisioned, or specifically called for, revisions to the SMFP.

The 2011 COPN Annual Report contained the following recommendations:

- *Make changes to the review criteria in the State Medical Facilities Plan necessary to remain current and continue applying the COPN program to the establishment of new medical care facilities for psychiatric services and the addition of psychiatric capacity at existing programs as currently mandated.*
- *Continue applying the COPN program to miscellaneous capital expenditures as currently mandated. The annual adjustment of the capital threshold defining the project keeps the review of this category in the range of very significant capital expenditures.*

The 2010 COPN Annual Report contained the following recommendations:

- *Make changes to the review criteria in the State Medical Facilities Plan necessary to remain current and continue applying the COPN program to the establishment of new medical care facilities for radiation therapy and the addition of radiation therapy capacity at existing programs as currently mandated.*
- *Support efforts to deregulate COPN as it applies to lithotripsy.*
- *Support efforts to deregulate COPN as it applies to the addition of obstetrical services while controlling the conversion of obstetric beds to prevent deregulation of obstetric services from being used as a means for circumventing COPN for the addition of other bed types.*
- *Make changes to the review criteria in the State Medical Facilities Plan necessary to remain current and continue applying the COPN program to the introduction of neonatal special care as currently mandated.*

The 2009 COPN Annual Report contained the following recommendations:

- *Expand the Request for Applications process to include the establishment of medical rehabilitation hospitals, the introduction of medical rehabilitation services, and the addition of medical rehabilitation beds based on a*

collaborative review with affected parties to determine the need for, and location of, such additional facilities and services. This would meet the planned need for new services in appropriate planning districts in a market competitive manner and improve access.

- *Expand the Request for Applications process to include the establishment of long-term acute care hospitals and the addition of long-term acute care beds based on a collaborative review with affected parties to determine the need for, and location of, such additional facilities and services. This would meet the planned need for new services in appropriate planning districts in a market competitive manner and improve access.*
- *Continue to apply the COPN program, with the Request for Applications element, to nursing home services with the modification of the State Medical Facilities Plan, as needed.*
- *Support any effort to complete the deregulation of ICF/MR services.*

The 2008 COPN Annual Report contained the following recommendations:

- *With appropriate standards in the State Medical Facilities Plan, COPN regulation of CT imaging appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to CT services with the modification of the State Medical Facilities Plan, as needed.*
- *With appropriate standards in the State Medical Facilities Plan, COPN regulation of MRI appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to MRI services with the modification of the State Medical Facilities Plan, as needed.*
- *With appropriate standards in the State Medical Facilities Plan, COPN regulation of PET appropriately limits the supply of the service and avoids unnecessary duplication of the service. Therefore it is recommended that Virginia continue to apply the COPN program to PET services with the modification of the State Medical Facilities Plan, as needed.*
- *Since nuclear medicine imaging has already be partially de-regulated in regards to COPN there seems to be little utility in continuing to require COPN authorization for the few circumstances still under COPN review. Therefore it is recommended that Virginia support any effort to complete the deregulation of nuclear medicine imaging services.*
- *Since the technology has not yet become generally available it is recommended that Virginia continue to apply the COPN program to MSI services with the modification of the State Medical Facilities Plan, as needed until such time as the service comes into general use and then re-evaluate the need to regulate MSI.*

The 2007 COPN Annual Report contained the following recommendations:

- *Consistent with the recommendation to the HWI COPN Task Force make no change to General Hospital Services outside the efforts to update the State Medical Facilities Plan.*

- *Consistent with the recommendation to the HWI COPN Task Force make no change to General Surgery Services outside the efforts to update the State Medical Facilities Plan.*
- *Consistent with the recommendation to the HWI COPN Task Force make no change to Cardiac Catheterization Services outside the efforts to update the State Medical Facilities Plan.*
- *Consistent with the recommendation to the HWI COPN Task Force make no change to Organ and Tissue Transplantation services outside the efforts to update the State Medical Facilities Plan.*

The 2006 COPN Annual Report contained the following recommendations:

- *Expand the Request for Applications process to include the establishment of facilities and addition of beds for psychiatric services based on a collaborative review with affected parties to determine the need for, and location of, such additional facilities and services. This would meet the planned need for new or expanded services in appropriate planning districts in a market competitive manner and improve access.*
- *Continue applying the COPN program to miscellaneous capital expenditures as currently mandated. Ongoing efforts to review, and where appropriate, update the SMFP will address necessary changes to the review criteria.*

This annual reporting requirement was repealed by the 2012 General Assembly.

If the type of “appropriateness analysis” contained with the COPN Annual Reports were to be re-instituted at the state level, the analysis would ideally incorporate and examine a wider range of data than was utilized prior to 2012. A robust analysis would be a staff-intensive effort for VDH. However, such analysis would involve not just the VDH Office of Licensure and Certification, but would be supported by VDH population health planning staff located in other parts of the agency. The envisioned data-driven analysis would be based on a framework in which the State Health Services Plan is aligned with the goals and metrics of Virginia’s State Health Improvement Plan. The analysis could be used to 1) help identify gaps and needs so as to inform development and update of State Health Services Plan, and 2) subsequently inform decision making concerning continued appropriateness of COPN requirements for specific facilities and services.

The workgroup discussed potential approaches to developing an appropriate analytical framework. Some workgroup members suggested focusing initially on projects that have never been or are rarely denied, have low capital requirements, and/or have previously been recommended for deregulation in the COPN Annual Reports. The three phases of the 2001 JCHC COPN deregulation plan were based on a recognition that COPN project categories differed in terms of their cost impact and complexity/risk. In developing an analytical framework to review projects for their continued appropriateness for COPN regulation, the construct utilized in the JCHC plan could be expanded upon to develop a multi-year schedule for review of COPN project categories in order of their relative cost impact and complexity/risk. For example:

- MRI, CT, PET, non-hospital capital expenditures;

- psychiatric hospitals, psychiatric inpatient services and psychiatric beds, ICF/IIDs, substance abuse treatment facilities, and inpatient rehabilitation hospitals and beds;
- Long term care and continuing care retirement community beds and facilities;
- radiation therapy (including stereotactic radiotherapy, brachytherapy, linear accelerators, superficial radiation therapy, proton beam therapy), cardiac catheterization, and open heart surgery; and
- Hospital facilities and beds (including long term acute care), outpatient surgical hospitals, operating rooms, organ transplant programs, and neonatal special care.

Other considerations in developing an analytical framework could include:

- Rate at which COPN requests for the service/equipment are denied by the State Health Commissioner compared to the total number of requests received;
- Average, inflation adjusted, cost to implement/purchase the service/equipment;
- Degree to which competition for the service/equipment already exists;
- Degree that the current population has reasonable financial and geographic access to the service/equipment;
- Extent to which there is evidence that the service/equipment is subject to a volume equals quality relationship; and
- Potential for adverse impact on the goals of the Plan for Well Being, or any plan of VDH or the Department of Behavioral Health and Developmental Services.

VDH DCOPN analyzed COPN applications, where there was at least one decision issued from FY11 through FY15, to identify projects for which there were no denials and the average cost of each approved project. Table 1 summarizes the results of the analysis.

To the extent that certain facilities and projects may someday no longer be subject to COPN requirements, there was general consensus within the workgroup that providers of such services should be required to provide a specified level of charity care, and that they be required to comply with certain quality assurance standards. These same general components were included within the JCHC’s 2001 COPN deregulation plan. Potential options for quality assurance standards could include incorporation into state licensure and data reporting requirements, or a requirement that service providers be accredited by a nationally-recognized accrediting organization.

Project Type	Number of Facilities/Beds/Units in Virginia	Number of Approved Applications	Average Cost of Approved Project
Establish a General Acute Care Hospital	88	4	\$75,952,689
Expand any Acute Care Bed Service*	17,475 (beds)	1	\$12,912,817
Introduce or Expand an Obstetrical Service	1407 (beds)	2	\$520,954
Add Operating Rooms in a General Acute Care Hospital	691	15	\$35,560,367

Table 1 (continued)			
COPN Project Applications with Zero Denials, FY2011 – FY2015			
Introduce or Expand an Open Heart Surgery Service	40	1	\$920,175
Relocate a Medical Care Facility to a New Site or Campus	N/A	4	\$68,102,003
Expand an Intermediate Care Facility for Psychological Treatment and Rehabilitation of Individuals with Substance Abuse	1	2	\$0 (zero capital cost project)
Establish a Specialized Center for PET Services or Introduce or Expand a PET Service in an Existing Medical Care Facility	8 and 37 mobile sites	1	\$16,525 (mobile sites only)
Establish a Specialized Center for Brachytherapy Radiation Therapy Services or Introduce or Expand a Brachytherapy Radiation Therapy Service in an Existing Medical Care Facility	6	9	\$437,802
Establish a Specialized Center for Lithotripsy Services or Introduce or Expand a Lithotripsy Service in an Existing Medical Care Facility	7 and 52 mobile sites	10	\$4,000 (mobile site only)
Note: Includes all acute care bed types except psychiatric, medical rehabilitation and long-term acute care hospital beds. Source: DCOPN staff analysis.			

Recommendations

- 6a. The General Assembly should consider amending the definition of “Project” to no longer include the following: lithotripsy, obstetrical services, magnetic source imaging, nuclear medicine imaging services, and replacement of a medical facility within the same primary service area.
- 6b. The Virginia Department of Health should develop an analytical framework that incorporates review of the SMFP to support development of recommendations concerning the appropriateness of continuing to impose COPN requirements on specific medical facilities and projects or whether such projects should be subject to administrative or expedited review. The analytical framework should be aligned with the goals and metrics of Virginia’s State Health Improvement Plan. The analytical framework should also take into consideration components of the approach utilized prior to 2012 in development of the COPN Annual Report. The analytical framework should include a recurrent three-year schedule for analysis of all COPN project categories, with procedures for analysis of at least three project categories per year. The recurrent three-year schedule should be developed such that COPN projects that are of relatively low complexity and low cost are analyzed first, and projects that are of relatively high complexity and high cost are analyzed subsequently. VDH should develop recommendations based on the results of its analysis and transmit those recommendations to the General Assembly, Governor and

- Secretary of Health and Human Resources. The analytical framework should also include appropriate metrics to evaluate the impact of introducing a more competitive health care framework that could reduce costs and increase access to health care services. The analytical framework will include a process for stakeholder involvement in review and public comment on any recommendations.
- 6c. Providers of services that are no longer required to obtain a COPN should be required to provide a specified level of charity care in services or funds that matches the average percentage of indigent care provided in the appropriate health planning region and to participate in Medicaid.
 - 6d. Providers of services that are no longer required to obtain a COPN, along with all prospective COPN holders, should be required to obtain accreditation from a nationally-recognized accrediting organization for the purposes of quality assurance, as approved by the Virginia Department of Health.
 - 6e. VDH should provide a status report on implementation and impact of workgroup’s recommended reforms to the Governor and General Assembly by December 1, 2017.

Virginia Department of Health Resources to Administer the COPN Program

The VDH DCOPN is funded solely by revenue from application fees. COPN fees are specified in statute and are set at 1% of the value of the project, with a minimum fee of \$1,000 and a maximum fee of \$20,000. COPN application fees have not been increased since 1996. North Carolina, Tennessee, Kentucky and West Virginia all have higher maximum application fees than Virginia (Figure 7). There are no general funds authorized or appropriated for the COPN program. DCOPN’s fee-based funding varies year-to-year based on the number and types of COPN projects. DCOPN funding has been reduced from \$883,041 in FY2010 to \$772,490 in FY2015.

Figure 7
State CON Application Fees

State(s)	Maximum Fee
South Carolina	\$7,000
Delaware	\$10,000
New Hampshire & Alabama	\$12,000
Michigan	\$15,000
Ohio, Vermont, Virginia	\$20,000
Iowa	\$21,000
Kentucky	\$25,000
Tennessee	\$45,000
Washington	\$46,253
Florida, Georgia, & North Carolina	\$50,000
Mississippi & Alaska	\$75,000
Oregon	\$90,000
Illinois & West Virginia	\$100,000

VDH has prepared an initial estimate of additional staff resources that would be necessary to implement the recommendations contained in this report (Table 2).

Timely Review and Update of the SMFP. If the technical work associated with developing the SMFP would be completed by a private firm / consultant with health planning expertise, no additional resources within DCOPN would be needed. VDH estimates an annual cost of \$200,000. On the other hand, if that work is to be accomplished internally within DCOPN with stakeholder workgroup participation, at least one additional analyst position, would be needed devoted entirely to SMFP production and update.

Streamline Process for Submission and Review of COPN Applications Through Greater Use of Expedited Review. A significant increase in the utilization of the expedited review process may require one additional analyst if the COPN regulations are not amended to require expedited reviews to follow the appropriate batching cycle until accepted for review. Expedited reviews are not now required to follow a batch cycle and recommendations to the commissioner for expedited reviews are due within 40 days from the date the submitted application has been deemed complete as opposed to 70 days for batched reviews. Expedited reviews therefore do not follow the planned workload that is spread out and managed by batching. This causes unexpected workload peaks that require additional staff time. At some point as program changes involving enhanced monitoring and shorter review schedules one additional clerical staff, beyond other listed staff enhancements, would be required.

Streamline Process for Submission and Review of COPN Applications Through Reducing Standard Review Process to Not More than 120 Days. A significant reduction in the length of the standard review cycle would require at least one additional COPN review analyst. It would also require at least one additional adjudication officer.

Strengthen Monitoring of Compliance with COPN Conditions. Monitoring compliance with conditions beyond the current process would require two additional analysts, especially if expanded conditioning authority is given to the State Health Commissioner.

Table 2 VDH Estimated Cost to Implement COPN Workgroup Recommendations			
Types of Resources	Number of Staff	Estimated Cost	
		FY2017	FY2018
Analytical and Technical Support Staff	6	\$479,140	\$565,380
Adjudication Officer	1	0	\$179,859
Clerical Staff	1	\$46,000	\$46,000
One-Time IT Development Costs		\$12,000	0
Annual IT Maintenance Costs		0	\$36,000
TOTAL	8	\$537,140	\$827,839
Note: Estimate includes cost of personal and non-personal services. FY2017 estimated costs are based on need for 6 additional staff positions. FY2018 estimated costs are based on the need for 8 additional staff positions. VDH estimates that two positions (one additional adjudication officer and one additional analytical staff position) will not be needed until FY2018. Source: VDH staff analysis.			

Increase Transparency of the COPN program by Making Extensive Information Available On-Line. There are significant costs associated with providing a large quantity of data online. If only LOIs are to be placed online, or emailed/faxed to a list of registered users, the cost would be much less. There is the cost associated with the server space to hold and provide access to roughly 10,000 pages of documents annually. VDH estimates this cost to be \$2,000 for initial start-up, and \$36,000 annually in maintenance costs. DCOPN would require one technical support staff to scan, upload and maintain the online document library. VDH also estimates \$10,000 in additional costs for VDH in order to implement data collection changes. Finally, without substantial development work it is unknown what would be the cost to develop, or adopt an existing, automated, web-based COPN application process.

Recommendations:

- 7a. VDH should have adequate resources to administer the COPN Program in cost-effective manner.
- 7b. VDH should assess the amount of funding required to administer the statutory and regulatory requirements of the COPN program in a cost-effective manner. This assessment should take into account the need for timely and rigorous updates of the SMFP, monitoring of compliance with COPN conditions, and use of technology to support the submission and processing of applications. Based on that assessment, VDH should determine if additional resources are needed for cost-effective administration. If additional resources are determined to be necessary, COPN application fees should be increased in order to provide additional funding to support cost effective administration of the program.

Appendices

A - Study Mandate

B - July 1, 2015 COPN Workgroup Minutes

C - August 19, 2015 COPN Workgroup Minutes

D - September 28, 2015 COPN Workgroup Minutes

E - October 27, 2015 COPN Workgroup Minutes

F - Summary of Written Comments Concerning Draft Framework Document

Appendix A
Item 278D of 2015 Appropriation Act
COPN Workgroup Study Mandate

The Secretary of Health and Human Resources shall convene a work group that shall include health care providers, consumers of health care services, representatives of the business community, and other stakeholders to review the current certificate of public need process and the impact of such process on health care services in the Commonwealth, and the need for changes to the current certificate of public need process. In conducting such review, the work group shall evaluate: (i) the process by which applications for certificates of public need are reviewed, the criteria upon which decisions about issuance of certificates of public need are based, and barriers to issuance of a certificate of public need; (ii) the frequency with which applications for a certificate are approved or denied; (iii) fees charged for review of applications for a certificate of public need and the cost to the Commonwealth of processing applications for a certificate of public need; (iv) applications for and the impact of the current certificate of public need process on establishment of new health care services, including the establishment of new intermediate-level or specialty-level neonatal special care services and open heart surgery services and the addition of new beds or operating rooms at existing medical care facilities; (v) the relationship between the certificate of public need process and the provision of charity care in the Commonwealth and the impact of the certificate of public need process on the provision of charity care in the Commonwealth; (vi) the impact of the certificate of public need process on graduate medical education programs and teaching hospitals in the Commonwealth; (vii) the efficacy of regional health planning agencies, the role of regional health planning agencies in the certificate of public need process, and barriers to the continued role of regional health planning agencies in the certificate of public need process; and (viii) the frequency with which the State Medical Facilities Plan is updated and whether such plan should be updated more frequently. The work group shall develop specific recommendations for changes to the certificate of public need process to address any problems or challenges identified during such review, which shall include recommendations for changes to the process to be introduced during the 2016 Session of the General Assembly and any additional changes that may require further study or review. In conducting its review and developing its recommendations, the work group shall consider data and information about the current certificate of public need process in the Commonwealth, the impact of such process, and any data or information about similar processes in other states. The Secretary shall report on the recommendations developed by the work group to the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees of Finance and Education and Health by December 1, 2015.

Appendix B

Certificate of Public Need (COPN) Work Group Minutes

**July 1st, 1:00-4:00 p.m.
General Assembly Building,
House Room C,
915 East Broad Street,
Richmond Virginia 23219**

In attendance: Virginia Department of Health Staff: Erik Bodin, Director of the Office of Licensure and Certification, Peter Boswell, Director of the Certificate of Public Need, Susan Puglisi, Policy Analyst, Joe Hilbert, Director of Governmental and Regulatory Affairs, and Doug Harris, Adjudication Officer Certificate of Public Need. Work Group Members: Dr. David Trump, Deborah Oswalt, C. Burke King, Dr. Richard Szucs, Dr. J. Abbott Byrd, Brian Keefe, Dr. Richard Hamrick, Jill Lobb, Karen Cameron, Dr. William Hazel, Eva Hardy, Mary Mannix, Pamela Sutton-Wallace, Laurie Kuiper, Douglas Suddreth, Carol Armstrong, and Robert Cramer. Non-voting advising member: Jamie Baskerville Martin. Members of the public also attended.

The Chair of the Work Group, Eva Hardy, called the meeting to order and requested all Work Group members to introduce themselves as well as all Virginia Department of Health (VDH) staff present.

Secretary Hazel gave some opening remarks regarding the expectations of the Work Group. He stated that it is the task of the Work Group to bring together providers, consumers, members of the business community, etc in order to assess the need for changes to the certificate of public need (COPN) program. Secretary Hazel is tasked with reporting the recommendations developed by the Work Group to the General Assembly by December 1, 2015. The Secretary noted that the group will be tasked with determining the answers to a number of questions: what the public good the Commonwealth is pursuing by utilizing the COPN program; how do we as a Commonwealth measure that public good: is the method the Commonwealth is using to pursue that public good working; why or why not; what needs to change?

Dr. Hazel presented the three aspects of the COPN program: the statute, the regulations and state plan, and the process and procedures. When reviewing the state plan the work group should consider if it is adequate. When reviewing the process and procedures the work group should consider if they are fair, open, transparent, equitable and cost effective. Dr. Hazel noted that COPN has been around for a long time and been studied before. However, a lot has changed in the health care environment since the last time Virginia's COPN program has been assessed. Specifically there has been expanded coverage through the federal exchange and other Affordable Care Act related changes. The Work Group will need to consider the repercussions for COPN should Medicaid expansion occur and also if it doesn't.

Next Secretary Hazel provided an abbreviated history of COPN. The first COPN statute was adopted by New York in 1964. Virginia enacted the COPN program in 1973. In 1974 a federal law was passed encouraging states to adopt COPN. Dr. Hazel noted that as early as 1983 there were questions as to whether COPN was working; in 1988 the federal requirement was allowed to expire. Virginia retained their COPN program. In 1996 the Joint Commission on Health Care (JCHC) conducted a study. In 2000 the JCHC presented a report on COPN deregulation which

was rejected by the 2001 General Assembly. Dr. Hazel noted that COPN laws vary around the US. Those states that do have COPN programs differ in the number of services that are regulated. Vermont has the highest number with 30, Virginia has 19 and there are states that regulate zero services.

Secretary Hazel then reviewed the Work Group's goals: 1) Review the COPN process in Virginia, exploring whether there is a need for change; 2) Consider the criteria used to make COPN decisions; 3) Evaluate how COPN process affects new health care services; 4) Examine the relationship between COPN and charity care, specifically how charity care is measured; 5) Examine how COPN effects medical education and teaching hospitals; and 6) Review the regional health planning agencies' role in COPN and determining whether the State Medical Facilities Plan needs to be updated.

Finally, Secretary Hazel presented the Work Group's timeline. He stated the next meeting is tentatively scheduled for September 28th. A final meeting will occur in late October and the final report of the Work Group shall be presented to the House Appropriations and Senate Finance Committees by December 1, 2015. Secretary Hazel stressed to the Work Group that they are members of a public body and therefore all meetings of members must be open to the public. Ms. Hardy the Work Group chair thanked Secretary Hazel for his opening remarks and stated that she hoped all members of the group have an open mind, that there are no preconceived notions about what the results of the group will be. Ms. Hardy stated that she hopes to hear a great deal of background and hear the issues so that the group can begin working towards the goals the Secretary mentioned.

Peter Boswell, Director of the COPN program was introduced and provided a presentation on the Certificate of Public Need in Virginia. Mr. Boswell explained that the COPN program is governed by the Code of Virginia, specifically §32.1-102.1 through §32.1-102.11, which requires the Board of Health to promulgate two sets of regulations: the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations (12VAC5-220) and the State Medical Facilities Plan (12VAC5-230). The COPN regulations set forth the COPN review process and the State Medical Facilities Plan provides review standards specific to each type of project that requires COPN authorization.

Next, Mr. Boswell reviewed those projects which require COPN Authorization. He stated the types of projects that require COPN authorization are considered in review cycles that are separated into 7 different batch groups. The batch groups are as follows:

- A. General Hospitals, obstetrical services, neonatal special care services, general capital expenditures
- B. Open heart surgery cardiac catheterization, ambulatory surgery centers, operating room additions, transplant services
- C. Psychiatric facilities, substance abuse treatment, mental retardation facilities
- D. Diagnostic imaging facilities and services
- E. Medical rehabilitation beds and services
- F. Radiation therapy, gamma knife surgery and linac based SRS, lithotripsy, diagnostic imaging equipment may be included in an application with radiation therapy
- G. Nursing home facilities and bed additions, nursing home capital expenditures

Mr. Boswell stated that there are two review cycles per year for each batch except Batch Group "G" which is reviewed every other month. For each of the project types the State Medical Facilities Plan provides service specific standards for evaluating the need for each type of project. Mr. Boswell noted that batching allows for the review of like or similar requests in the same planning area, which are considered to be competing applications. The state is divided into five planning regions and twenty two planning districts.

Mr. Boswell then moved on to the COPN Review Criteria and Standards. There are eight criteria listed in the Code that the Commissioner considers in determining need for a project. They are:

1. The extent to which the proposed service or facility will provide or increase access to needed services.
2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:
 - a. The level of community support
 - b. The availability of reasonable alternatives
 - c. Any recommendation or report of the regional health planning agency
 - d. Any costs and benefits of the project
 - e. The financial accessibility of the project; and
 - f. Any other factors that may be relevant; which is at the discretion of the Commissioner.
3. The extent to which the application is consistent with the State Medical Facilities Plan (SMFP). Changes to the SMFP come about through the SMFP Task Force. The Code of Virginia requires that the SMFP Task Force meet once every two years, complete a review of the plan, and update or validate existing criteria once every four years. The SMFP was last updated in 2009. A Task Force met in 2013 and proposed changes to the standards for cardiac catheterization services and nursing homes which will be published soon. Another SMFP Task Force is scheduled to convene at the end of this month to consider improvements to the review standards for mental health services.
4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area.
5. The relationship of the project to the existing health care system of the area, including the utilization and efficiency of existing services or facilities
6. The feasibility of the project.
7. The extent to which the project provides improvements or innovations in the financing and delivery of health care services
8. Any project which affects a teaching hospital association with a public institution of higher education or a medical school in the area to be served:
 - a. The unique research training and clinical mission of the teaching hospital or medical school, and
 - b. Any contribution the teaching hospital or medical school may provide in the delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

Next, Mr. Boswell reviewed the specifics of the SMFP. He stated for each type of project the SMFP provides service specific standards when evaluating the need for a project. Of these specifics there are two that are applicable to ever review. They are travel time and the need for additional service capacity. Both of these elements aim to assure that access to needed services

is adequate. To assess travel time and need for additional service capacity VDH uses outside data sources.

Next, Mr. Boswell reviewed the specifics of the application review process. He stated there are three basic phases in the review process: the pre-application phase, the review phase and the decision phase. Mr. Boswell clarified that the formal process starts 70 days prior to the start of the established batch review cycle with the applicant submitting a letter of intent. Applicants are due thirty days after the letter of intent is due.

At this point a Work Group member asked some clarifying questions regarding the SMFP. The member asked what were the two elements of the SMFP that the Task Force worked to update. Mr. Boswell stated that they were cardiac catheterization and nursing homes. The Work Group member then stated that the turnaround time for the updates has been two years and asked if that was typical. Mr. Boswell stated he would have to do some research to determine the typical time for SMFP updates. Another Work Group member asked how benefits are assessed? Mr. Boswell stated that he would need to research and get back to the Work Group. There were further questions regarding the SMFP. The Work Group Chair Ms. Hardy requested an update on the SMFP and a presentation explaining the SMFP in more detail at the next meeting.

Mr. Boswell then returned to his presentation. After an application is submitted the Division of COPN reviews the submission for completeness and submits any questions regarding completeness to the applicant and submits any questions regarding completeness to the applicant and submits any questions regarding completeness to the applicant in ten days. The applicant has 25 days to respond to the completeness questions and pay the filing fee. Mr. Boswell reviewed the cost of an application fee; he also stated that applicants frequently use consultants and attorneys in the development, presentation or defense of the COPN application, as well as staff time and other resources. He stated that those costs are not reported to VDH and therefore the Department cannot report on those costs. The Division of COPN has five days to review the completeness responses and either deem the application complete for the start of the review cycle and accept it for review or reject it as incomplete.

Next, Mr. Boswell went over the specifics of the review phase. If an application is accepted for review, the cycle starts on the 10th of the month. Next a public hearing is conducted. Mr. Boswell then reviewed the Decision phase, which is the series of steps leading from the recommendations of the reviewing agencies to the State Health Commissioner's decision and can last up to 120 days. Mr. Boswell then presented estimates of the time different elements of the decision process takes, based on data from 2011 the last time the review cycle was studied. Mr. Boswell noted that the Code of Virginia mandates that the review cycle cannot take more 190 days unless extended by the applicant. Only the applicant has the authority to extend deadlines. In the event the Commissioner has not issued a decision by the 190th day of the review cycle and the decision schedule has not been extended by the applicant, the request is deemed to be approved. VDH classifies such an occurrence as a default, which has never occurred.

Mr. Boswell then reviewed the Request for Applications (RFA) process. Applicants to increase the number of nursing home beds in a planning district can only be accepted when filed in response to an RFA. The RFA process was designed to replace the moratorium on all new nursing home beds, which was in effect from 1988 to 1996, and to control the inventory of beds. The COPN program determines need for the RFA process by conducting an annual calculation by planning district. Age specific use rates are used which are derived from the statewide nursing

home patient origin survey. From that information future need is projected. Need is determined to exist when the calculated bed need forecast exceeds the current inventory, the average annual occupancy for all existing and authorized Medicaid certified nursing facility beds was at least 93% and there are no authorized but unconstructed nursing facility beds in the planning district. The Department of Medical Assistance Services is consulted and must approve the RFA, certifying that funds are available.

Next Mr. Boswell reviewed conditions on COPNs. The State Health Commissioner has the authority to condition the issuance of a COPN on the applicant's agreement to certain conditions: 1) the provision of indigent care, 2) facilitation of the development and operation of primary care services and 3) accept patients requiring specialized care. Requiring the direct provision of health care services to the indigent is the most common condition recommended by the Division of COPN and imposed by the Commissioner. Mr. Boswell stated there is no regulatory guidance on the application of conditions; therefore the Commissioner can utilize all of the conditions or none of them, or anything in between. However conditions cannot be arbitrary or capricious. The Division of COPN recommends an indigent care condition to the regional average rate if: 1) The applicant is a new provider under COPN with no history of providing charity care or 2) the applicant is an existing COPN provider who failed to provide charity care at a rate equal to or above the regional average during the previously reported 12 months. The rate of required charity care percentage in a condition is calculated using the most recent data from Virginia Health Information (VHI). The rate is the total annual charges for the charity care provided by hospitals in the planning region divided by the total annual charges for all hospital services. Mr. Boswell noted the conditioned facility is required to provide charity care for the COPN-approved service each year as a percentage of the total charges by the conditions facility for that service for the same year. The facilitation of primary care is added to most conditions as an acceptable way to meet conditions by supporting safety net providers either with a check or in kind.

Mr. Boswell continued to review the conditioning of COPNs. He stated that the number of active conditions changes for a number of reasons, including: conditions expiring, certificates being surrendered, the project that the certificate permits is never built or completed, the certificate has been superseded by new COPNs or a condition has been rolled into a system wide condition at a higher percentage. Then Mr. Boswell reviewed the number of conditioned COPNs: there are 655 COPNs issued, 195 are active and 108 are not yet completed.

Next, Mr. Boswell reviewed the amount of care reported as provided in compliance with conditions. In 2013, the amount was \$1.34 billion with \$35.8 million in cash contributions to safety net providers. Mr. Boswell stated that many COPN holders would have provided some level of charity care without the conditions, therefore the entire \$1.34 billion cannot be ascribed entirely to COPN but it is believed that some portion of it is directly the result of COPN. However, the value of contributions to safety net providers is solely the result of COPN conditions, as only contributions made over and above the amount that an applicant had been making prior to COPN approval count toward satisfying the condition.

Mr. Burke King asked how the \$1.34 billion is valued. Mrs. Boswell stated that the care is provided to the indigent, those without insurance and therefore the care is valued at charges. A Work Group member asked what the process is if the provider fails to reach the conditioned requirement of the certificate. Mr. Boswell noted that should the provider fail to make the required percentage of care the provider can make up the difference by writing a check to a charity or safety net provider. Another Work Group member asked what the process is for

ensuring compliance. Mr. Boswell noted that providers report to the Division of COPN annually and if they do not meet the levels of compliance the provider must create a plan of correction which requires a payment to a safety net provider. The payment to a safety net provider is not directed by the Division of COPN but rather provided directly to the clinic. Secretary Hazel noted that the process is self-reported, the Division of COPN does not have the resources to audit, however if compliance is not reported action is taken.

Deborah Oswalt asked how the term "safety net provider" is defined. Mr. Boswell stated that he would have to research that question and return with an answer. Secretary Hazel asked what the Division of COPN allows. Mr. Boswell stated that the Division of COPN has a Guidance Document which can be provided to the Work Group. Ms. Hardy noted that it would be helpful if the Division of COPN published this information on its website, that way the safety net providers could alert VDH if they did not receive the payment. Ms. Oswalt noted that the Healthcare Foundation has received some money when conditions are not met but it is nowhere near the amount of \$35.8 million. Work Group members asked further follow up questions regarding the cash contributions, the work group asked for more follow up information regarding this issue for the next meeting.

Mr. Brian Keefe asked how much indigent care is provided under a COPN which is conditioned versus one that is not, in other words, does conditioning make a difference? Mr. Boswell noted that there is evidence that the percentage of indigent care has grown over the years. Another member of the Work Group asked how it is determined whether to condition one certificate over another. Again Mr. Boswell reviewed the two circumstances in which the Division of COPN suggests conditioning a certificate as: 1) The applicant is a new provider under COPN with no history of providing charity care or 2) the applicant is an existing COPN provider who failed to provide charity care at a rate equal to or above the regional average during the previously reported 12 months.

Dr. Szucs asked where the determination of need for charity care comes from. Mr. Boswell stated that the determination of need is a process separate from the review process. Dr. Szucs asked for clarification regarding the Commissioner's authority regarding conditioning, whether she could condition the color of the walls of a provider. Mr. Boswell stated no, that the Commissioner may only condition: 1) the provision of indigent care, 2) facilitation of the development and operation of primary care services and 3) accept patients requiring specialized care. Secretary Hazel asked whether Mr. Boswell has any information regarding the history of legislation around conditioning. Mr. Boswell stated that he would have to research to find that information and return to the Work Group.

Dr. Hazel then asked what the difference between the value of the service provided and the charges listed is. Dr. Hazel asked if VDH OLC has ever thought about utilizing Relative Value Units. Secretary Hazel stated that he believes charges incentivize providers to charge more, they seem irrelevant. He voiced concern that utilizing charges affects the transparency of the system, as the charge does not correlate with what the provider paid or what the provider is paid. Karen Cameron noted that charges are used because every provider charges differently, utilizing charges allows VDH to compare "apples to apples", if VDH utilizes costs individual providers may be able to "game" the numbers. Mr. King stated that charges are numbers on a piece of paper, and that true value is what Medicare or a commercial payer would pay. Ms. Oswalt stated that uninsured would have to pay the charge amount, especially if they are not aware to ask for a

discount. Ms. Mary Mannix noted the Affordable Care Act now makes it against the law to charge at full price. Mr. Keefe asked how many non-conditioned COPNs are issued.

At this point Ms. Jamie Baskerville Martin summarized what the Work Group has asked for from OLC: the charity care guidance document, a sample of a MOU between OLC and a safety net provider, information regarding the levels of charity care provided to different safety net providers, research into whether the three conditions listed within the statute are the only conditions the Commissioner may impose on a certificate, and a list of all providers who have conditions on their certificates.

At that point Mr. Boswell returned to his presentation. He reviewed the program volume of COPN from 2010 -2014. COPN receives an average of 87 letters of intent per year, an average of 59 applications per year, an average of 16 applications are heard at 13 informal fact findings per year, an average of 52 decisions are made per year with 85.7 % approved and 14.3 % denied. Mr. Boswell stressed that the high approval rate should be regarded with the understanding that the existence of the COPN process itself culls out more speculative requests, resulting in only certain requests moving forward for consideration. Between 2010 and 2014 there was an average of \$434 million in approved projects and \$43 million in denied projects. Previously the COPN capital threshold, the dollar amount that at which and above which is defined as a project, is about \$18 million. That amount continues to be inflated annually.

Mr. Boswell then reviewed the program revenue in 2010 and 2015. He noted that with the decrease of program volume there has also been a decrease in revenue. Finally Mr. Boswell reviewed the program staffing, which has been adjusted from 7.5 full time equivalents (FTEs) to 5. The Director and Supervisor positions are now split between two programs. Mr. Boswell finished his presentation and asked the panel if they had any questions.

A panel member asked what the biggest reason for the denial of a COPN is. Mr. Boswell stated a request to build a new facility near a facility which is underutilized. Mr. Keefe asked what the most common complaints from applicants are. Mr. Boswell noted he has not personally heard any complaints. Mr. Keefe asked if there are complaints from consumers or the public. Mr. Boswell stated that occasionally at public hearings members of the public will complain about the process or a determination of need; however Mr. Boswell was unable to recall specifics. Dr. J. Abbott Byrd asked for an explanation of the capital threshold requirement. Mr. Boswell noted that the capital threshold is currently 18 million dollars, which means that the facility wants to spend 18 million dollars or more to renovate. That concluded the panel's questions for Mr. Boswell.

Mr. Patrick W. Finnerty from PWF Consulting then introduced himself and began his presentation: A Review of the Joint Commission on Health Care's 2000 Certificate of Public Need Deregulation Plan. Mr. Finnerty began with a "roadmap" of his presentation, he stated he would begin with the legislative authority and directive, then turn to the process, the deregulation plan and finally the proposed legislation and the outcome of that legislation.

Senate Bill 337 (2000) as introduced would have repealed most of the COPN program. The approved legislation instead directed the Joint Commission on Health Care (JCHC) to develop a "transition plan" to eliminate the COPN program; the legislation would have allowed 3 years for such a plan. The key elements of the plan were to include meeting the health care needs of indigent and uninsured population, establishing licensure standards and providing adequate

oversight for deregulated services, determining the effect of deregulation on academic health centers, long-term care facilities, and rural hospitals and monitoring the effect of deregulation during and after transition period. He stated the end game of the plan was to eliminate COPN.

Then Mr. Finnerty began reviewing the process. A COPN Subcommittee was formed chaired by Senator Bolling. The Subcommittee had 12 other members and met during the summer and fall of 2000. The Subcommittee assisted the JCHC in crafting a deregulation plan and involved stakeholders in addressing key issues during the development of the plan. The three key stakeholders were the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, and the Virginia Health Care Association. The meetings were very well attended and at least 40 meetings were held to develop the plan. There were four key areas that the Subcommittee focused on and workgroups were established to focus on these areas: access, quality, medical education, and fair payment/funding. There were five overall goals for Deregulation Plan adopted by the workgroups and JCHC: 1) offer more choices to patients; 2) ensure access especially to the indigent and uninsured; 3) quality protections; 4) financial support for medical education at academic medical facilities; and 5) ensure Commonwealth's financing programs pay market rates.

Mr. Finnerty then reviewed the three phases of the plan. The deregulation of each service was assigned to each of these phases based on cost impact on hospitals, complexity and risk. Phase I was MRI, CT, PET, Non-cardiac nuclear imaging and Lithotripsy. Phase II was cardiac catheterization, radiation therapy, and gamma knife surgery. Phase III was ambulatory surgery centers, OB services, neonatal special care, organ transplants, and open-heart surgery. The deregulation plan retained COPN requirements for certain facilities: nursing homes, hospital beds and mental health and substance use disorder facilities.

A key element of the plan was the consideration that paying patients who were receiving regulated services in a deregulated environment may go to other locations outside of the hospital, and that may have an effect on the hospital. Mr. Finnerty noted the intent of the plan was to cushion the impact of that effect.

There were specific actions that each phase depended on. Certain quality and data reporting provisions are applicable in all three phases. Mr. Finnerty noted that new licensure systems for each deregulated service were to be in place and applied equally across all care settings. Also providers of newly deregulated services would have been required to submit claims data, additional quality outcome information for selected high risk procedures and annual financial information on the level of indigent care. Mr. Finnerty then reviewed the specific action to be accomplished in each phase. Within Phase 1 the following actions were to take place: 1) the full funding of indigent care at academic health centers; 2) the improvement of adequacy of Medicaid hospital reimbursement; 3) the elimination of faculty-earned clinical revenues to fund core cost of undergraduate medical education; and 4) a JLARC study of Medicaid physician reimbursement. Within Phase 2 the following actions were to take place: 1) continued action to fully fund indigent care at academic health centers; 2) increasing Medicaid eligibility for caretaker adults; 3) increasing Medicaid eligibility for Aged Blind and Disabled individuals; 4) the improvement of adequacy of Medicaid hospital reimbursement; and 5) the continued elimination of faculty earned clinical revenues to fund core cost of undergraduate medical education. Finally in Phase III the following actions were to take place: 1) continued action to fully fund indigent care at academic health centers; 2) increasing Medicaid eligibility for caretaker adults; and 3) increasing Medicaid eligibility for ABDs.

Mr. Finnerty noted that the overall cost of the plan was \$135 million. He stated that 308 individuals and organizations generally supported the JCHC Deregulation Plan and that the JCHC did not hear clear opposition. House Bill 2155 and Senate Bill 1084 were introduced to implement the deregulation plan. The bills left their committees but were left in the House Appropriations and Senate Finance committees, respectively. Therefore the plan was not implemented.

Secretary Hazel thanked Mr. Finnerty for his presentation. He asked if Mr. Finnerty had any idea what the plan would cost today and whether he believes that Medicaid expansion would cover some of the cost. Mr. Finnerty stated he believed that Medicaid expansion would definitely solve part of the funding problem. Ms. Pamela Sutton-Wallace asked whether any consideration was given to the impact of non-listed services, specifically those services not covered under the three phases but where service revenue does not cover the hospital's cost of providing the service. Mr. Finnerty noted that the consensus for deregulation was a fragile one, he stated he is sure those specifics were discussed but he did not have any specific memory. Dr. Richard Hamrick stated that in 2000 Virginia was a dramatically different Commonwealth and the Work Group should be careful not to overstate what we can learn from 2000. With no further questions Mr. Finnerty concluded his presentation.

Ms. Susan Puglisi then introduced herself and began her presentation on COPN in other states. Ms. Puglisi began with an overview and history of COPN. She noted that in most other states Certificate of Public Need is commonly referred to simply as Certificate of Need (CON) and as heard from other presenters CON laws were initially put into effect as part of the federal Health Planning Resources Development Act of 1974. Just six years later in 1980, 49 of 50 states had CON laws. Ms. Puglisi then showed a graphic of the 35 states including Virginia which have CON laws.

Ms. Puglisi provided an overview of all the categories of services regulated in each state. The most highly regulated service is nursing home or long-term care beds. There is a significant drop from the number of states regulating the next highly rated service: acute hospital beds. Virginia regulated each of the top-ten most regulated services. The most notable service Virginia does not regulate is home health agencies, 18 other states do regulate home health agencies and there are in excess of 900 home health agencies in the Commonwealth of Virginia.

Ms. Puglisi then noted the length of the CON review process across the country. The most common review period is 90 days. Of those states with CON programs Virginia has the longest review period of 190 days. Ms. Puglisi noted it is important to note certain caveats to the data which portray much shorter review periods in some other states. For example, Oklahoma has a review period of 45 days however that review period only begins after a CON hearing, none of the application process up until the hearing is considered as part of the review period. Likewise, Alabama has a review period of 50 days however that does not include the filing of the letter of intent, which must be submitted 30 days before filing an application.

Ms. Puglisi then reviewed the individuals or entities across the country that have the authority to issue a CON. In Virginia, the State Health Commissioner holds the authority to issue a COPN. The most common authority is the Department of Health with 7 states which provide the Department with this authority, followed by the Commissioner of Health which 6 states providing the Commissioner this authority. 5 states provide the authority to a "Review Board", 4

to an "Agency", 3 an "Office, and 3 a "Director." Secretary Hazel asked if these other entities hold similar authority that the Commissioner holds. Ms. Puglisi responded that although the legal authority may be placed with the Department, the Commissioner may make that decision. It is also possible that the Office, delegation and practice can't be determined from reading statute and regulations, interviews with each state would be required to know for sure.

Ms. Puglisi then moved on to the application fees charged across the country. She began with the maximum fee prescribed by law; the nationwide median maximum fee is \$45,000. Virginia's maximum fee is \$20,000. Secretary Hazel asked when the last time the fee within Virginia has changed. Mr. Bodin noted he believed the last time was in 1999 or 2000 but he would have staff look up the answer and report back to the Work Group. Secretary Hazel asked how much time and effort goes into a simple review versus a complex review. Mr. Bodin stated that fees are based on the estimated capital cost of the project, therefore there is not a good correlation between the fee and the amount of work goes into a review. Secretary Hazel asked if Virginia's review cycle was shortened would VDH OLC need more staff. Mr. Bodin stated yes. Secretary Hazel asked why there was a reduction in staff. Mr. Bodin noted that fee revenue has gone down and therefore the number of staff had to be cut. He noted that the number of applications has declined a bit, particularly for projects that would have been assessed the maximum fee. Therefore VDH OLC still has a relatively high number of reviews but a decrease in revenue. Secretary Hazel noted that whatever the Work Group decides they need to ensure there is enough staff to be able to act on the decision.

Ms. Puglisi then continued her review by presenting the minimum application fee prescribed by law. She noted fewer states prescribe a minimum fee. Again, Virginia falls below the nationwide median minimum fee of \$2,000. Virginia's minimum fee is \$1,000. The most common minimum fee across the nation is \$1,000, with 3 other states also using \$1,000 as a minimum fee.

Ms. Puglisi then reviewed conditional certificates across the nation. A total of 24 states permit conditioning of CONs, Virginia is one of those states. Of those states which permit conditional certificates, Virginia is the most restrictive. The Code of Virginia in Section 32.1-102.2 states exactly what type of conditions that the Commissioner may put on a COPN. There are only 3: 1) provide a level of care at reduced rate to indigents; 2) provide care to persons with special needs; and 3) to facilitate the development of medical services in medically underserved areas. In contrast 11 states do not have any limitations set on what conditions can be placed on certificates. Those which do have limitations on conditions usually state simply that the conditions must be related to the specific project within the application, and the conditions must be related to the state's CON statute and regulations.

Next Ms. Puglisi reviewed moratoria which exist across the country in relation to CON. Seven states have a moratorium of some sort in place; several others have had moratoria over the years which have been lifted. Both New Jersey and Virginia require a call for applications before long term care applications can be submitted. A majority of the moratorium are related to long term care.

Ms. Puglisi then reviewed post-issuance monitoring. A majority of states require monitoring after a CON is issued. Twenty-one states require progress reports, which can be required on a quarterly basis or when a project reaches specific benchmarks such as when construction begins, when the foundation is laid, etc. Ten states, including Virginia, require annual reporting. Virginia requires annual progress reports until completion of the project for every COPN. Those

certificates which are conditioned require an annual report regarding compliance with the condition(s). One state requires all CON regulated facilities to report annually in perpetuity.

Finally Ms. Puglisi reviewed those states which do not currently have a CON program. She again reviewed that the federal Health Planning Resources Development Act was passed in 1974 and by 1980, 49 states had some form of CON. In 1987, the federal government repealed the Health Resources Planning Development Act, and over the next few years states began repealing their CON program. By 1990, 12 states had repealed their programs. By 2000 an additional three had repealed their programs. Since 2000 Wisconsin is the only state to repeal its program Wisconsin repealed its program in 1987, reinstated it in 1993 and repealed it again in 2011. In addition, Indiana repealed its program in 1996, reinstated it in 1997 and repealed it again in 1999. With that Ms. Puglisi ended her presentation and asked if there were any questions.

A panel member asked if any states modified their program but did not repeal it. Ms. Puglisi stated she would look into that and return to the panel. Another panel member asked if other states have restrictions on the development of beds that are not called "CON" but something else. Again Ms. Puglisi stated she would look into it. A panel member asked if there is any dedicated health planning staff at VDH. Mr. Bodin stated only the Division of COPN staff.

Secretary Hazel asked if we know anything about what happens in states after there has been deregulation, in terms of access, cost and private sector payment, as it would be instrumental in determining if we could achieve the same public good with a different method. Dr. Trump asked Secretary Hazel if he was directing his question to Ms. Puglisi or to the panel. Secretary Hazel clarified to the panel as a whole. Ms. Hardy thanked Ms. Puglisi for her presentation and stated that when looking at healthcare in the future it is important to look back to learn from lessons of the past but also to look forward and determine what is necessary to improve access, quality and costs.

At this point the Work Group had time for public comment. No members of the public came forward to speak. At that point, Ms. Hardy stated that the panel was open for discussion and closing statements which began with Ms. Oswalt. She stated that there are several possible scenarios for which the future of health care could look like and there will need to be some systematic protections in place whether the coverage gap is improved or not. She stated she is particularly interested in focuses on access for the uninsured and care charity care obligations.

Mr. Keefe stated that in a post-Affordable Care Act world there are more patients seeking healthcare and he wondered whether CON prevents access to care. He noted he is still interested in hearing what complaints regarding the program exist. Finally Mr. Keefe noted that learning from other states is important and would like to hear what was learned from those states that repealed multiple times.

Mr. King stated that he wanted to ensure that the Work Group puts the purchaser and consumer at the forefront of the discussion and consideration, specifically how they are impacted by CON. He stated that consolidation of health care providers drives up costs significantly. He went on to stress that protecting the supply of services for the uninsured is important however the Work Group must understand the magnitude and impact of restricted competition on everyone.

Dr. Szucs stated there needs to be an obligation of everyone who is providing services to participate in providing charity care unless Medicaid expansion occurs. He noted that when there

is an increase in facilities there is a rise in utilization, particularly with office-based imaging. He stated there will need to be a method to control runaway utilization.

Dr. Abbot Byrd stated that 2-3% of his organization's business is indigent care. He states it is necessary to have a cushion to spread those losses out. He went on to state that the Affordable Care Act has done a lot of good but has also increased co-payments for patients and COPN is also an anticompetitive measure which directly affects the patient. He stated more competition would drive prices down. He finished by stating if you review the data COPN restricts access and competition and does not add to quality; therefore he believes there is room for adjustment.

Dr. Richard Hamrick stated that he believes there will be increasing difficulty in the operating environment. He stated the patients are living longer and therefore cases are becoming more complex. He also stated that we have the technology to do more for patients now than we could ever do in the past. He also stressed that the Work Group should recognize the shortage in mental health beds in Virginia.

Ms. Jill Lobb noted that as a representative of employers she believes she is coming from a different background from many of the other members on the Work Group. She stated she had a lot to learn about COPN. She noted that in terms of utilization her organization's workforce was utilizing emergency room services because many members of the workforce were unaware about primary care. She stressed the importance of educating patients. She stressed that she couldn't agree more that the Work Group should focus on cost competitiveness.

Ms. Karen Cameron noted that the consumers of healthcare include every resident of Virginia. She stated her biggest concern is the lack of health planning within Virginia. She assured other members of the Work Group that there are components of quality of healthcare that have been ensured by the COPN process and there are elements within the COPN that allow for competition such as the batching process. She finished by stating she wanted to ensure the public is represented within this process as she has concerns about indigent patients being left out stating "That which get paid gets provided."

Ms. Pamela Sutton- Wallace stated that there is a lot of conflicting data on the impact of COPN and it should be the task of the Work Group to sort through to the truth. She noted her concern for academic medical centers as removing COPN may leave them with the inability to cover services which are not profitable. She noted that the cost of certain services are not well reimbursed which can effect academic medical centers' ability to train the health care professionals of the future, which is alarming when the Commonwealth is already experiencing significant shortages in specialists and those supplying primary care.

Ms. Mary Mannix stated that this is a challenging time to evaluate COPN as it will be necessary to evaluate the program while considering both the possible circumstance of Medicaid expansion and the possibility expansion not occur. She noted that there is a real dynamic regarding competition for services that are reimbursed, and stated that some services will suffer. For example, providers are not going to "rush to the finish line" to open psychiatric beds. Ms. Mannix stressed the need to learn from other states that have deregulated such as Pennsylvania. She went on to argue competition is good as long as the Work Group addresses the inherent flaws and recognize that it will not be a free market economy if the group decides to repeal COPN. Also Ms. Mannix stated that in a lot of communities the hospitals are also the largest

employer and lots of families depend on the strength of the hospital for both services and employment.

Mr. Douglas Suddreth stated that COPN's impact is different for different services. He stated that it is important to look at experiences of different states rather than getting tied up in ideology. He also stressed that healthcare is not a free market economy but rather the second most regulated industry. He stressed that no one wants a loved one within a nursing home that is losing money.

Carol Armstrong noted that she too is concerned about aging patients and is interested in how the Work Group can bring more value to purchasers and consumers.

Mr. Robert Cramer noted issues arise when competition is restrained. He asked if we are actually in a position of restrained competition. He noted that COPN is an elaborate process but a there is a mere 10% of "fall out". Therefore he noted the Work Group must look at what is really being rejected. He further stressed that when you add facilities you increase utilization. He stated there are many efforts to make consumers smarter and he hopes that should there be too many facilities consumer would chose the right one. He ended by noting that this is the first taskforce he has taken a part of that a real problem was not identified at the outset. He was surprised by that fact.

Ms. Jamie Baskerville Martin noted that as an advising member she does not have an opinion to present to the Work Group. She noted that she heard a number of questions and comments regarding the substance and process of the law. She stated that when it comes to COPN it is hard to separate the substance from the process. She stated there is a lot of literature regarding the effects of COPN on costs, access and quality however that literature does not fall 100% on either side of the argument.

Dr. David Trump noted that he is also on the Governor's Task Force on Prescription Drug and Heroin Abuse and members of that group recommended including methadone services within COPN.

Secretary Hazel noted that COPN has been a tool and the Work Group should determine if they think it's appropriate to recommend another better tool to achieve the same purpose. He asked if retaining COPN makes sense. He noted that we are in a period of unprecedented innovation and the Work Group must consider whether the COPN process can keep up, can it allow for innovation? He stressed that have the longest review process in the country is not good. He stated that the goal of the Work Group at a minimum would be to make the process faster, better and tighter. He noted that COPN is not the only tool out there.

Ms. Eva Hardy stated that the next Work Group meeting is set for September 28th. She stated additional information will be posted on the website and noted that Joe Hilbert will be the point of contact for the group should they have any information they wish to share or have posted. With that Ms. Hardy closed the meeting.

Appendix C

Certificate of Public Need (COPN) Work Group Minutes

August 19th, 1:00-4:00 p.m.
General Assembly Building,
House Room C,
915 East Broad Street,
Richmond Virginia 23219

In attendance: Certificate of Public Need. Work Group Members: Eva Hardy (Chair), Secretary of Health and Human Resources Dr. Bill Hazel, Dr. David Trump, Deborah Oswalt, John Syer, Dr. Richard Szucs, Dr. J. Abbott Byrd, Brian Keefe, Dr. Richard Hamrick, Karen Cameron, Mary Mannix, Pamela Sutton-Wallace, Douglas Suddreth, Carol Armstrong, and Robert Cramer. Non-voting advising member: Jamie Baskerville Martin. Virginia Department of Health Staff: Erik Bodin, Director of the Office of Licensure and Certification, Peter Boswell, Director of the Certificate of Public Need, Susan Puglisi, Policy Analyst, Joe Hilbert, Director of Governmental and Regulatory Affairs, and Doug Harris, Adjudication Officer. Members of the public also attended.

The Chair of the Work Group, Eva Hardy, called the meeting to order.

Dr. Marissa Levine, State Health Commissioner, provided the workgroup with an overview of Population Health Improvement Planning in Virginia. During the presentation, there was discussion by, and questions from, several workgroup members concerning:

- How Virginia's population health improvement plan will be implemented;
- Importance of behavioral health issues for assuring a strong start for children,
- Importance of inter-agency collaboration in population health improvement planning;
- Performance of community health assessments;
- Role of health systems in population health improvement planning; and
- Role of COPN and the State Medical Facilities Plan (SMFP) in population health improvement planning.

Erik Bodin provided the workgroup with a detailed Review of the Statutory and Regulatory Provisions governing COPN. During the presentation, there was discussion by, and questions from, several workgroup members concerning:

- Extent to which "pain clinics" are regulated by the state ;
- Statutory requirements for reviewing and updating the SMFP;
- History of the SMFP Task Force;
- Amount of time required to update the SMFP regulations;
- Extent to which the state's emergency rulemaking process can be used to amend the SMFP regulations;
- Regional Health System Agency boundaries;
- Amount of time required to complete the nursing home Request for Applications process;
- Process used by VDH to monitor adherence to COPN requirements; and
- Types of "facilities" and "projects" that are covered by COPN requirements.

Koren Wong-Ervin, Attorney Advisor with the U.S. Federal Trade Commission (FTC) provided the workgroup with comments, on behalf of FTC Commissioner Joshua Wright, concerning COPN. Ms. Wong-Ervin stated that her comments did not necessarily reflect the views of all the FTC Commissioners, other than Commissioner Wright. During the presentation, there was discussion by, and questions from, several workgroup members concerning:

- Extent to which non-COPN policy mechanisms, such as those described in a 2007 study by Lewin, may be used to address a variety of health care issues;
- Evidence of cross-subsidization of health care services within a single health system;
- Comparison of cross-subsidization in states with CON and states without CON;
- Extent to which there is transparency to health care consumers in terms of price and quality;
- Extent to which health care outcomes improve with increased utilization;
- Impact that elimination of COPN actually has on the availability of hospital beds or other types of health care services;
- Impact that CON has on health care costs;
- Whether or not health care services are a commodity;
- Need to ensure that COPN does not serve as a barrier to market entry and competition;
- Need to ensure that COPN applicants do not engage in tactics designed to delay decision on the application

Joe Hilbert provided the workgroup with additional information concerning COPN in Other States. During the presentation, there was discussion by, and questions from, several workgroup members concerning:

- Virginia's current interest in developing a Delivery System Reform Incentive Payment waiver application for submission to the Center for Medicaid Services; and
- Extent to which Virginia's 2001 proposed COPN deregulation plan contained provisions to address quality of care of deregulated services.

Next, Secretary Hazel told the workgroup that he and Eva Hardy would be meeting prior to the September 28 workgroup meeting in order to discuss how to further frame the study issues. He told the workgroup that he would share his ideas and suggestions with the workgroup at the September 28 meeting. Ms. Hardy said that she would like to have a close-to-final list of issues and topics to review and discuss at the October meeting in order to arrive at a set of final recommendations.

Ms. Hardy then asked each of the workgroup members to briefly identify additional issues or topics that they believe need to be addressed in order to develop recommendations. She told the workgroup that she wants to focus on the Triple Aim: cost, quality and access.

Mr. Suddreth: Services that can be exempted from COPN should be identified while, at the same time, services for which COPN should be retained should also be identified. He said that COPN does not affect all services in the same way.

Dr. Szucs: The COPN process/system needs to be modernized. There should be some method for assuring quality, be it licensure or some other approach, put in place. In addition, there needs

to be an equitable approach for the provision of charity care – one that does not depend on hospitals and academic medical centers.

Ms. Mannix: Concerning the FTC presentation, she said that he would appreciate hearing a critique of the FTC’s findings and conclusions. Mr. Hilbert said that the American Health Planning Association (AHPA) has published such a critique. Secretary Hazel directed Mr. Hilbert to send the AHPA critique to the workgroup members, and to contact AHPA to see if a representative would be able to make a presentation to the workgroup at the September 28th meeting.

Mr. Cramer: The COPN statute needs to assure proper use of capital resources.

Ms. Sutton-Wallace: How do we modify COPN given the future of health care? Population health requires a proper mix of primary care and specialty care services. What are we doing to address cost, quality and access?

Ms. Cameron: She noted that \$24 million in charity care contributions/care were provided in 2013 as a result of conditions placed on COPNs. If Virginia does not expand Medicaid, then we are going to need to look at this very carefully. She said that COPN is the only mechanism currently available for assuring provision of charity care.

Dr. Trump: He told the workgroup that part of VDH’s statutory responsibility is to assure the provision of care.

Mr. Keefe: He told the workgroup that he would like to see a case study describing how, why and under what circumstances VDH denies COPN applications.

Ms. Oswalt: Virginia’s regulatory approach needs to be in synch with the way health care is evolving. The COPN program is antiquated. If the COPN program is modified, would the conditioning of COPNs also be modified? Right now we condition for access. Could we also condition for health improvement or other things? She told the workgroup that she would continue to advocate for access conditions. She also said that VDH needs appropriate infrastructure to do the work necessary to administer the COPN program.

Dr. Byrd: We need to look at ways to contain costs. COPN has served this purpose in the past but with changes in health care, perhaps now is the time to make modifications. He also noted that health care costs keep increasing.

Mr. Syers: Value-based payment has changed the context. He would like to see an actuarially-vetted analysis of costs in CON vs. non-CON states.

Ms. Armstrong: She would like to hear more about COPN applications that have been denied.

Dr. Hamrick: Most of the studies that are cited are old and no longer applicable. The good news is that we can measure cost and quality outcomes as we move forward. He also said that he has observed “mission creep” within the State Medical Facilities Plan, particularly concerning participation in disease registries.

Ms. Baskerville-Martin: She told the workgroup that it is important to look at the COPN process. It is possible to have good substance undone by bad process. She mentioned the need to examine requirements and process concerning: Letter of Intent, the COPN application form, COPN enforcement, and the level of review performed by the VDH Division of COPN as compared to that performed by the VDH Adjudication Officer.

Secretary Hazel concluded the discussion by stating that there may be some things that the workgroup can agree on by December 1, while other items may require more work over the next 1-2 years in order to reach agreement.

The workgroup approved the minutes from the July 1, 2015 meeting.

The meeting adjourned at approximately 4:00 p.m.

Appendix D

Certificate of Public Need (COPN) Work Group Minutes

**September 28th, 1:00-4:00 p.m.
General Assembly Building
House Room D
915 East Broad Street,
Richmond Virginia 23219**

In attendance: Virginia Department of Health Staff: Erik Bodin, Director of the Office of Licensure and Certification, Peter Boswell, Director of the Certificate of Public Need, Susan Puglisi, Policy Analyst, Joe Hilbert, Director of Governmental and Regulatory Affairs, and Doug Harris, Adjudication Officer, Certificate of Public Need. Work Group Members: Dr. David Trump, Deborah Oswald, C. Burke King, Dr. Richard Szucs, Dr. J Abbott Byrd, Brian Keefe, Dr. Richard Hamrick, Jill Lobb, Karen Cameron, Dr. William Hazel, Eva Hardy, Mary Mannix, Pamela Sutton-Wallace, Laurie Kuiper, Douglas Suddreth, Carol Armstrong, and Robert Cramer. Non-voting advising member: Jamie Baskerville Martin. Members of the public also attended.

The Chair of the Work Group, Eva Hardy, called the meeting to order at 1 p.m. and opened the floor to Secretary's Hazel's initial comments. Secretary Hazel noted that at the end of the meeting the Work Group would review a framework that the Virginia Department of Health (VDH) staff has created. He stressed that the document was simply a tool to give the Work Group ideas and a starting point to work from in terms of creating final recommendations.

Ms. Hardy then entertained a motion to approve the minutes from the previous meeting. The minutes were unanimously approved without any edits.

Erik Bodin, Director of the Office of Licensure and Certification provided the Work Group with a presentation entitled: Review of COPN Case Studies; the presentation focused on the denial of COPN applications. Mr. Bodin noted that over the past fifteen years that there have been 1,168 COPN decisions and 147 of those have been denials, therefore only 12.6% of applications are denied. Mr. Bodin introduced the case study to be reviewed for the Work Group, which was a request to expand an entity's CT service through the placement of an additional CT scanner. Mr. Bodin noted that the request came from Northern Virginia, specifically Planning District 8. Planning District 8 is the last remaining planning district with a Regional Health Planning Agency. Therefore, in the case study, prior to the Commissioner's decision on the application she received 3 recommendations: 1) from the Regional Health Planning Agency; 2) from The Division of Certificate of Public Need (DCOPN); and 3) from the Adjudication Officer. Mr. Bodin noted that when providing recommendations to the Commissioner, the policy and practice of the Regional Health Planning Agency and the VDH Adjudication Officer has not necessarily been to adhere to a strict interpretation of the COPN statute and the State Medical Facilities Plan (SMFP). However, it has been the policy and practice of DCOPN to adhere to a strict interpretation. DCOPN's intention in adhering to a strict interpretation in developing a recommendation has been to provide the Commissioner with a "bright line" reference to utilize in making a decision, while recognizing that the Commissioner retains discretion.

Next, Mr. Bodin reviewed the status of the CT Service within the Planning District. He noted that the request to add a CT scanner would have been the third for the hospital and the stated intent of the application was to decompress a CT scanner 8 miles away. First, DCOPN reviewed capacity of CTs in the district; there were 50 operational CTs at 32 different sites. Mr. Bodin then explained to the Work Group that the foundation for DCOPN's recommendation to the Commissioner and the Commissioner's decision is based on the evaluation of the COPN Request against the 8 required considerations laid out in Code of Virginia. He explained that his presentation will walk through the evaluation for each consideration for the case study's particular COPN request.

The first consideration is the extent the proposed service or facility will provide or increase access to care. In this case the planning district was well served geographically, and financial access was not a problem. Therefore the project did not meet this consideration. The second consideration is the extent to which the project will meet the needs of the residents of the area to be served. Mr. Bodin noted that for this project as with many projects there was ample support and dissent. Also several reasonable alternatives existed for the project including doing nothing, or relocating an underutilized CT. The third consideration is whether the project is consistent with the SMFP. In this case the proposed project was consistent with the SMFP but it was an unusual request, to offload a third site and wasn't really necessary as several other CTs within the planning district were not operating at utilization rates suggested by the SMFP.

Eva Hardy asked if the determination for consideration 3 would have been different if the application had been for a different hospital. Mr. Bodin noted the proposed alternatives would have been different.

Consideration 4 is the extent to which the proposed service or facility fosters competition. In the case study granting the COPN would not have fostered competition and may have been anticompetitive. Mr. C. Burke King asked if an applicant gets points for adding competition. Mr. Bodin noted that DCOPN's recommendation is not a score card; that it isn't broken down into points. Dr. Hamrick asked if there is a standardized set of criteria to determine whether or not an application will increase competition or if it's a judgment call. Mr. Bodin stated that DCOPN looks at a number of factors, such as whether the proposed service or facility serves a new geographic area, a new population group and whether the applicant is the dominant player in the market or if they are a new player. Mr. King asked all other factors the same would a "new player" win? Mr. Bodin answered, potentially assuming a number of criteria, including that public need exists. Also, Mr. Bodin noted that it's important to remember in a number of cases there is not a "winner" or "loser."

Secretary Hazel asked if there is an algorithm written down somewhere regarding how to gauge each consideration of an application. Mr. Bodin noted that there is not and stated that he does not believe such an algorithm would be useful in practice as each application is unique.

Consideration 5 is the relationship the project has to the existing health care system. In the case study, the project was associated with an existing system that operated 41% of the CTs in the planning district and more than half of the CTs within the planning district were underutilized. Mr. C. Burke King noted that a facility can keep the utilization rate of a piece of equipment artificially low. Ms. Karen Cameron also stated that she believes utilization rates do not necessarily indicate patient need as patients can choose to go elsewhere and doctors can refer patients elsewhere.

Consideration 6 is the feasibility of the project. In the case study the project would have been feasible; the pro forma budget demonstrated profitability and the project would have been funded through internal resources reducing the cost of capital. Secretary Hazel asked why this consideration exists. He noted if a facility hasn't done their homework, they lose and it shouldn't be public policy to ensure that each project is a winner. He asked how the consideration adds value. Mr. Doug Suddreth asked what requires the applicant to use internal resources after submitting such an application. Mr. Bodin stated that after the approval of a COPN an applicant is required to submit annual reporting. Mr. Suddreth stated that he didn't believe that requiring an applicant to use internal resources is enforceable. Secretary Hazel noted that the Code requires a new review to occur whenever the applicant makes a significant change to a project. Secretary Hazel asked if VDH has ever halted or revoked a COPN due to a significant change. Mr. Bodin stated that VDH may have modified a certificate or placed additional conditions on one but was not aware of any certificates revoked due to a significant change.

Consideration 7 is the extent to which the project provides improvements or innovations. In the case study the project would have provided improvement as newer equipment is more efficient. Finally the last consideration, consideration 8 is considered when a project is proposed by or affects a teaching hospital. The case study project was not affiliated with a teaching hospital. The regional health planning agency recommended approval. The DCOPN recommended denial based on the fact that the proposed project was generally inconsistent with SMFP criteria. The Adjudication Officer also recommended denial as the proposed project was inconsistent with the SMFP and there was already adequate CT Scanner capacity within the planning district. The Commissioner denied the application.

With that Mr. Bodin finished his presentation and asked if any members of the Work Group had any questions. Mr. Suddreth asked if there are any limitations on the conditions of a COPN that the Commissioner can impose. Mr. Bodin noted that the Code of Virginia is very specific regarding what conditions can be placed on COPNs; they are related to charity care, primary care and underserved areas. Mr. Bodin noted that VDH OLC has asked the Attorney General's office to determine if the Commissioner may impose conditions outside of the three listed within Code. VDH OLC has yet to hear from the Office of the Attorney General. Hearing no further questions the Work Group moved on to the next presentation.

Mr. Richard Thomas from the American Health Planning Association (AHPA) presented on the AHPA's perspective concerning COPN. Mr. Thomas noted that the AHPA is the longest existing health planning organization. The AHPA does not have a full time staff. Mr. Thomas stated that the AHPA is the most knowledgeable organization in existence regarding COPN, but stressed that the AHPA is not a COPN advocate. Mr. Thomas then reviewed his credentials. He again stressed that the AHPA is not a proponent or opponent of COPN rather the AHPA has an interest in the promotion of orderly development of the health care system. Therefore, the AHPA does support certain COPN actions but only so far as they promote the orderly development of the health care system.

Mr. Thomas noted that he would begin his presentation by "debunking" a number of COPN myths. Myths like: 1) the primary purpose of COPN is to control healthcare costs, 2) the primary purpose of COPN is to limit entry into the market, and 3) the primary purpose of COPN is to protect existing providers or limit the expansion of services. Mr. Thomas reviewed the purpose of the National Health Planning Act, which was to manage through regional planning

and supportive regulation the supply and distribution of health services. Mr. Thomas stated that COPN performs a number of subsidiary functions but the most important is that it creates a forum for public involvement in the creation of a health care system.

Mr. Thomas stated that there have been numerous attempts over the years to evaluate the impact of COPN. He noted that a majority of studies are biased against COPN and flawed in some major way. He stated there are a number of difficulties in conducting an evaluation of COPN. Specifically, there are no objective and meaningful metrics to study; COPN is usually "measured" by quality of care and access to care. These metrics, according to Mr. Thomas, are difficult to define, more difficult to measure, and nearly impossible to compare across states. Mr. Thomas noted that most studies concentrate on cost which is the hardest metric of all to assess across jurisdictions. He stated that the differences among states make comparison of one COPN program with another pretty useless.

Mr. Thomas noted that the healthcare market is not a market in a traditional sense; in that, the healthcare market does not have the characteristics of a competitive market. A lot of factors distort the market but most importantly consumer/patients are not making purchasing decisions and are not aware of prices or taking them into account. Mr. Thomas then went on to say that detractors argue that COPN prevents entry of new providers. He noted that in many places there is some localized shortage of certain personnel and services but he went on to argue that often the problem is "maldistribution" not limited supply. Mr. Thomas stated COPN can assist with "maldistribution."

Mr. Thomas then provided his response to the FTC testimony that the Work Group heard in their August 19th meeting. He stated the testimony provided by the FTC is of questionable value as it includes information that is outdated, misleading, irrelevant and unsubstantiated. He stated the testimony was based on results of 2003 FTC hearings and therefore is outdated as the healthcare market is very different today. Mr. Thomas reviewed the population/bed ratio information the FTC presented which he argued was presented in a manner to imply that Virginia residents were/are deprived of needed beds. Mr. Thomas provided data and asserted the alternative view that the U.S. rather had and has too many beds and Virginia had and has a more appropriate number of beds. Mr. Thomas argued that is corroborated by the fact that many Non-COPN states have a lower population/bed ratio than Virginia. Mr. Thomas maintained that nationwide there are too many facilities, too much equipment and too much testing. He went on to say that Virginia's rates and experience it could be argued to reflect a more appropriate balance of supply and demand.

Next Mr. Thomas reviewed whether changes in the healthcare system have eliminated the need for COPN. He stressed again that the main purpose of COPN is not cost control, but despite that fact COPN may reduce costs. Further he noted that increases in health disparities may indicate a continued need for COPN.

Mr. Thomas concluded by stressing once again that AHPA has no vested interest in COPN; rather the organization has an interest in the promotion of the orderly development of the health care system. AHPA supports COPN regulation to the extent it promotes orderly development of the health care system. Mr. Thomas noted that COPN is far from perfect but stated it is the only modicum of planning within the states which still have it. He noted that the process can be improved through an update of the regulations especially with a focus on healthcare technology.

With that Mr. Thomas concluded his presentation and asked the Work Group if they had any questions.

Ms. Hardy asked Mr. Thomas which state in his opinion has the best health planning process. Mr. Thomas answered New York. Some Work Group members asked for clarification regarding AHPA's stance as they viewed supporting health planning and then stating that the organization is not a proponent of COPN as incongruous. Mr. Suddreth noted that different health care providers are affected differently by COPN and medically underserved areas should be considered in any proposed changes to legislation. Mr. Thomas concurred stating that there should not be a one size fits all approach to each service.

A Work Group member asked if it was Mr. Thomas's opinion that if COPN is lifted that the "maldistribution" of services and facilities will continue or be exacerbated. Mr. Thomas stated yes and offered to provide the Work Group studies to support this opinion. Ms. Debbie Oswalt asked if the AHPA has done any forward thinking or planning regarding the future of COPN. Mr. Thomas stated that the AHPA does not have a plan regarding the future of COPN but there are some tools and papers that certain members of the organization have published and he would be happy to share them with the Work Group.

Mr. Keefe asked how the AHPA is supported. Mr. Thomas noted that AHPA is supported by member fees and the annual sale of COPN directories. Mr. C. Burke King asked if Mr. Thomas can provide empirical evidence that COPN is beneficial. Mr. Thomas stated he will provide the Work Group with some studies. Secretary Hazel also asked that Mr. Thomas provide some examples of ideal states in terms of health planning, besides New York. Secretary Hazel also asked Mr. Thomas for other tools in health planning besides COPN. Mr. Thomas stated the SMFP would be a tool; however Virginia's is not comprehensive or up to date. Secretary Hazel asked Mr. Thomas what needs to be measured and demonstrated within the SMFP. Mr. Thomas stated that there needs to be a move from individuals to patient groups and finally to social determinants. With no further questions Mr. Thomas was dismissed and the Work Group moved on to the last presentation.

Mr. Stephen Weiss from the Joint Commission on Health Care (JCHC) provided the Work Group a review of certain health care system characteristics in states with and without COPN. Mr. Weiss began by stressing the JCHC has no opinion regarding COPN and that Mr. Weiss was presenting at the request of Secretary Hazel. Finally, Mr. Weiss stated that the results within his report are observational and not intended to imply causation.

Mr. Weiss began with a brief history of the COPN. Then, Mr. Weiss presented a number of graphs displaying raw data. First, Mr. Weiss presented the per capita health care expenditures in those states with COPN compared to those without COPN. Next, he provided the per capita health care expenditures in states that have discontinued their COPN programs. Finally, Mr. Weiss presented the availability of hospital beds and ambulatory surgical centers in states with and without COPN programs.

Mr. Weiss stressed when reviewing the data he presented that it is important for the Work Group to consider all contributing factors. A Work Group member asked if the study controlled for other factors. Mr. Weiss answered no. Ms. Oswalt noted when reviewing this data it is important to remember that shortages occur because of a lack of a market; she stated that providers don't locate in certain areas because they would not be able to survive. She stated it is important the

Work Group is realistic about what COPN can and can't do. Ms. Mary Mannix asked Mr. Weiss why Virginia expenditures are lower than non-COPN states. Mr. Weiss stated again that the study is observational and he does not know why the disparity occurs.

Mr. Suddreth noted that some of the states listed as non-COPN states within Mr. Weiss's presentation have moratoriums on facilities and services and are actually more restrictive than COPN states. Dr. Trump also noted that the data regarding spending per capita is not adjusted for population age and other factors. Dr. Trump observed that certain states have older populations and that can have an effect on per capita expenditures. Dr. Hamrick also noted that Virginia physicians are conservative when diagnosing and treating which may also be reflected within the data. Hearing no further questions, the Work Group thanked Mr. Weiss and moved on to public comment.

There was no public comment.

The Work Group then moved on to the framework document. Ms. Hardy noted that there are three potential scenarios laid out within the framework document: 1) to retain COPN as is; 2) to retain COPN but with modifications; or 3) eliminate COPN. She stated she wanted to hear from each member now and members should submit longer comment to Joe Hilbert via email by October 10th. Finally Ms. Hardy concluded that the October meeting shall be an extensive public hearing and it is her hope that there will be public comment. Dr. Byrd asked how the Group will determine the recommendation(s) it makes, whether it shall be majority rule. Ms. Hardy stated that the Work Group shall have to come to a consensus.

Secretary Hazel began the conversation stating that it is well accepted the Work Group likely will not retain COPN as is. So he asked that the Work Group focus on Scenario 2 which is to retain COPN but with modification. Secretary Hazel began the conversation by asking what would be necessary to update the SMFP. Mr. Suddreth noted that a planning document requires resources and a lot of staff. Pamela Sutton-Wallace asked how the SMFP can be linked to the metrics Dr. Levine presented to the Work Group. Ms. Karen Cameron stated the Work Group should look into integrating the SMFP into a greater resource plan and that there ought to be community based individuals involved in developing both. Ms. Cameron noted that charity care conditioning must be considered especially in light of the increased coverage under the Affordable Care Act (ACA). Ms. Marry Mannix noted that services and resources must be kept in perspective, rather than just facilities. Secretary Hazel also noted that the Work Group must remember that the Commonwealth cannot mandate services absent payments.

Ms. Jamie Baskerville Martin noted that currently there is a lack of specificity within the SMFP and there is difficulty in the required process of updating it. She would like to see a more regular and seamless update and more specifics regarding technology.

Next the Work Group discussed exemptions, specifically, anything that shouldn't be included in COPN review. Mr. C. Burke King stated that he believes the marketplace should be allowed to determine which services exist, and that the marketplace is a much better determinant than a work group in Richmond trying to put together an SMFP. Mr. Suddreth stated that in theory, the marketplace would put facilities where they are needed, but in practice that is not the case. Mr. Suddreth stated that Virginia needs COPN and the SMFP.

Dr. Byrd suggested a blended approach. He stated that it's not reasonable to get rid of the COPN program completely however there is certainly room to improve. He noted that deductibles keep going up and there is not enough competition within the marketplace. He suggested looking at imaging services first and then moving towards ambulatory care. He noted that physical health is important but so is financial health as individuals do not seek out healthcare if they cannot afford it. Ms. Hardy argued that Scenario 2 isn't meant to be tinkering around the edges.

Ms. Pamela Sutton-Wallace asked how the Work Group can integrate quality into the COPN process. Dr. Byrd suggested utilizing conditioning to require high quality and lower costs and noted that mental health care facilities should be a focus. Secretary Hazel noted that the shortage of mental health care facilities in the state is due to a lack of providers and incentives are necessary to cure the problem. Mr. Keefe stated that COPN is not limiting access to mental health, and noted that is a funding issue.

Ms. Karen Cameron asked if additional staff for the COPN program is off the table. Secretary Hazel advised the Work Group should reach consensus on what recommendations the group should make prior to determining what level of staff and funding is necessary. Mr. C. Burke King stated it is his opinion that acute care hospitals should be carved out of COPN review. He stated high end services such as transplants and any areas where funneling a higher number of patients to one area creates a higher quality of care should remain under COPN review.

Secretary Hazel then asked the group if they have any comments regarding improvements to the application process. Mr. Suddreth asked why a new COPN review is necessary for equipment replacement especially if it's within the same jurisdiction. Ms. Jamie Baskerville Martin noted that access can vary drastically across a jurisdiction. Ms. Karen Cameron stated that Virginia has a unique application process and noted that an application deadline should be considered to speed up the review and make the review process fairer to competitors. Ms. Mary Mannix suggested that there should be greater use of the expedited review.

Secretary Hazel then moved the conversation on to revisions to COPN conditioning. Ms. Oswalt noted that there should be more clarification regarding charity care conditioning and it should be measured in some other means than the dollar value of care. Secretary Hazel stated that he would like to see Relative Value Units (RVUs) and Medicare multipliers in Virginia used to measure charity care. Ms. Pamela Sutton-Wallace stated that conditioning is one area where the Work Group can "incent" what isn't naturally incentivized.

Then the Work Group moved on to Post-COPN Approval Monitoring and Compliance. Ms. Oswalt stated that currently there are not enough resources to allow for post approval monitoring and compliance and argued there should be. Secretary Hazel asked what the group would think of a "Loser pays" provision within the Code. Ms. Karen Cameron expressed concern regarding such a provision as it may prevent some from having their day in court. Ms. Martin noted such a provision would be difficult to enforce. Ms. Hardy stated such a provision should be considered as some applicants utilize litigation to "game the system." Ms. Cameron asked DCOPN to report next meeting how many COPN cases have gone to court next meeting.

The Work Group wrapped up their conversation and Ms. Hardy stated that it is really important for members of the Work Group to share what they really think and encouraged more public comment. Ms. Hardy noted that Work Group members should send any additional comments to

Mr. Hilbert via email by October 10th. Mr. Hilbert noted he will send out a synopsis of all collected comments before the next meeting, which will be held on October 27th.

The meeting was adjourned.

Appendix E
Certificate of Public Need Work Group Minutes

October 27, 2015
1:00 p.m. – 4:00 p.m.
General Assembly Building,
House Room C
915 East Broad Street,
Richmond, Virginia 23219

In attendance: Virginia Department of Health (VDH) Staff: Erik Bodin, Director of the Office of Licensure and Certification, Peter Boswell, Director of the Certificate of Public Need, Susan Puglisi, Policy Analyst, Joe Hilbert, Director of Governmental and Regulatory Affairs, and Doug Harris, Adjudication Officer, Certificate of Public Need. Work Group Members: Dr. David Trump, Deborah Oswalt, C. Burke King, Dr. Richard Szucs, Dr. J Abbott Byrd, Brian Keefe, Dr. Richard Hamrick, Jill Lobb, Karen Cameron, Dr. William Hazel, Eva Hardy, Mary Mannix, Pamela Sutton-Wallace, Laurie Kuiper, Douglas Suddreth, Carol Armstrong, and Robert Cramer. Non-voting advising member: Jamie Baskerville Martin. Members of the public also attended.

The Chair of the Work Group, Eva Hardy called the meeting to order at 1 p.m. She noted that the meeting was the second to last meeting of the Work Group and wanted to thank to the workgroup for their comments which were sent to Joe Hilbert prior to the meeting. Ms. Hardy also thanked those who have signed up to speak during the public comment period of the meeting. She stated that the purpose of the public comment is for members of the public to present one or two points they feel are critical. She noted the public comment may be repetitive and stated that new points are always very helpful.

Ms. Hardy then entertained a motion to approve the minutes from the previous meeting. Karen Cameron noted that she had a few corrections to the meeting minutes and presented them. With these corrections the minutes were approved unanimously.

Then Ms. Hardy opened the floor to public comment.

Charlotte Tyson from Lewis Gale began public comment by stating that COPN affects the ability to provide treatment to newborn babies. She stated that Lewis Gale has submitted an application for a NICU which has been denied three times on the basis that the application was duplicative of nearby services. Ms. Tyson stated that this causes newborn patients to be transferred 30 minutes away during the "golden hour," which can cause mortality and provided an example.

Dr. Michael Fabrizio then spoke and stated he wanted to use his time to dispel some COPN myths. First he stated that COPN does not control costs but rather keeps costs high as the law inhibits competitive markets. He then stated another myth is that hospitals need higher fees to

cover indigent care. However, Dr. Fabrizio stated that "nonprofit" hospitals do not pay taxes. Finally Dr. Fabrizio stated that COPN discriminates against physician centers.

Mr. John Duvall from VCU Hospitals commented next. He began by saying medical discovery is not static and noted that Virginia laws and regulations must be able to be amended quickly to introduce new technologies. Mr. Duval charged the Work Group to update the SMFP more frequently and comprehensively and noted when he asked for comprehensive amendments he meant amendments with an eye towards long term consequences. Mr. Duval finished by saying should the COPN program be deregulated institutions of medical education would be put at risk, as other entities will cherry pick profitable services leaving teaching hospitals and other such institutions vulnerable.

Next, Don Adam provided his remarks. He stated that additional access to emergency medical care is needed across the nation and in Virginia. He argued that COPN does not allow this additional access as it restricts expansion. Dr. Adam stated he would be happy to provide additional information to the Work Group.

Mr. Jim Dunn from Bon Secours said that he favored comprehensive reform of the COPN program. Then referring to the COPN Work Group Draft Recommendation Document stated that Bon Secours particularly supports Recommendation 2, 5 and 7.

Mr. Paul Matherne of UVA Health System then spoke stating that there are many reasons to keep COPN in Virginia. One such reason to maintain COPN is for neo-natal care. He stated that outcomes for this type of care are crucial and in order to obtain positive outcomes standardization is needed. He argued that patient volume is necessary for standardization. He finished by saying that COPN protects patients by ensuring that NICU decisions are made with an eye on outcomes rather than money.

Mr. Alan Matsumoto from UVA Health System spoke stating he favored increased flexibility in COPN. He stated COPN provides access to charity care for patients however he noted that COPN is not well regulated or monitored during the post approval process. He stated healthcare is not a free market and if COPN is eliminated there is no evidence that cost or quality of care will improve. He argued that the COPN process is inflexible and impractical and provided a number of suggested changes for the Work Group to consider.

Mr. Don Harris from INOVA stated that the recommendations before the Work Group mirror the Joint Commission on Health Care's plan that was presented years ago. He noted, the JCHC's plan was never fully implemented because the goals of the first part of deregulation were never reached. Mr. Harris noted that INOVA supports the process recommendations within the Work Group Recommendation Document but that his organization finds #7 concerning. He stated there is not enough information available about the impact of deregulation on the market. He finished by stating the idea that healthcare is a "free market" is a myth as healthcare is provided regardless of a patient's ability to pay.

Jamil Khan from Children's Hospital of the King's Daughters spoke in support of COPN. He stated the program helps regionalize highly specialized services such as NICUs. He argued that in highly specialized services the volume of patients affects outcome, in that more volume means better outcomes. He stated that in a recent report the American Academy of Pediatrics touched on the importance of having regionalized care. He finished by noting that a physician's experience comes from a higher volume of patients and more experience means better quality of care for patients.

Mr. Brent Rawlings from the Virginia Hospital and Healthcare Association (VHHA) stated that the law must remain intact but meaningful reforms must occur. He noted that VHHA supported the legislation which created the Work Group and that VHHA created its own Work Group which worked concurrently with the COPN Work Group. VHHA's Work Group came up with a set of recommendations that are similar to the COPN Work Group's recommendations. Mr. Rawlings noted that VHHA disagrees with Recommendation #7 within the COPN Work Group Draft Recommendation Document. Mr. Rawlings stated that the services which are being considered within that Recommendation for deregulation would be better suited for expedited review rather than deregulation. VHHA supports Recommendations #1-6 and 8. Mr. Rawlings noted that he and VHHA would like to commend the Work Group on their work.

Mr. Paul Speidell from Sentara Healthcare added his comments, saying that Virginia's healthcare system is far from perfect. He stated that the healthcare system is broader than COPN, he worried that the Work Group is getting pulled into the trees when the need is to consider the forest. He noted that COPN has been a part of the "forest" for forty years and several policy decisions have "grown up" around it, such as limited reimbursement for indigent care, teaching hospitals and the uninsured.

Mr. Doug Gray was the last of the public commenters and spoke on behalf of the Virginia Association of Health Plans. He provided a written statement to the Work Group. He stated that it is important to have a process that fosters competition while still keeping the best interests of consumers, payers, and providers in mind. Mr. Gray stated that the health plans agree on reforms to the process and making conditions on COPN certificates more uniform and transparent. Further the health plans also support more oversight of charity care. Mr. Gray noted that some plans favor restricting COPN over several years. Mr. Gray finished by stating that all the health plans oppose Certificate of Public Advantage.

At this point the Work Group turned to the COPN Work Group Draft Recommendation Document. Mr. Hilbert presented this document. He noted that the recommendations within the document all originated from Work Group members. Secretary Hazel reminded the Work Group that the three options in front of the Work Group are 1) Keep the program as is, 2) Amend the program, or 3) Repeal the program. Secretary Hazel noted that the recommendations in front of the Work Group are related to amending the program and stated that none of these recommendations are set in stone.

Mr. Hilbert began reviewing the recommendations. Recommendation 1 is that the Code of Virginia should be amended to include a statement of purpose for the COPN program. Mr. Hilbert noted that within the Code COPN does not current have a "goal statement," this recommendation would propose an amendment to the Code to include one. Numerous Work Group members expressed support for a goal statement. Both Karen Cameron and Mary Mannix suggested amendments to the proposed goal statement. Ms. Mannix suggested that the Work Group members provide wordsmithing comments to Mr. Hilbert prior to the next meeting so as move the Work Group's discussion forward. Ms. Debbie Oswalt stated that a few years ago there was a very deliberate move to remove goal and purpose statements from the Code of Virginia. She suggested that the Work Group investigate whether that is still the current preference. Ms. Hardy stated that although the General Assembly may not include the goal statement within the finalized legislation it is still important for the Work Group should include such a statement so as to inform the General Assembly. Ms. Jamie Baskerville Martin stated that the guiding principles within the COPN regulations should be read and considered in place of the suggested goal statement.

Mr. Hilbert then presented Recommendation 2 which is that the State Medical Facilities Plan should be reviewed and updated in a timely and rigorous manner. Mr. Hilbert provided a summary of the latest activities of the SMFP task force, noting that a NOIRA was published on June 29th of this year and the public comment period following that action closed on July 31, 2015. Mr. Hilbert noted that the Virginia Department of Health has prepared proposed amendments to the SMFP which have not yet been submitted pending the outcome of the COPN Work Group. Further the SMFP Task Force met on July 29, 2015 to review provisions concerning mental health services. Mr. Hilbert noted that two subcommittees of the Task Force were formed at that they were to meet the very next day. Recommendations to amend the SMFP related to mental health services have not yet been issued.

Ms. Hardy asked whether the Work Group would like to keep the SMFP in the Virginia Administrative Code or to take it out and make it a Guidance Document. Mr. Hilbert noted that this is Recommendation 2e and that the Office of the Attorney General is currently reviewing issues pertaining to this option, including whether the SMFP is less enforceable if it is not in regulation. Ms. Hardy asked Mr. Hilbert to request that the Attorney General's advice on the matter be provided to the Work Group at least a week before the next meeting of the Work Group. Secretary Hazel asked if the SMFP should be taken outside of the Administrative Process Act process.

Mr. Hilbert noted recommendation 2d which suggested that the SMFP be integrated into the State Health Improvement plan and be renamed the State Health Services Plan. Debbie Oswalt asked if the State Health Improvement Plan was the plan that Dr. Levine presented to the COPN Work Group and asked how the two would mesh. Mr. Hilbert answered in the affirmative and stated that the idea is just conceptual at this point and cannot answer specific questions but can say that the SMFP would "feed into" the quality of care pillar. Ms. Karen Cameron asked if any

regional or local analysis of need shall be integrated into the State Health Services Plan. Mr. Hilbert noted that the State Health Improvement plan will integrate regional analysis. Secretary Hazel stated he wouldn't suggest integration but alignment. Dr. Richard Hamrick stated that the Work Group needs to know the direction of the COPN program before determining what direction is best for the SMFP.

Secretary Hazel turned the conversation to Recommendation 2c which stated to require annual review of the SMFP and an update of it every two years. Mr. Hilbert noted that should this recommendation be adopted it would likely require the SMFP be removed from the Virginia Administrative Code as most standard regulatory actions take 18 to 24 months to complete. Ms. Hardy noted that should this be the route the Work Group decides upon there should be a requirement for an extensive public comment process.

Mr. Hilbert moved on to Recommendation 3 which was that the process for submission and review of COPN applications should be streamlined. Recommendation 3a is that VDH should evaluate the COPN application forms to ensure that only data necessary to the review of an application is required to be submitted and that the forms reflect statutory requirements. The Work Group expressed assent with this recommendation. Mr. Suddreth noted that the applications can be repetitive as the criteria for consideration was reduced from 21 to 8. Recommendation 3b is that the Code of Virginia should be amended to require that a COPN be fully complete at the time of submission by the established deadline in order to be considered. A member of the Work Group noted that providers try to game the system using an incomplete application. Jamie Baskerville Martin argued for more refined forms and stated that a reasonable completeness bar is appropriate. She stated it will be ideal to determine a line regarding what is complete but not bar the department obtaining further information should they require it. The Work Group expressed a desire to see new forms and that the recommendation should be wordsmithed. The new recommendation should require an answer to each question and a deadline for added information. Mr. Hilbert noted that VDH would work on this recommendation.

Mr. Hilbert moved on to Recommendation 3c which states SMFP compliance requirements and the role of SMFP in the COPN should be clarified. He explained this recommendation would allow DCOPN to recommend approval of an application, and the Commissioner to authorize a project, that is "in general agreement with" the SSMFP, even if not strictly compliant with it. Jamie Baskerville Martin noted that this change would allow compression of the COPN review process and would allow more COPNs to avoid expensive IFFCs. Ms. Mary Mannix noted that if the SMFP is more dynamic and updated more frequently this recommendation would not be as much of an issue. Karen Cameron stated there is caselaw regarding this issue which needs to be reviewed prior to making a decision. Ms. Hardy noted that she believes this recommendation is a bad idea as it would open up the Department to litigation. Dr. Byrd noted agreement with Ms. Hardy.

Mr. Hilbert moved on to recommendation 3d which is that the requirement for registration of replacement medical equipment should be repealed. Karen Cameron stated that registration of replacement medical equipment is important as it creates tracking and inventory. She stated that if the Department is going to be able to participate in populations based planning the Department will need to know both the resources within the area and the quality of those resources. This prompted Ms. Martin to state that it is necessary for the Department to be notified if the replacement is being "replaced up" or "replaced down."

Mr. Hilbert then presented Recommendation 3e which states a process should be developed for increased utilization of an expedited review of certain COPN applications. Mr. Hilbert noted that greater use of expedited review would require statutory and regulatory change. Mr. Hilbert noted that expedited review is only currently allowed for any capital expenditure of \$15 million or more other than by a general hospital. Mr. Hilbert stated that capital expenditure of \$15 million or more would not be made by any other entity other than a general hospital and therefore there is in practice no circumstance which qualifies for expedited review. Secretary Hazel asked for a summary of expedited review. Mr. Erik Bodin provided such an explanation. Mr. Hilbert noted that in Michigan there are: Expedited, Substantive and Comparative review. Mr. Hilbert suggested this could be used as a model for Virginia. Ms. Martin asked how much the Work Group plans on compressing the review period; because if the standard review period is sufficiently compressed an expedited review may not be necessary. Ms. Hardy suggested that the Work Group members provide comments regarding expedited review to Mr. Bodin and Mr. Hilbert.

Mr. Hilbert then moved on to Recommendation 3f which is that the requirements for public hearing should be reduced, to be required only when: 1) The review is for competing requests; 2) requested by an affected party within 30 days of the application being accepted for review; 3) requested by an elected local government official or member of the Virginia General Assembly, or 4) requested by the State Health Commissioner. Ms. Hardy asked how the public is notified of public hearings. Mr. Bodin noted that the notice of public hearing is published in newspapers. Ms. Cameron noted that this publication is usually in the legal notice section which most individuals do not read. She argued for better notification of the public, suggesting online notification. She further stated that this recommendation removes the public from the public hearing process and that a public hearing should be required if a member of the public requests a public hearing. Mr. Suddreth stated that long term care facilities are required to notify any entity within 45 minutes who provide the same services of their application. He asked what the definition of an affected party is and reaffirmed that both affected parties and members of the public should be allowed to request a public hearing. Mary Mannix stated that there are different methods other than a public hearing for members of the public to submit comments such as a web domain. Ms. Eva Hardy asked if the Department should submit notifications regarding public hearings as newspaper ads and have the applicant pay for it. Secretary Hazel stated that the Work Group members should provide their suggestions and comments and Mr. Hilbert should present this recommendation again next meeting. Secretary Hazel noted that it is clear

that there is a consensus that there is no need to have hearings no one is showing up for but perhaps there are better ways to get the public involved.

Mr. Hilbert moved on to Recommendation 3g which states provisions concerning "Good Cause" petitions should be revised. The Work Group requested an explanation of the "Good Cause" petition from Doug Harris, which Mr. Harris provided. Dr. Hamrick noted that the "Good Cause" petition is part of the checks and balances of the COPN program.

Mr. Hilbert then presented Recommendation 4 which is that the rules regarding the conditioning of COPNs should be clarified, standardized and enforced. After some discussion Ms. Hardy suggested that the Department should provide a definition for COPN charity conditioning by the next meeting. Mr. Hilbert moved on to Recommendation 4c which would be to codify requirements of the Virginia Department Health Guidance Document concerning compliance with conditions on COPN. Ms. Karen Cameron stated that she does not believe this is necessary and the document should remain guidance so that it remains flexible. Dr. Byrd suggested that the guidance document be put into regulation instead of within the Code. This permits flexibility and enforcement. Mr. C. Burke King stated that charity care should also have a consistent measure; he noted that he believes the current measure is meaningless. Ms. Hardy suggested that the Department combine recommendations 4c and 4d and present the new recommendation to the Work Group at the next meeting. Ms. Hardy asked what the penalty for not complying with the charity care condition would be. Mr. Bodin noted that there are currently penalties for not complying with charity care requirements, with the penalty being \$100 per day. It was noted that, for most COPN holders, paying the fine is less expensive than actually providing the charity care.

Mr. Hilbert then presented Recommendation 5 which is that the transparency of the COPN program to the public should be increased. Pamela Sutton-Wallace stated that public comment could be tied into this recommendation.

Ms. Hardy noted that at the next meeting Mr. Hilbert and the Department should present these Recommendations be organized in the following manner: 1) those that would require legislation; 2) those that would require budget language; 3) those that would require administrative action/action by the Commissioner. Mr. Hilbert stated he would do so.

Then Mr. Hilbert moved on to Recommendation 6 which is that the Virginia Department of Health should have adequate resources to administer the COPN Program in a cost-effective manner. Mr. Suddreth stated that the current fees are on the low end. He noted that the current fees are simply not enough to run the program effectively and that the General Assembly must fund the program or it must be self funded through fees. Dr. Byrd asked that the Department of Health provide a recommendation regarding how much these changes would cost to execute. Secretary Hazel stated that putting such a task to the Department is a bit problematic as the Work Group has not told the Department what changes the Work Group will recommend. Ms. Hardy stated that the Department should present ball park figures of the cost of implementing the

Recommendations before the Work Group. Secretary Hazel noted that it is the consensus of the Group to provide appropriate funding. Mr. C. Burke King clarified that providing appropriate funding does not necessarily mean increasing fees.

Mr. Hilbert then presented Recommendation 7 which is the implementation of any new exemptions of certain medical facilities/projects from COPN Requirements should be phased-in and occur within the framework of a specified deregulation plan. Dr. Hamrick stated that all projects determined to be exempt from COPN should be required to report quality assurance standards. Secretary Hazel asked why there should be two different standards. Dr. Hamrick noted that not just newly exempted projects should be required to report quality assurance standards but all projects should. Pamela Sutton-Wallace stated that the devil is in the details, she asked what the quality assurance standards proposed would be and how would they be monitored.

Ms. Jamie Baskerville Martin noted that the wording of Recommendation 7 is different from the other recommendations. She asked for clarification from Mr. Hilbert as to whether the Recommendation is to tell the General Assembly to consider exempting certain medical facilities/projects or if the Work Group should consider exempting certain medical facilities/projects. Mr. Hilbert clarified that the recommendation is that that the Work Group consider this possibility.

Regarding Recommendation 7c which is to consider exempting certain medical facilities from COPN "approval" based on SMFP volume and/or geographic criteria while still retaining them within the COPN program. Mr. Hilbert clarified that in lieu of establishing new licensure categories with associated regulations and inspection programs, applicants could submit a COPN application which would be "automatically" approved with conditions. The conditioning would establish charity care and quality assurance standards which would be subject to ongoing compliance monitoring and reporting. Mary Mannix asked would this become "expedited review." Secretary Hazel asked what would fall under this category. Members of the Work Group answered CT, MRI etc. Pamela Sutton Wallace suggested that the list should include services which are needed such as mental health services and noted that the list would change over time.

Ms. Hardy noted that this is the opportunity to move forward as there have been discussions about scaling back COPN for 30 years, she believes this is the opportunity to move forward cautiously. Mr. C. Burke King stated that he believes that today's conversation is reflective of why the program needs to be scaled back, as the Work Group spent so much of the meeting time discussing process and didn't get to the meat of the issue until the end of the meeting. Mr. King further noted that the panel is polarized on this issue and may not be able to come to consensus. Ms. Mary Mannix stated that the Work Group was charged with reviewing the process.

Mr. Hilbert reviewed Recommendation 7d which is a two phase deregulations plan. Mary Mannix noted that this recommendation would take the Work Group towards repeal. Ms. Hardy stated that hospital and nursing home beds would remain under COPN.

Ms. Hardy suggested that each member of the Work Group provide their comments regarding recommendation 7. Ms. Jamie Martin stated that Recommendation 7 is really the meat of the recommendations. Mr. Doug Suddreth stated he did not want to rush though the meat of the Recommendations. Secretary Hazel stated that he did not believe there was enough time for substantive and meaningful comment during the remainder of the meeting. Ms. Hardy agreed and stated that each member of the Work Group needs to provide Mr. Joe Hilbert with their thoughts and opinions regarding all recommendations but especially Recommendation 7 by the next meeting.

Secretary Hazel noted that there may be a need for 2 more meetings rather than 1. He stated that the Work Group shall keep the November meeting and may add one additional meeting.

The Work Group adjourned at 4:30.

Appendix F

COPN Workgroup – Summary of Written Comments

The following is a summary of written comments received in response to the “Framework of Potential Ideas for Recommendations” discussed at the September 28, 2015 Workgroup meeting. Comments were received from the following Workgroup members:

- Dr. Richard M. Hamrick III
- Mary Mannix, FACHE (Augusta Health)
- Burke King (Anthem Blue Cross and Blue Shield)
- Dr. Abbott Byrd (Virginia Orthopaedic Society)
- Dr. Richard Szucs (Virginia Chapter – American College of Radiology)
- Doug Suddreth – (Virginia Health Care Association)
- Karen Cameron (Virginia Consumer Voices for Healthcare)
- Pamela Sutton-Wallace (University of Virginia Medical Center)
- Jamie B. Martin – COPN Workgroup Advisor (McCandlish Holton)

Comments were also received from the following individuals and organizations:

- Virginia Hospital and Healthcare Association (Brent Rawlings)
- Dr. Kinloch Nelson
- McGuire Woods Consulting (Tyler Bishop)
- M.H. West & Co., Inc. (Marilyn H. West)
- LeadingAge Virginia (Bob Gerndt/Dana Parsons)
- Kemper Consulting (Joel Andrus)

Workgroup Members

Dr. Richard M. Hamrick III

Supports looking at the structure of the SMFP and ways to update and improve it. However, it is impossible to evaluate any specific proposal or suggestion in isolation. Whether any of these ideas merits action depends on the overall approach to restructuring the SMFP.

No objection to changing name of SMFP to “State Health Services Plan.” However, the Plan, and any amendments to it, should remain a regulation that is part of the Virginia Administrative Code.

Any discussion of eliminating services or facilities from the COPN requirements should not be done in isolation. Instead, such discussion should involve a review of all services currently regulated by the state and detail the justification for retaining the current level of regulation. The DCOPN should retain the completeness review. Rather than eliminating it, a better approach would be to update the application forms so that meaningful information is requested in the application form.

Improvements to the public hearing requirements should be evaluated. Public comments can be more cost-effectively submitted in writing.

Support for a proposal to consider revising application fee schedule would depend on how any revised fees would be used.

Strongly supports a requirement that all documents be submitted electronically through a website that posts documents in real time.

While it is generally preferable to have decisions made more quickly, supporting greater use of the expedited review process would depend on the specific alternatives being proposed.

To the extent that the current COPN system remains substantively intact, the letter of intent is essential for competitive applications for similar services.

To the extent that the current COPN system remains substantively unchanged, the ability to extend the timeline for review by the applications should remain as well. The current process provides an appropriate degree of flexibility.

To the extent that the current COPN system remains substantively unchanged, the current requirements for good cause standing should remain.

The idea of making sure that providers are approaching the provision of charity care in similar ways may be beneficial to the system as a whole.

Based on the presentations so far to the workgroup, it does not appear that the DCOPN has available resources or expertise to engage in ongoing monitoring of clinical quality.

Existing inpatient hospitals should be able to add acute and mental health beds and inpatient operating rooms without COPN approval.

Existing inpatient hospitals should be able to add open heart services, provided the facility meets all of the clinical standards for such services, without being subject to objections by competing providers.

COPN regulations pertaining to NICU services should be updated to reflect the advances in the standard of care in treating pre-mature births. A hospital that wants to add a “specialty-level” NICU in order to keep mothers and babies together and to ensure prompt treatment of babies in distress are blocked from adding such services under current regulations if such addition has a “significant” impact on the utilization of competing providers of such services.

Encourages the workgroup to consider the need to evaluate whether the Northern Virginia Regional Health Planning Agency continues to serve a need in the COPN process.

Mary Mannix, FACHE (Augusta Health)

State Medical Facilities Plan

- Enforce Statutory Review Requirements and Amend Statute to Require Review Every Year and Updates Every Two Years to be sure intended policy goals are being met - Board of Health could require the SMFP Task Force to provide status updates.
- Appoint a Third Party to Lead SMFP Task Force -Consideration should be given to having the technical work associated with developing the SMFP completed by a private firm with health planning expertise as is done in Michigan.
- Create a Robust SMFP that is More Objective and Data-Driven-A SMFP with more specific definitions and formulas for determining need, utilization data, and service expansion requirements would help to minimize the amount of discretion required in DCOPN and Hearing Officer recommendations and Commissioner decisions.

Charity Care

- Continue Application of Conditions- To the extent policymakers are concerned that there is inadequate supply of primary care or specialist physicians accepting Medicaid patients, the statute and regulations could be modified to include the ability to condition an application on an agreement by the applicant to participate in Medicaid and accept Medicaid patients.
- Charity Care Reporting Guidelines Should be Revised to be Consistent with Industry

Standards and Practices

- Increase Transparency in Application of Charity Care Conditions
- Improve Monitoring and Enforcement of Conditions

Streamlining COPN Review

- Consider Limiting Need for Public Hearing
- Make Greater Use of Expedited Review

Burke King (Anthem Blue Cross and Blue Shield)

Anthem recommends deregulation of COPN in Virginia in two phases:

Phase 1

- MRI
- CT
- PET
- Non-cardiac nuclear imaging
- Lithotripsy
- Cardiac catheterization
- Radiation therapy
- Gamma knife surgery
- Ambulatory surgery centers
- Mental health and substance use disorder facilities

Phase 2

- General acute care hospital beds and services
- Obstetrical services
- Neonatal special care

Further, the COPN law should not apply to new medical technologies and advancements. COPN should remain in place for nursing facilities, organ transplants and open heart surgery. Charity requirements should be established that apply consistently to all providers who wish to offer services that are no longer subject to COPN approval. The proposed charity care requirement should be based on a consistent fee schedule such as Medicare or the volume of charity services offered. Providers should commit to retain access for patients who receive services under the Medicaid and Medicare programs.

The Commonwealth must make the commitment to provide the necessary oversight and monitoring of these charity care and government-sponsored program requirements. These resources already exist as the Department of Health staff can be repurposed from their traditional role administering COPN to the oversight of charity care requirements.

Dr. Abbott Byrd (Virginia Orthopaedic Society)

Supports making significant modifications to the current COPN law (Option 2) that will benefit Virginia patients and result in better health outcomes.

Recommendations should combine changes in the current application process, as well as relaxing the COPN laws on certain services.

Quality issue may be addressed by requiring any relaxed service to adhere to national parameters on utilization rates, as well as the quality of the equipment and services provided.

If COPN protected services were released from the COPN requirement, sufficient indigent care could be assured by coupling those services with an indigent care requirement.

Imaging services (CT scanners and MRIs), as well as ambulatory surgery centers, should not require a COPN. Quality data on these services is readily available. Providers could easily be required to comply with an indigent care requirement.

Dr. Richard Szucs (Virginia Chapter – American College of Radiology)

If COPN is reformed or eliminated with regard to imaging there are certain things that must be addressed:

Maintenance of quality must be ensured. The quality of the imaging equipment can be maintained through requirements for licensure and inspection. The quality of performance of examinations can be addressed by requiring accreditation of facilities (ACR accreditation or equivalent). The quality of interpretation of exams can also be addressed through accreditation or credentialing of providers.

There needs to be a mechanism to prevent increased utilization that does not improve patient and population health outcomes. There are existing programs to do this such as ACR Select from Clinical Decision Support.

Finally, there must be adequate access for charity patients and requirements for equitable participation in provision of charity care with monitoring and oversight

Doug Suddreth – Virginia Health Care Association

Retain COPN for nursing facilities.

Eliminate the requirement to obtain a COPN for relocation or replacement of medical care facilities within the same primary service area.

Revise COPN application forms to reflect the current statutory requirements

Eliminate extended, time-consuming completeness reviews in the COPN process.

Eliminate the public hearing requirement if the review is not competitive or if no request for a public hearing is received by the Department from an affected party within 30 days of the application being accepted for review.

If there is no competitive review, IFFC, or public hearing required, expedite COPN decision timeline to 120 days.

Ensure that the Department tracks compliance with all conditions placed on COPNs by the Commissioner.

The fee schedule required for COPN applications should reflect the complexity of the reviewable project.

Karen Cameron (Virginia Consumer Voices for Healthcare)

Ensuring Access to Care for Low Income/Uninsured Persons

- Any deregulation of services should have a requirement that all providers of those services do their fair share of indigent/charity care.

Incorporation of a Population Health Basis to State Health Planning & COPN

- Virginia needs to move aggressively to incorporate population health into a state health plan and identified health care resources should emanate from that plan, rather than a state medical facilities plan.
- VHI patient level database should be used to make decisions about population health needs and the appropriate placement of regulated facilities and services.
- VDH current staffing level devoted to development and regular update of a state health plan, use of population-based planning, and rigorous charity care compliance monitoring and enforcement is very low.

Improve Transparency

- VDH COPN program should publish COPN applications and related documents (e.g. staff analyses/evaluations, adjudication officer reports, case decisions, charity care reports) on-line.
- Virginia may want to change its regulations/practices such that applicants would not be able to submit additional information or make changes once the completeness review was complete and the application was accepted.

Encourage Public Involvement

- Mechanisms for consumer participation need to be incorporated should COPN be maintained and in order for effective population based health planning.
- Support for regional agencies should be provided.

Coverage Changes

- Eliminate COPN coverage of lithotripsy services.
- Eliminate COPN coverage of brachytherapy and stereotactic radiosurgery services. Both of these services are forms of radiation therapy. There is no need to regulate them as distinct separate services.
- COPN regulation of cyberknives/gammaknives should be retained.
- The ratio of nursing home beds to domiciliary care beds in continuing care retirement communities should be changed to 10% (reduced from the current 20%).

COPN Fees

- Virginia's COPN filing fees are low compared with states regulating similar services. Fees should be raised to a level comparable to those of neighboring jurisdictions to help adequately fund program needs.

Pamela Sutton-Wallace (University of Virginia Medical Center)

Strongly opposed to elimination of COPN, but program needs meaningful reform.

Updating the State Medical Facilities Plan

- The SMFP Task Force should be reconvened to consider how the SMFP might be restructured, updated and otherwise revised.
- Once reconvened, the Task Force should re-examine the structure and content of the SMFP to determine how the document might function better as a health planning tool.
- An SMFP with more specific definitions and formulae for determining need, and one that relies upon verifiable, well-sourced utilization data, would help to increase transparency.
- Enabling the Board of Health to approve and re-issue the SMFP as a non-regulatory form would simplify the current review process.

Exemptions for Certain Facilities and Projects

- Any deregulation must be considered in the overall context of health planning.

Improvements to Application Processing

COPN program should increase availability of online information through a dedicated portal maintained by VDH.

- Eliminate public hearings – Instead of conducting hearings DCOPN should post public notice online through a dedicated portal or through existing electronic notice boards used by the Commonwealth, and solicit public comments in writing.
- Consider revising the application fee schedule, and consider whether the current fees are adequate to cover program costs
- All applications should have “expedited reviews” – Ideally, all review could be expedited if public hearings were eliminated and review cycles were shortened. In the absence of such widespread reforms, expedited review could be made available to additional categories of products such as lithotripsy, substance abuse treatment services, intermediate care facility/mental retardation services, and nuclear medicine.

Revisions to COPN Conditioning

- Clear definition of charity care is needed. Definition should focus upon a patient’s ability to pay for services at the time they are provided, and should not include bad debt or contractual allowances.
- More transparent methodology for setting charity care conditions is needed. One approach might be to require the COPN applicant to provide the same level of Medicaid service as the average for some defined area such as the planning district. If the Certificate holder fails to meet that condition, it would be required to make a financial payment to a health care organization or “the state indigent care fund.”

Post COPN-Approval and Monitoring

- There is clearly a need for better monitoring of compliance with charity care conditions.
- There is currently no mechanism in place to monitor how approved services are actually being delivered. Other states (e.g., Michigan) require annual reports from their providers on volumes and outcomes of certain services as a condition of continued authorization to continue providing those services.

Promote Greater Transparency

- DCOPN must make information much more readily available to stakeholders and the public. Thoughtful implementation of information technology systems would be a tremendous step in the right direction.
- DCOPN needs improved access to data sources so that it has current, reliable information it needs to assist the Commissioner in making fair, impartial decisions.

Jamie B. Martin – COPN Workgroup Advisor (McCandlish Holton)

Establish more regular and rigorous reviews/revisions of the State Medical Facilities Plan (“SMFP”).

- Update and implement the SMFP as a non-regulatory health planning document, to include:
 - a) Comprehensive review of services and facilities to be regulated (for example, exclude brachytherapy services, and perhaps lithotripsy, from the definition of a reviewable project).

- b) Revision of standards for services to be regulated so they more accurately reflect public need and care delivery models. For example, the psychiatric/substance abuse beds for adult and pediatric patients are currently combined, even though those populations' needs can be different and are often served differently. As another example, the diagnostic imaging SMFP provisions do not clearly apply to some of the models by which diagnostic imaging services are provided.
- c) Clarification of standards for neonatal special care services. The current standards reference utilization at certain levels, but bassinets can be added without COPN authorization, so the levels are meaningless.
- d) Incorporating the State Health Commissioner's (the "Commissioner's") SMFP interpretations in case decisions (such as what types of projects qualify as "expansions" rather than "new" projects).
- e) Providing for regular and rigorous reviews and revisions by the SMFP Task Force and establishing the composition of that Task Force.

Clarify SMFP compliance requirements and the role of the SMFP in COPN decisions.

- The role of the SMFP in COPN decisions should be clarified to allow DCOPN to recommend approval of an application, and the Commissioner to authorize a project, that is "in general agreement with" the SMFP, even if not strictly compliant with it. Suggestions include:
 - a) Clarifying that strict compliance with the SMFP is not required for approval of an application and that DCOPN has the ability to recommend approval of an application that does not strictly comply with the SMFP.
 - b) Granting the Commissioner the authority to approve COPN applications based on additional unique factors not reflected in the SMFP (for example, the travel burdens within a particular community) and clarifying that DCOPN's recommendation may likewise reflect such factors.

Delineate balanced competitive considerations relevant to the determination of a public need for health care services and facilities.

- Implement balanced competitive considerations relevant to the determination of a public need for a project, to include:
 - a) Distribution of existing facilities and services within a planning district.
 - b) Promotion of new technologies and innovative and more efficient ways of delivering health care services.
 - c) Potential for lowering costs and charges.

- d) The relationship of a project to other service lines and facilities of a provider or to its role as a “safety net” or specialized provider.
- e) Quality improvements.

Improve the transparency of letter of intent (“LOI”) activity.

- Implement a real-time automated/electronic tracking and posting mechanism for LOI filings to make LOIs available to the public as soon as they are received.

Improve the transparency of the COPN process and COPN activity.

- Create an online library where all relevant COPN information and documents are posted and easily available to the public. Relevant information includes:
 - a) COPN review documents and information, including applications, completeness responses, public hearing scheduling information, staff reports, commentary from opponents and interested parties, good cause petitions, and Commissioner’s decisions.
 - b) Extension and significant change requests and decisions.
 - c) Applicability determinations.
 - d) Updated capital expenditure thresholds for registration and COPN authorization.

Improve collection and availability of data.

- Improve and standardize the collection of COPN-relevant data and the availability of such data by:
 - a) Requiring all licensed and COPN-authorized facilities and services to report utilization.
 - b) Clarifying rules for reporting utilization of operating rooms and procedure rooms.
 - c) Expediting publication of VHI reports.
 - d) Maintaining an accessible inventory of all COPN-authorized (operational and not yet operational) providers/beds/units for all COPN-reviewable services.

Clarify good cause petition filing timelines and thresholds.

- a) Consider allowing the filing of good cause petitions only if there is a substantial material mistake of fact or law in either the DCOPN or regional agency staff report.
- b) Clarify the good cause petition filing timeline. The statutory and regulatory guidance should be consistent to enhance predictability of the COPN process.
- c) Consider implementing a filing fee, perhaps equal to the minimum application fee.

Revise COPN forms to enhance efficiency and effectiveness of the COPN review.

- a) Update existing application forms to better suit the various types of projects.
- b) Reconsider the information needed for the review of projects (for example, certain required submissions, such as a hospital's entire medical staff or a physician group's staffing, which can be difficult to produce yet seem to have little relevance to a review).
- c) Implementing additional forms to standardize the process (for example, a letter of intent form).

Consider options for reducing the length of the review cycle.

- Consider condensing the COPN review cycle to enhance efficiency of the process by:
 - a) Setting minimum acceptability thresholds for application submittal, thereby reducing the burden on DCOPN staff to ask for materials, and potentially reducing the time between the application deadline and the completeness response deadline.
 - b) Condensing the staff review period. Currently, the DCOPN staff report is due 75 days after the due date for completeness responses. Such reduction would be more achievable if initial application submittals were more complete.
 - c) To the extent that reducing the review cycle length (or, as suggested above, implementing a more rigorous SMFP review process) imposes additional staffing costs on VDH, considering raising application fees. Fees have not been raised for more than 20 years.

Standardize and clarify rules regarding COPN conditions.

- Simplify and clarify rules regarding COPN conditions by:
 - a) Standardizing charity care requirements across the Commonwealth.
 - b) Establishing uniform guidelines for system-wide conditions and policies for implementation of a new condition on a service line.
 - c) Expanding guidance on compliance with charity care conditions, documentation of compliance, and permissible plans of correction.
 - d) Exempting Disproportionate Share Hospitals ("DSHs") from charity care requirements.
 - e) Authorizing other, project-specific conditions on COPNs.

Formalize the process for COPN applicability determinations.

- a) Clearly define the process for requests for applicability determinations and turn-around time frames.
- b) As noted above, include applicability determinations among resources available online.

Non Workgroup Members

Virginia Hospital and Healthcare Association (Brent Rawlings)

Does not recommend any additional medical facility or project exemptions to COPN requirements

Streamline Process

- Eliminate public hearing with limited exceptions
- Expand use of expedited review
- Further consolidate eight statutory considerations

Modernize SMFP

- Revise and update SMFP to make it more robust, objective, and data-driven
- Integrate SMFP with population health initiatives

Improve Transparency

- Digitize all COPN filings and records and make available online in real-time
- Update application forms to reflect current information needs

Improve Accountability

- Enforce statutory SMFP review requirements
- Amend statute to require SMFP review every year and updates every two years
- Appoint third party to lead SMFP Task Force
- Improve monitoring and enforcement of charity care conditions

Improve Uniformity

- Develop mechanisms to bolster local input and region-specific analysis in COPN review

Ensure Adequate Funding for Program

- Consider whether application fees are sufficient to meet program needs
- Assess funding required to implement process improvements such as real-time online access to COPN records, improvements and timely updates to the SMFP, and more timely and accurate information for COPN review

Reinforce COPN charity care conditions

Reinforce COPN provisions related to Medical Education

McGuire Woods Consulting (Tyler Bishop)

Virginia's COPN process should not be held as sacred – it is in need of streamlining

- The current COPN process takes too long, is not efficient and is unpredictable.
- Notwithstanding the requirement that the plan be reviewed every four years, the current review process is less than thorough.
- The SMFP regulations governing neonatal intensive care services (NICU) have not been substantially updated in 20 years.

COPN reform can be accomplished without reducing charity care delivery

- If COPN regulations are relaxed, charity care conditions can be written into statute and required for those services subject to fewer or no COPN regulations.

Providers should be allowed flexibility to add or expand some services without permission from the state

- Protection of patient volume by incumbent providers should not be the primary factor in determining whether to allow a new entrant to provide the same service in the immediate service area.
- A provider is not going to invest in offering a new service without meeting all the applicable clinical and licensing standards. To do otherwise, would open the provider to being sued for negligence – a risk the provider will do everything it reasonably can to minimize.
- A provider is not going to invest millions of dollars in a facility or a service without confidence the market demand supports the investment.

Dr. Kinloch Nelson

Remove the COPN regulations from all licensed hospitals

Licensed outpatient hospitals “have an obligation to treat all comers and to provide a level of indigent care. If they do not meet the level of indigent care then they pay into the indigent care fund which is available to in-patient hospitals.”

Most ambulatory surgery centers and endoscopic suites and imaging centers are unlicensed and cannot and do not provide care to Medicare or Medicaid patients. This has allowed them to evade the COPN and avoid contributing to the indigent care fund as well as denying care to the needy.

M.H.West & Co., Inc. (Marilyn H. West)

- The applications for COPN require overhauling and better aligned with what the review criteria are.
- The SMFP just does not reflect what is occurring in the healthcare industry at the present time.
- The comment made about using the COPN process to help fulfill the State Health Commissioner's vision of healthcare of the future seemed to be right on target.
- Additional administrative hearing officers and staff are needed to evaluate applications subject to review.
- Not sure that the batching process works well for applicants as long as decisions on projects are delayed and applications for most projects now can only be filed every six months with the exception of nursing home beds which are governed by the RFA process or provisions that allow for nursing home beds to be developed in CCRCs. Significant changes to existing approved projects can be filed at any time.
- **If a decision is made to eliminate COPN**, it should be eliminated in phases.

LeadingAge Virginia (Bob Gerndt/Dana Parsons)

Supports the COPN law remaining intact, but believes the process could be significantly streamlined:

- Update the State Medical Facilities Plan (SMFP) as required by law every two years.
- Modernize the SMFP to reflect the changing health care environment and the shift to more integrated care.
- Eliminate unnecessary steps in the COPN review process, such as holding public hearings, and consider more effective ways of obtaining public input. In lieu of hearings, consider developing a public comment timeframe where interested parties could submit written comments to VDH, COPN Division. VDH could then have the discretion to hold a public hearing if the comments warranted such action.

- Consider implementing a flexible interpretation as to when an Informal Fact-Finding Conference (IFFC) is necessary. As a result, the Department may find that an IFFC is not needed in certain cases.
- Increase transparency of the COPN process by making all filings available on-line.

Kemper Consulting (Joel Andrus)

The COPN Taskforce should consider recommending to the General Assembly removing the preference given to CCRCs to establish or expand nursing home beds, except for their residents. This action would create a more level playing field between CCRCs and traditional nursing homes.