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:

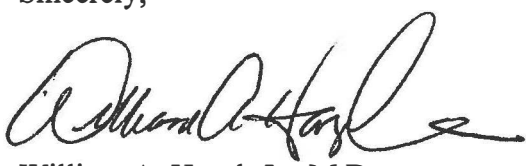
- Purpose and Objectives of the COPN Program,
- Review and Update of the State Medical Facilities Plan,
- Process for Submission and Review of COPN Applications,
- Conditioning of Certificates,
- Transparency of the Program,
- Process for Evaluating Whether Certain Facilities and Projects Should Remain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



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

Certificate of Public Need Workgroup – Final Report

Table of Contents

Workgroup Members and Staff 2

Executive Summary 3

Introduction 8

Certificate of Public Need in Virginia 11

Certificate of Public Need in Other States 21

Framework of Issues Developed by Workgroup 26

Appendices 46

Certificate of Public Need Workgroup Members

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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*
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Staff

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

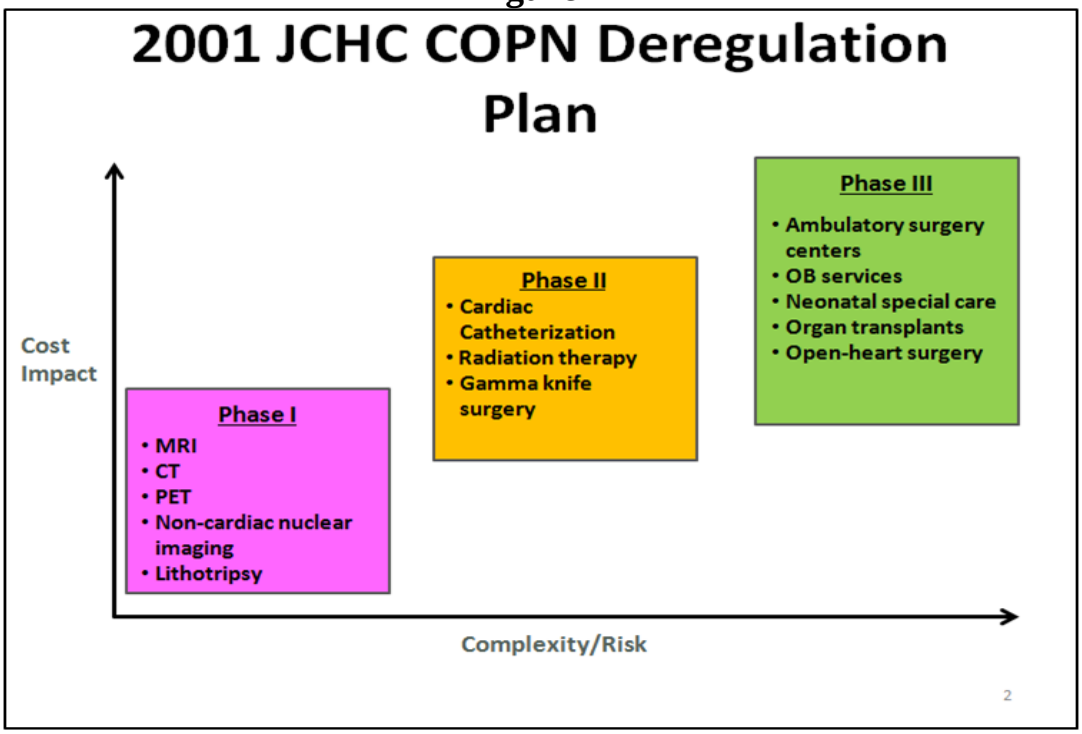
- Meeting health care needs of indigent and uninsured populations;
- Establishing licensure standards and providing adequate oversight for deregulated services;
- Determining effect of deregulation on academic health centers, long-term care facilities, rural hospitals; and
- Monitoring effect of deregulation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

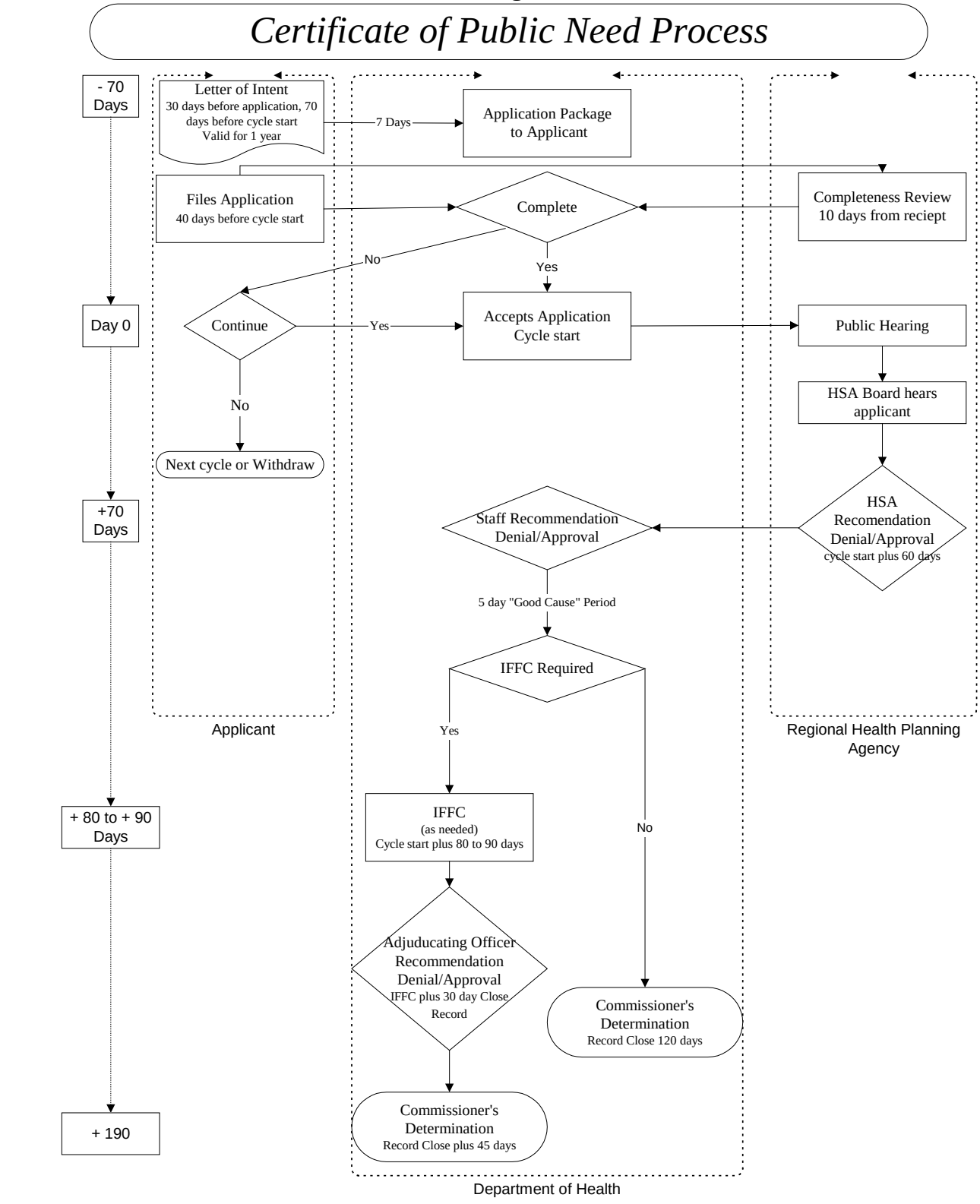
<u>COPN Application Review Process and Decisionmaking</u>

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.

<u>COPN Conditioning</u>

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).

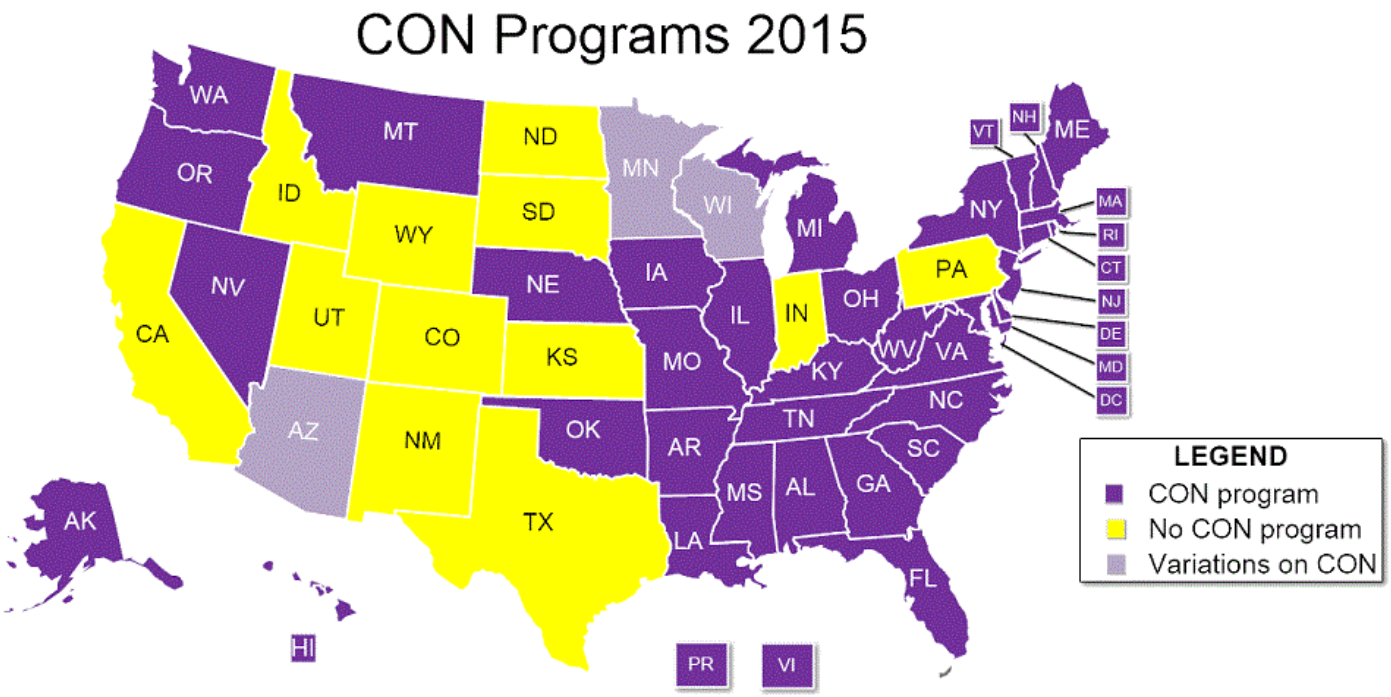
Attempts to Evaluate Impact of CON Programs Have Been Largely Inconclusive

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.	

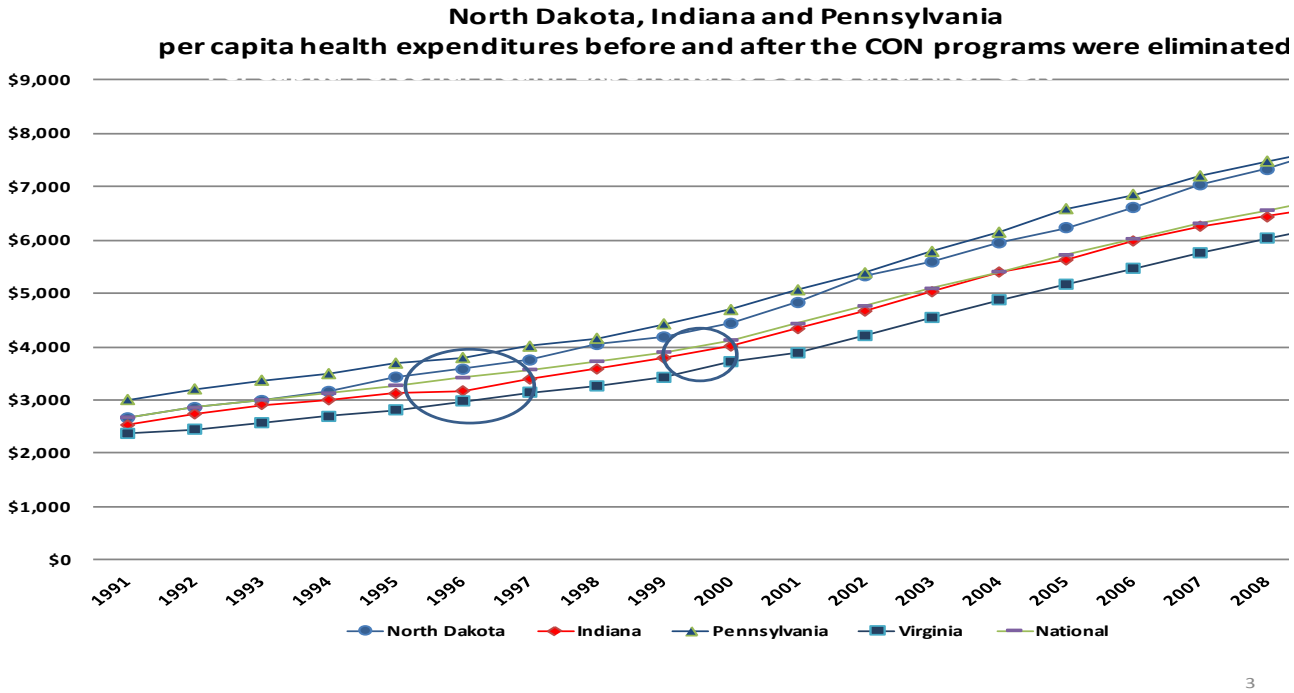
- Difficult to measure the relevant variables (e.g., quality, access, costs) or to even track the utilization of services
- Many difficult to measure factors affect the operation of the system and its attributes
- Very difficult to isolate, much less assess, the effect of CON regulation

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 COPN 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



Source: Joint Commission on Health Care.

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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
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 study conducted by the "big-three" automakers claims lower health care costs in CON states then 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.	"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 *contribute* 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. 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. 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.

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 than100% 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.

<u>Transparency of the COPN Program</u>

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.

Table 1

COPN Project Applications with Zero Denials, FY2011 – FY2015

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 chain 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 asses 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 n 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 as 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 1 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 stated 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 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. 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 noted 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. Marry 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 approve 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.

Report of the Public Health and Health Planning Council on Redesigning Certificate of Need and Health Planning

Adopted: December 6, 2012

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TABLE OF CONTENTS

PUBLIC HEALTH AND HEALTH PLANNING COUNCIL MEMBERS 2
ACKNOWLEDGMENTS 6
EXECUTIVE SUMMARY 7
THE COUNCIL'S CERTIFICATE OF NEED REDESIGN PROCESS 11
The PHHPC's Charge 11
Solicitation of Stakeholder Comments 12
Phase 1 – Administrative Streamlining 12
Phase 2 – Fundamental Redesign 14
HEALTH SYSTEM PERFORMANCE IN NEW YORK STATE 15
A HEALTH CARE DELIVERY SYSTEM IN TRANSITION 17
New Care Models and Payment Mechanisms Drive New Relationships 19
Evolving Roles of Inpatient and Ambulatory Care 19
Building Blocks of New Models: Governance, Capital, and Health IT 20
Population Health 21
Opportunities and Challenges 22
ADVANCING THE TRIPLE AIM THROUGH REGIONAL PLANNING 24
Recommendation #1 24
Recommendation #2 25
Recommendation #3 26
Recommendation #4 27
Recommendation #5 28
ADVANCING THE TRIPLE AIM THROUGH CERTIFICATE OF NEED AND LICENSURE 29
Purpose and Utility of CON 29
CON's Impact on Cost, Quality and Access 30
CON and New Models of Care and Payment 33
Recommendation #6 34
Recommendation #7 34
Recommendation #8 35
Recommendation #9 35
Recommendation #10 36
Recommendation #11 36
Recommendation #12 37

Recommendation # 13 37

PROMOTING IMPROVEMENTS IN QUALITY AND EFFICIENCY THROUGH GOVERNANCE 39

Recommendation #14 39

Recommendation #15 40

Recommendation #16 41

Recommendation #17 41

Recommendation #18 43

Recommendation #19 43

I**NCORPORATING QUALITY AND POPULATION HEALTH INTO CON REVIEWS; STREAMLINING FINANCIAL FEASIBILITY REVIEWS; AND RELAXING THE REVENUE SHARING PROHIBITION** 45

Recommendation #20 45

Recommendation #21 46

Recommendation #22 46

Recommendation #23 46

CONCLUSION 47

APPENDICES

Appendix A: Stakeholder Comments

Appendix B: Mission, Vision, and Principles

Appendix C: Administrative Streamlining Recommendations

Appendix D: Health Planning Committee Meetings from June 2012 through December 2012 and PowerPoint Presentations

Appendix E: Trends and Changes in the New York State Health Care System: Implications for the Certificate of Need (CON) Process

Appendix F: New York's CON Program

FIGURES

Figure 1: Regional Planning Map

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EXECUTIVE SUMMARY

New York State, like the rest of the nation, faces daunting health and health care challenges and is developing strategies to address them through Governor Cuomo's Medicaid Redesign Team (MRT) and the implementation of initiatives under the federal Affordable Care Act. An epidemic of chronic disease is crippling individuals and taking an economic toll. Health care spending nationally is rising at an unsustainable rate. Moreover, there is growing evidence that a substantial portion of the nation's health care expenditures –estimates range from 20 to 47 percent -- is wasted due to failures in care delivery or coordination, overtreatment, administrative complexity, pricing failures, and fraud and abuse.[1] New York's health care delivery system contributes to those wasted dollars. It ranks 50th in the nation in avoidable hospital use and only 22nd for prevention and treatment quality.[2] And, New Yorkers continue to experience significant disparities in health and health care based on such factors as race, ethnicity, disability, and socioeconomic status.[3]

The Affordable Care Act (ACA) and the MRT are providing innovative approaches to tackling these challenges and advancing the Triple Aim of better care, better health and lower costs. These approaches include access to affordable health insurance (under the ACA) and new models of care and payment that improve care coordination and incentivize quality and better outcomes, while reducing overall costs. New York is pursuing an amendment to its federal Medicaid waiver that will support these new models, and it is implementing a comprehensive State Health Improvement Plan to promote improvements in population health.

These initiatives, along with broad market forces, are driving a dramatic transformation of the healthcare delivery system. Health care providers are breaking out of their service silos and creating strategic linkages along the care continuum and across geographic regions to support care coordination, and improve quality, outcomes and efficiencies. Likewise, payers are developing payment strategies, networks and benefit designs that promote higher quality care and better outcomes at a lower overall cost. Ambulatory care is assuming a dominant position in the health care delivery system, and physician practices are growing in size and scope.

Recognizing that New York's health care regulations need to adapt to these sweeping changes and that regional strategies will be key to advancing the Triple Aim, Governor Cuomo and Commissioner Shah charged the Public Health and Health Planning Council with redesigning the State's certificate of need (CON) program and developing a framework for regional health planning. Its goal has been twofold: (1) to streamline the CON process by eliminating administrative steps that no longer serve their intended purpose, impede achievement of policy goals, or are not cost-effective; and (2) to develop a regulatory and health planning

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[1] Berwick, Donald M., and Andrew D. Hackbarth. "Eliminating Waste in US Health Care." *JAMA: the Journal of the American Medical Association* 307.14 (2012): 1513-1516. *See also, Better Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Institute of Medicine. (Sept. 6, 2012): 3-9 (estimating that 30 percent of health care spending in the US-- roughly $750 billion in 2009-- was wasted).

[2] The Commonwealth Fund Commission on a High Performance Health System, State Scorecard (2009), available at http://www.commonwealthfund.org/Maps-and-Data/State-Data-Center/State-Scorecard/DataByState/State.aspx?state=NY

[3] *See* Medicaid Redesign Team Health Disparities Work Group Data and Information, available at www.health.ny.gov/statistics/community/minority/medicaid_redesign_team.htm.

framework that, together with payment incentives and other policy tools, drives health system improvement and population health.

New York's evolving health care environment poses new opportunities and new risks that call for new regulatory responses. The creation of integrated systems of care holds promise for improving quality and outcomes through better care coordination, use of evidence-based practices, robust data analysis, and systematic performance improvement. Payment arrangements that reward quality and outcomes have the potential to reduce delivery system fragmentation and preventable and unnecessary utilization, while improving population health. The scale of integrated systems promises to produce administrative efficiencies and enable providers to spread fixed costs and risk. Together, all of these factors have the potential to bend the cost curve and improve the quality of life for New Yorkers.

While the new models of care and payment show great promise, they also raise concerns. Large integrated systems and physician practices that accept risk-based or value-based payments have the potential to improve outcomes while reducing overall costs; but they may also exercise market power to drive out competition and drive up prices. Thus, essential and safety net providers may be destabilized by the growth of physician practices and integrated systems that attract lucrative patients, but decline to serve Medicaid beneficiaries and the uninsured. Payment arrangements that transfer risk to providers may contribute to instability and diminished access to necessary services. Risk-based payments may also discourage the provision of medically-necessary care.

CON is not an all-purpose, regulatory tool that can be deployed to maximize all of the opportunities created by health care reform or address all of the risks. CON impacts the supply and distribution of health care resources. It is best suited to curbing excess health care capacity that drives unnecessary utilization and spending. It can also promote access to services by channeling development to under-served areas and may help to protect the viability of essential providers. CON does not, however, provide funding for struggling providers, nor does it monitor payment arrangements, affect the health status of populations or prevent the delivery system failures that may generate preventable utilization and excess spending. Other policies and regulatory approaches, such as licensure and surveillance, insurance oversight, grants, public health interventions, and regional planning, may provide more effective responses to these issues.

Where CON is deployed, its policies and processes must be adapted to promote beneficial innovations, while mitigating risks. The PHHPC identified several shortcomings of CON in relation to advancing the Triple Aim in the context of the changing health system. For example, CON does not cover services provided by physician practices that may destabilize essential providers or drive up health care spending. CON may delay the development of licensed primary care sites that will be needed to address the needs of newly-insured New Yorkers and support new models of care. And, CON's process for reviewing the character and competence of health care facility and agency operators is misaligned with the growing complexity of health care organizations, the need to develop integrated systems, and the authority exerted by non-established entities.

At the threshold of what promises to be a major transformation in health care delivery, the PHHPC recommends changes to New York's CON and licensing process to support successful integrated systems of care and new care and payment models. Its recommendations facilitate an expansion of the primary care capacity needed to serve the one million New Yorkers newly-insured under the Affordable Care Act – capacity that will also serve as the foundation for new care models. The recommendations also create a path to equalizing and clarifying the regulatory oversight of physician practices in comparison with licensed health care facilities in New York. In addition, the PHHPC recommends modifications to the process of establishing new health care facility and home care agency operators, in order to support the integration of health systems. Finally, the PHHPC's recommendations strengthen oversight of health care facility and health system governance, support expanded access to hospice, and incorporate quality and population health factors into CON reviews.

All the same, the health and health care challenges facing New York cannot be overcome through the efforts of one type of regulation or one sector alone. They are heavily influenced by local and regional factors that demand local and regional strategies. Advancing the Triple Aim requires multi-sector collaboration at the regional level – among all health stakeholders, including the State and local governments, consumers, business, public health officials, providers, payers, unions, transportation, education, social services, and more. Accordingly, the PHHPC recommends the creation of Regional Health Improvement Collaboratives (RHICs) to convene and actively engage stakeholders, analyze data, and develop a consensus around strategies to promote the Triple Aim.

This report is organized in seven parts:

- Part I describes the Council's CON Redesign process;
- Part II evaluates health system performance in New York;
- Part III describes health system trends;
- Part IV provides recommendations for regional planning;
- Part V provides recommendations for CON and licensure that relate to the supply and distribution of services;
- Part VI sets forth recommendations for strengthening governance and streamlining reviews of the character and competence of new health care operators; and
- Part VII sets forth recommendations related to streamlining the financial component of CON reviews, facilitating provider relationships that involve innovative payment arrangements, and incorporating quality and population health considerations in to CON reviews.

The report includes the following recommendations:

1. Regional planning can be an effective tool to bring together a broad range of stakeholders to advance the Triple Aim. In this time of rapid change, health planning should be reinvigorated on a regional basis through multi-stakeholder collaboratives to promote better care for individuals, better health for populations and lower per capita costs.
2. Create multi-stakeholder Regional Health Improvement Collaboratives (RHICs) to conduct regional planning activities.
3. Create 11 geographic planning regions.
4. Each RHIC should advance each dimension of the Triple Aim in its region**.**
5. PHHPC should consult with the RHICs concerning the regional health and health care environments, unmet needs, and effective planning strategies and interventions that could be disseminated statewide to advance the Triple Aim and eliminate health and health care disparities.
6. Eliminate CON for primary care facilities, whether D&TCs or hospital extension clinics; retain licensure requirements.
7. Exempt projects funded with State Department of Health grants from public need review and provide for limited financial review.
8. Enter into a contract with a research institute to advise the Department and the PHHPC concerning emerging medical technologies and services that might be appropriate for CON.
9. Reconsider the utility of CON for hospital beds in the next three to five years.

10. Consider the use of ACO certification, in lieu of CON for certain facilities, to promote appropriate distribution of facilities and services and Prevention Agenda 2013 goals.
11. Update the CON process for hospice.
12. Update the CON process for approved pipeline projects**.**
13. Update the criteria that trigger the facility licensure requirement and equalize the treatment of physician practices and facilities with respect to CON.
14. Rationalize "taint" policies to eliminate barriers to integration and recruitment of experienced governing body members.
15. Streamline character and competence reviews of established not-for-profit corporations.
16. Streamline character and competence reviews of complex proprietary organizations (e.g., publicly-traded, private-equity-owned) and new, complex not-for-profit systems.
17. Align "passive parent" oversight with powers exerted by parents and promote integrated models of care.
18. Improve the transparency of major changes in board membership.
19. Strengthen the Department's authority to respond to failures in governance**.**
20. Consider performance on quality benchmarks and relationship to the SHIP, when reviewing applications to expand services or sites.
21. Pursue a more calibrated approach to financial feasibility reviews.
22. Relax the prohibition on revenue sharing among providers that are not established as co-operators.
23. The Council recommends that DOH work with stakeholders to review, and update as necessary, the construction and environmental standards and other requirements for health care facilities and agencies to improve the resiliency and sustainability of health care facilities and ensure that patients/residents, staff and facilities are protected in the event of severe weather events, flooding, and other natural disasters.

This report is not intended to be the final word on regulatory reform in the context of an evolving health care delivery system. Rather, it is intended to lay the groundwork for an extended conversation about the strategic direction of New York's regulatory oversight of a health care delivery system in transition. The long-term effects of the Affordable Care Act and Governor Cuomo's Medicaid Redesign Team initiatives remain to be seen. As the delivery system changes and adapts in response to these reforms, the Department of Health and the PHHPC will undoubtedly revisit the alignment of regulations with new models of health care organization and payment.

THE COUNCIL'S CERTIFICATE OF NEED REDESIGN PROCESS

The PHHPC's Charge

Governor Cuomo and Commissioner Shah charged the PHHPC, in January 2012, with the redesign of the CON process. The Council's work was to encompass:

- A fundamental re-thinking of CON and health planning in the context of health care reform and trends in health care organization, delivery and payment.
- Development of a regulatory and health planning framework that, together with payment incentives and other policy tools, drives health system improvement and population health.

The Health Planning Committee of the PHHPC took the lead in convening stakeholders and in analyzing issues and options for CON redesign. The Committee's work proceeded in two phases: (1) administrative streamlining of the CON review process; and (2) fundamental re-thinking of CON in the context of current and forthcoming changes in the organization, financing and delivery of health care.

The Triple Aim framework for health system improvement provided the foundation for the Committee's deliberations. First introduced by the Institute for Healthcare Improvement, the Triple Aim demands simultaneous health system improvement efforts on three dimensions:

- Better care, including improvements in safety, effectiveness, patient-centeredness, timeliness, efficiency and equity;
- Better health for populations; and
- Lower per capita costs.[4]

As the State and federal governments ask health care providers and payers to adopt systematic approaches to advance the Triple Aim, government regulations and payment policies should be aligned to support those approaches. Accordingly, the Council's recommendations for the future of CON and regional health planning were developed with the Triple Aim in mind.

This work to redesign New York's Certificate of Need program complements earlier and ongoing efforts by the Department to reform and improve the CON process. Prompted by stakeholder concerns over processing times for CON applications and by the need to align the scope of the program with increasingly limited State resources, the Department over the past several years has implemented a number of changes in CON requirements and in the ways in which applications are submitted and reviewed. These are:

- Increases in the project cost thresholds for administrative and full CON review;
- Exemption of certain types of major medical equipment from full review, in favor of administrative or limited review;

[4] *See* IHI Triple Aim Initiative, available at http://www.ihi.org/offerings/Initiatives/TripleAim/Pages/default.aspx.

- Improvement in the efficiency and transparency of the CON process through implementation of NYSE-CON, an electronic system for the submission of CON applications;
- Consolidation of the former State Hospital Review and Planning Council (SHRPC) and the Public Health Council (PHC) into the Public Health and Health Planning Council (PHHPC) to eliminate the dual CON review functions of the two councils, and to combine the public health mission and expertise of the PHC with the SHRPC's mission and expertise in health care delivery systems in a mutually supportive fashion;
- Exemption from CON review of projects for the construction, renovation and replacement of nonclinical infrastructure and equipment;
- Development of a Memorandum of Understanding (MOU) between the Department and the Dormitory Authority (DASNY) to expedite reviews of architectural drawings for CON projects;
- Implementation, on a pilot basis, of a process for architectural self-certification of CON projects of less than $15 million.

Solicitation of Stakeholder Comments

To inform its work, the Committee twice solicited comments from stakeholders, in September, 2011 and June, 2012. The general themes that emerged from the stakeholder comments were:

- The importance of timeliness in the issuance of decisions on CON projects and the need for further streamlining of the CON review process;
- The need for equitable regulatory treatment of licensed health care facilities and physician practice-based services with respect to the initiation and expansion of major services and medical equipment;
- The importance of CON support for new models of care, such as co-located programs and freestanding emergency services;
- The need for strengthened regional and local health planning, of a type that would not become a regulatory barrier to development and innovation;
- The need for health planning and CON to promote population health and eliminate health disparities;
- The importance of transparency in the CON and planning processes, including the engagement of consumers and other community stakeholders.

Stakeholder comments are attached at Appendix A.

Phase 1 – Administrative Streamlining

The Committee held six meetings between January and June, 2012, to undertake Phase 1 of its work as well as one joint meeting with the PHHPC's Public Health Committee. It developed a statement of mission, vision and principles (attached as Appendix B) to guide both Phases. The Committee also called for background papers on the history of CON, recent reforms, and the current process. The Finger Lakes Health Systems Agency provided assistance in developing these papers.

In June, 2012, the full PHHPC adopted the Committee's mission and vision statement, and principles for reform, along with its recommendations for administrative streamlining of the CON program (attached as Appendix C). The main features of these proposed changes entail the elimination of CON public need review for certain construction projects that do not involve changes in beds or service capacity; reduction in the number of ambulatory and outpatient services subject to certification in favor of an on-line registration process for information and tracking; simpler architectural review of construction projects prior to CON approval, with a greater focus on post-CON licensure (physical plant safety); and more streamlined review of character and competence for changes in ownership of health care facilities and in the establishment of new owners and operators.

The following principles for reform guided both phases of the redesign process:

- The Certificate of Need program should support:
    - Preservation and expansion of access to needed health care services;
    - Containment of costs and improved cost-effectiveness;
    - Health care quality and reliability; and
    - Improved population health and elimination of health disparities.

- The mechanisms that CON uses to promote the alignment of health care resources with community need must evolve in the face of dramatic changes in the health care environment. CON should complement related planning initiatives, payment reforms and emerging models of care that promote care coordination and reduce inappropriate utilization.

- CON decisions should be informed by local/regional planning based on data and community input. Health planning, including that performed by the PHHPC, should be comprehensive and should consider health care resources of both institutional providers and physician practices. The PHHPC and health planning organizations should play a proactive role in promoting health care development that is aligned with community needs. Regional planning should encompass not just the supply of health care, but also strategies regarding the organization and delivery of care, population health and health care utilization.

- CON is one of several regulatory tools that can be used to affect the configuration and operations of healthcare delivery systems. It should be applied only: (i) where it is likely to be cost-effective in comparison with other tools available to achieve desired goals; (ii) where the goal sought is directly related to the development, reconfiguration, or decertification of health care facilities, programs or services.

- The CON program should focus on health care projects and services that have a significant impact on health care costs, access or quality, such as those that are supply-sensitive or volume-sensitive,[5] require major capital investment, generate high operating costs, compromise access to care, require highly-specialized expertise, or involve emerging medical technologies.

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[5] For purposes of this document, a health care capital project or service is supply-sensitive if the supply of the health care resource in question influences the utilization of that resource, and the level of utilization driven not by medical theory or evidence, but rather by capacity and payment incentives. (Dartmouth Atlas of Health Care, available at http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2937). A health care service is volume-sensitive if a high volume of the service is associated with improved quality or outcomes.

- Certification or licensure alone, without consideration of public need, is sufficient for projects that do not require major capital investment, are not supply- or volume-sensitive, do not generate high operating costs or compromise access to care, and do not involve emerging medical technologies.

- The CON program should facilitate coordinated and integrated delivery of all health care services, including behavioral health, developmental disability, and physical health services. Certification or licensure processes should be examined and updated to promote integration of behavioral and physical health services.

- Proposals for administrative streamlining should be considered in light of longer term issues, such as reinvigorating health planning, approval of new types of facilities, role of private capital, impact of payment reforms, and delivery system configurations.

Phase 2 – Fundamental Redesign

In June of 2012, the Council, through the Health Planning Committee, began examining CON in a more fundamental manner. To assist in this process, the Department retained the United Hospital Fund and its Director of Innovation Strategies, Gregory Burke, to identify and analyze trends in organization and payment and their implications for the CON process. The Committee convened nine public meetings between June and November, covering topics ranging from health system performance in New York to innovations in health care financing and organization, to regional health planning, among others (a list of the meetings and associated materials are attached as Appendix D; Mr. Burke's report is attached as Appendix E).

The Committee's deliberations were informed by a review of New York's health system performance today and an analysis of new directions in health care organization and payment. The Committee worked to ensure that its recommendations would drive health system improvement, by supporting beneficial innovation and mitigating associated risks.

HEALTH SYSTEM PERFORMANCE IN NEW YORK STATE

To inform its deliberations, the Committee examined the strengths and weaknesses of New York's health system. By many accounts, New York's health care delivery system is characterized by fragmented care, overuse of inpatient services, insufficient primary care, uneven quality, and disparities in health status and health care. In an effort to compare New York's health system performance to other states', the Committee looked to The Commonwealth Fund's state and local scorecards, as a comprehensive assessment of state health system performance.[6]

The Fund's state scorecard evaluates performance across five key dimensions based on more than 30 indicators for which data is collected nationwide. The dimensions are:

- **Access** - rates of insurance coverage for adults and children and indicators of access and affordability of care;
- **Prevention and treatment** – indicators that measure three related components: effective care, coordinated care, and patient-centered care;
- **Potentially avoidable use of hospitals and costs of care** – indicators of hospital care that might have been prevented or reduced with appropriate care and follow-up and efficient use of resources, as well as the annual costs of Medicare and private health insurance premiums;
- **Equity** – differences in performance associated with patients' income level, type of insurance, or race or ethnicity; and
- **Healthy lives –** indicators that measure the degree to which a state's residents enjoy long and healthy lives, as well as factors such as smoking and obesity that affect health and longevity. [7]

According to the Commonwealth Fund's 2009 state scorecard, New York's health system scores well on access and equity, near the median on prevention and treatment, and poorly on avoidable hospitalizations and costs. Overall, New York ranked 21st in the nation, with the following rankings among five categories:

- Access: 18
- Prevention and treatment: 22
- Avoidable hospital use and costs: 50
- Equity: 11
- Healthy lives: 17 [8]

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[6] Other dashboards and report cards focus on particular elements of health system performance. For example, the AHRQ produces a dashboard focused on quality using some of the same data elements used by the Commonwealth Fund. Agency for Healthcare Research and Quality, New York Dashboard for Health Care Quality Compared to All States, 2011, available at http://statesnapshots.ahrq.gov/snaps11/dashboard.jsp?menuId=4&state=NY&level=0. On the 2011 AHRQ quality dashboard, New York State ranks.in the low average range. It scores well on preventive measures, such as vaccines and mammograms, but below average on the acute, chronic care, hospital, home health, heart disease and respiratory disease measures. The County Health Rankings, produced by the Population Health Institute of the University of Wisconsin, focus on population health measures by county, (available at http://www.countyhealthrankings.org).

[7] McCarthy, Douglas, et.al. Aiming Higher: Results from a State Scorecard on Health System Performance, The Commonwealth Fund, October 2009.

Clearly, the category of avoidable hospital use and costs deserves attention. In that dimension, the Commonwealth Fund's scorecard ranks New York below the median on every measure, and in the bottom 10 for:

- Medicare admissions for ambulatory care sensitive conditions
- Percent of home health patients with a hospital admission
- Inpatient care intensity in the last two years of life among chronically-ill Medicare beneficiaries
- Total Medicare reimbursements per enrollee[9]

The Commonwealth Fund's Local Report Card, shows that costs, quality, and access vary significantly by region within New York State. The Fund's Local Report Card ranks the nation's 306 hospital referral regions (HRRs) across four dimensions (access, prevention and treatment, avoidable hospital use and costs, and healthy lives) based on 43 indicators. Overall rankings for New York's HRRs are:

- First Quartile: Albany, White Plains, Buffalo, Rochester, and the eastern Adirondacks, which is included in the Burlington, Vermont region[10]
- Second Quartile: Manhattan,[11] Elmira, Syracuse, Binghamton, and Eastern Long Island
- Third Quartile: Bronx

Accordingly, the Committee concluded that, while there is room for improvement in every dimension, priorities for the state to drive health system performance must include reducing avoidable hospitalizations and costs, and improving prevention and the effectiveness of treatment. In addition, the Committee observed that statewide approaches will not always suffice. Local and regional approaches will be necessary to address weaknesses in delivery system performance and population health.

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[8] The Commonwealth Fund Commission on a High Performance Health System, State Scorecard (2009), available at http://www.commonwealthfund.org/Maps-and-Data/State-Data-Center/State-Scorecard/DataByState/State.aspx?state=NY.

[9] *Ibid.*

[10] Radley, David C., et. al. Rising to the Challenge: Results from a Scorecard on Local Health Performance, 2012, The Commonwealth Fund, March 2012. Small portions of certain Pennsylvania, New Jersey and Connecticut hospital referral regions also extend into New York State.

[11] The Manhattan hospital referral region includes Manhattan, Brooklyn and Staten Island.

A HEALTH CARE DELIVERY SYSTEM IN TRANSITION

The Health Planning Committee considered not only the current state of New York's health care delivery system but also its future. New York is charting a new course in health care aimed at improving quality and population health and bending an unsustainable cost curve through innovations in payment and care models. We are doing so in response to significant challenges. An epidemic of chronic disease is crippling individuals and taking an economic toll. Health care spending reached almost 18 percent of the gross domestic product (GDP) in 2011 and is projected to reach 20 percent by 2020.[12] There is growing evidence that a substantial portion of those expenditures – estimates range from 20 to 47 percent -- represents waste attributable to failures in care delivery or coordination, overtreatment, administrative complexity, pricing failures, and fraud and abuse.[13] At the same time, government support for health care providers is shrinking, and safety net providers are struggling to stay afloat. While we spend a disproportionate amount on health care compared to other industrialized nations, the quality of the care we purchase and the outcomes we experience are too often less than optimal.[14] And, health care quality, outcomes and accessibility are too often worse for racial and ethnic minorities and people with low incomes.[15]

Governor Cuomo and Commissioner Shah are tackling these challenges through initiatives advanced by the ACA and the Governor's Medicaid Redesign Team (MRT) that address the imperatives of the Triple Aim. These initiatives include new models of care, such as accountable care organizations (ACOs), patient-centered medical homes (PCMHs), and health homes, among others. These models emphasize care coordination, chronic disease management, and reduction of preventable inpatient admissions. PCMHs receive enhanced payments in exchange for meeting performance standards related to access and continuity, chronic disease management, use of health information technology, care coordination and performance improvement. Health homes also receive enhanced payment (and potential for shared savings) for providing care coordination across a network of providers to Medicaid beneficiaries with multiple chronic conditions, including behavioral health concerns, who are at high risk for avoidable hospitalizations. ACOs are organized networks of providers responsible for the health of a defined population of insured beneficiaries. Fifteen Medicare ACOs have been designated in New York State, and providers are creating similar models for commercially-insured and self-insured populations.[16]

New payment models are replacing fee-for-service payments with value-based and risk-based payments that reward prevention and quality. While the fee-for-service model rewards individual providers for the volume of services they provide, the new payment models require avoidance of preventable utilization and often demand coordination among different types of providers. For example, avoiding penalties for preventable readmissions requires careful post-discharge coordination among hospitals, nursing homes, home care agencies, and other community-based providers. Value-based payments are not limited to Medicare and

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[12] National Health Expenditure Projections 2010-2020, CMS Office of the Actuary, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2010.pdf .

[13] Berwick, Donald M., and Andrew D. Hackbarth. "Eliminating Waste in US Health Care." *JAMA: the Journal of the American Medical Association* 307.14 (2012): 1513-1516. *See also,* Better Care at Lower Cost: The Path to Continuously Learning Health Care in America. *Institute of Medicine*. (Sept. 6, 2012): 3-9 (estimating that 30 percent of health care spending in the US-- roughly $750 billion in 2009-- was wasted).

[14] AHRQ. National Health Care Quality Report, 2011, Key Themes and Highlights, available at. http://www.ahrq.gov/qual/nhqr11/key.htm.

[15] AHRQ. National Health Care Disparities Report, 2011, Key Themes and Highlights, available at http://www.ahrq.gov/qual/nhqr11/key.htm.

[16] "Trends and Changes in New York's Health Care Delivery and Payment Systems: Implications for CON and Health Planning," presentation by Gregory Burke, United Hospital Fund, July 25, 2012.

Medicaid. Commercial insurers and self-insured purchasers are reportedly following suit, expanding the use of arrangements such as shared savings, episodic payments, partial capitation, and global capitation.[17]

In addition to advancing these new care and payment models, the State is expanding its Medicaid managed care program and pursuing a long-term strategy of fully-integrated care management for all Medicaid beneficiaries.[18] Benefits previously delivered on a fee-for-service basis, such as prescription drugs and personal care, have been added to the managed care benefit package. Also, populations previously excluded or exempt from managed care are now being enrolled as program features are developed to ensure the continuity of their services. This includes the mandatory enrollment of individuals receiving community-based long term care into managed long term care plans. In addition, the State is developing models of care to address the provision intensive behavioral health services to those currently enrolled in mainstream managed care plans.

New York's pending 1115 Medicaid waiver amendment will support the development of new models of care and payment. With Medicaid savings from prior years, New York proposes to fund twelve new programs:

Proposed 1115 Waiver Programs

Primary Care Expansion
Health Home Development Fund
New Care Models
Vital Access Provider and Safety Net Provider Programs
Public Hospital Innovation
Supportive Housing
Long Term Care Transformation and Managed Care Integration
Safety Net Hospital Capital Stabilization
Hospital Transition to Integrated Systems
Health Workforce
Public Health Innovation
Regional Health Planning

This funding will provide the capital necessary to create new alignments among providers, to build and test innovative, cost-effective care models, to complete the transition to managed long-term care, and to integrate evidence-based public health interventions into the Medicaid program. It will also support regional health improvement collaboratives that convene stakeholders to develop data-driven regional strategies to advance the Triple Aim and optimize the impact of the ACA and the waiver funds.

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[17] *Ibid*.

[18] "A Plan to Transform the Empire State's Medicaid Program: Multi-Year Action Plan," 2012, available at http://www.health.ny.gov/health_care/medicaid/redesign/docs/mrtfinalreport.pdf.

The expansion of Medicaid managed care and the emergence of the new payment and care models are already fueling transformation of the health care delivery system by encouraging new relationships among providers and payers that support care coordination and disease management. They are also promoting ambulatory care as a means to improve outcomes and reduce expensive inpatient care. The success of this transformation will depend on several building blocks: effective governance of new systems of care, health information exchange and robust data analysis, capital investment, and a sustained and systematic focus on population health.

New Care Models and Payment Mechanisms Drive New Relationships

Spurred by new payment incentives, new care models, and the imperatives of a managed care expansion, providers and payers in New York are forging new relationships. Hospitals are expanding their regional reach and their ability to leverage beneficial payment arrangements from payers and purchasers by affiliating with facilities outside of their primary service areas. They are also partnering with physician practices to enhance their ability to coordinate care along the continuum and strengthen referral relationships. The silos between behavioral health and physical health are breaking down with these providers integrating and co-locating services. Behavioral health and physical health providers are organizing into health home networks and working with regional behavioral health organizations (BHOs). Long-term care systems are coalescing to link nursing home care with home care, hospice, and assisted living. Hospitals, nursing homes, and home care agencies are creating linkages to strengthen post-discharge care and prevent readmissions.[19]

Efforts to align payment incentives with desired outcomes, while containing costs, are stimulating not only linkages among providers, but also linkages among health care payers, purchasers and providers. Payers and purchasers are partnering with health systems to create exclusive and tiered networks supported by value-based payments.[20] In at least one case, a health insurer and a health system have entered into a joint venture to sponsor an IPA that will serve as the exclusive network for a portion of the insurer's products. Another insurer has created a physician practice to provide a particular chronic disease management model to its Medicare Advantage enrollees. While reminiscent of the staff-model HMOs of the 1980s and 1990s, these models rely on benefit design and provider payment incentives to influence utilization and spending, rather than gatekeepers and utilization review agents.

Evolving Roles of Inpatient and Ambulatory Care

Although inpatient care will remain essential to the delivery system, it will play a diminishing role in 21st century health systems. Inpatient utilization has been declining gradually over the past several years due to medical advances that have reduced lengths of stay and permitted increasingly complex procedures to be conducted on an ambulatory basis.[21] If new care and payment models are successful in improving health and preventing avoidable admissions, this trend will accelerate.

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[19] "Trends and Changes in New York's Health Care Delivery and Payment Systems: Implications for CON and Health Planning," presentation by Gregory Burke, United Hospital Fund, July 25, 2012. Gregory Burke, "Trends and Changes in the New York State Health Care System: Implications for the Certificate of Need (CON) Process," United Hospital Fund, unpublished report (Nov. 2012); 19-20.

[20] *Ibid.*

[21] SPARCS, Annual Report Generator, Inpatient Discharges by Major Service Category, 2000-2010.

In order to maintain their financial viability, hospitals must find ways to replace shrinking inpatient revenues and to partner with other providers to deliver services more efficiently. While academic medical centers and strong community hospitals are aligning with other providers to create regional systems of care, many rural and safety net hospitals are struggling to find a viable path in this changing environment.

By contrast to inpatient services, ambulatory services are growing in importance as the foundation for new care models and a vehicle for capitalizing on new payment arrangements.[22] New primary care capacity must be developed to support these models and serve the one million New Yorkers expected to become insured under the ACA. Accordingly, many hospitals are opening extension clinics, acquiring physician practices, and expanding their faculty practice plans. Independent physician practices are growing in size, scope and market power, with multi-specialty groups offering surgery, imaging and even radiation therapy services. One indicator of the rising strength of physician practices in New York State is the sizeable number of physician practice-led ACOs here – two-thirds of the accountable care organizations (ACOs) designated by the federal Centers for Medicare and Medicaid Services (CMS) in New York State are led by physician practices.[23]

Federally-qualified health centers (FQHCs) -- diagnostic and treatment centers (D&TCs) that provide comprehensive primary care regardless of ability to pay -- are likewise growing in size and geographic scope with an infusion of capital through federal grants authorized by the ACA. These health centers, along with hospital extension clinics, will continue to serve as a major source of primary care, particularly for rural and low-income populations.[24]

Building Blocks of New Models: Governance, Capital, and Health IT

New models of care and payment impose new operational, administrative, and financial demands on health care providers. To succeed, they require strong governance and management to manage payment risk and costs, to promote clinical integration and ensure effective coordination along the continuum, and to engage in continuous performance improvement.[25]

Capital investment in primary care capacity and information technology is also essential. High-quality primary care is the key to achieving the savings necessary to succeed under new payment mechanisms. Collection, analysis and exchange of individual and population health information are critical elements of these models. Interoperable electronic health records (EHRs) enable communication and coordination among providers; clinical decision support systems promote adherence to evidence-based practices; and patient registries support population health initiatives, chronic disease management and quality

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[22] See Berkowitz, Scott A., and Edward D. Miller. "Accountable care at academic medical centers—lessons from Johns Hopkins." *New England Journal of Medicine* 364.7 (2011):e12. Abrams, Melinda, et al. "Realizing Health Reform's Potential." *The Commonwealth Fund: New York* (2011). Kutscher, B. "Outpatient Care Takes the Inside Track." *Modern Healthcare* 42.32 (2012): 24.

[23] Gregory Burke, "Trends and Changes in the New York State Health Care System: Implications for the Certificate of Need (CON) Process, unpublished report, United Hospital Fund (Nov. 2012): 26.

[24] Adashi, Eli Y., H. Jack Geiger, and Michael D. Fine. "Health Care Reform and Primary Care – The Growing Importance of the Community Health Center." *New England Journal of Medicine* 362.22 (2010): 2047-2050.

[25] Burns, Lawton R., and Mark V. Pauly. "Accountable Care Organizations May Have Difficulty Avoiding The Failures Of Integrated Delivery Networks Of The 1990s." *Health Affairs* 31.11 (2012): 2407-2416.

Shortell, Stephen M., Robin Gillies, and Frances Wu. "United States Innovations in Healthcare Delivery." *Public Health Reviews* 32.1 (2010): 190-212.

improvement. Information technology is also needed to measure provider performance and manage utilization and costs.[26]

Population Health

Sustained improvements in population health represent both the goal and the rationale for new models of care and payment.[27] Along with improvements in health care delivery, success will depend on community-wide strategies to establish primary and secondary prevention programs, eliminate health care disparities, and address the social determinants of health.

To promote improvements in health status, initiatives advanced by the MRT and the ACA link population health and the health care delivery system. For example, the federal ACO regulations require ACOs to manage the health of a designated population of Medicare beneficiaries, to focus on prevention and intervene early to address the care needs of various population segments. Other care models that involve value-based or risk-based payments demand a similar focus in order to succeed. In addition, the ACA requires hospitals to conduct community health needs assessments and develop community benefit plans. The Department of Health has asked hospitals to work with local health departments and other stakeholders in developing their assessments and in addressing at least two priorities in the State's Prevention Agenda 2013, including one directly related to addressing racial, ethnic, socioeconomic, disability-related or other health disparities.

The Public Health Committee of the PHHPC is taking the lead in developing, with stakeholders, the Prevention Agenda 2013 (also known as the State Health Improvement Plan) -- a five-year strategic plan for population health improvement in New York. This comprehensive plan includes evidence-based practices for improving population health in each of five priority areas and provides guidance for local health departments, hospitals and other stakeholders in their efforts to assess and improve community health.

The plan identifies five statewide priorities for the next five years:

- Prevent Chronic Diseases
- Promote a Healthy and Safe Environment
- Promote Healthy Women, Infants and Children
- Promote Mental Health and Prevent Substance Abuse
- Prevent HIV, STDs, Vaccine-Preventable Diseases and Healthcare-Associated Infections

Prevention Agenda 2013 establishes focus areas and goals for each priority area and defines indicators to measure progress toward achieving these goals, including reductions in health disparities among racial, ethnic, and socioeconomic groups and among persons with disabilities. The plan also identifies interventions for action for each goal. (Prevention Agenda 2013 is available at http://www.health.ny.gov/prevention/prevention_agenda/health_improvement_plan/index.htm.)

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[26] *See* "Features of Integrated Systems Support Patient Care Strategies and Access to Care, but Systems Face Challenges," U.S. G.A.O, November 2010.

[27] Berwick, Donald M., Thomas W. Nolan, and John Whittington. "The Triple Aim: Care, Health, and Cost." *Health Affairs* 27.3 (2008): 759-769.

The Prevention Agenda 2013 will provide a framework not only for local health department activities, but also for the community health needs assessments and community benefits activities required of hospitals by the ACA. Regional health planning activities (described in detail in Part IV below) will also use the Prevention Agenda as the blueprint for their efforts to improve population health.

Opportunities and Challenges

New models of care and payment are creating tremendous opportunities for health care consumers, providers and payers in New York. The movement toward horizontal and vertical integration holds promise in improving quality and outcomes through better care coordination, robust data analysis, systematic performance improvement, and the ability to align incentives and manage risk. Payment arrangements that reward health have the potential to reduce delivery system fragmentation and decrease preventable and unnecessary utilization, while improving population health. The scale of integrated systems promises to produce administrative efficiencies and enable providers to spread fixed costs and risk. Together, all of these factors have the potential to bend the cost curve and improve the quality of life for New Yorkers.

At the same time, the new alignments and payment arrangements face challenges and pose significant risks. Large integrated systems and physician practices that accept risk-based reimbursement raise financial, quality and access concerns for New York State and its health system, including:

- **Cost and Quality:** Vertically- and horizontally-integrated health systems and large physician practices may absorb or overwhelm their competitors and exercise market power to drive up prices, without improving quality or access.[28] They may reduce options for consumers who want the opportunity to choose among high-quality health care providers.
- **Managing Risk:** Health systems and physician practices may manage payment risk unwisely. If they become dominant in a region and fail, they may bring down the entire delivery system in that region.
- **Access to Medically-Necessary Care:** In an effort to manage payment risk, providers may become over-zealous in their efforts to control costs and institute practices that restrict access to necessary care.
- **Viability of Essential Providers and Disparities:** Essential and safety net providers may be destabilized by the growth of physician practices and integrated systems. As physician practices grow in size and scope, they may attract lucrative patients and eliminate needed revenue for safety net providers, while declining to serve Medicaid beneficiaries and the uninsured. In addition, essential providers that serve rural or low-income communities may be left behind in the race to create integrated systems. To the extent that success under new payment mechanisms relies on the provision of services to a large, well-insured population, these providers may not be attractive partners in the development of regional systems. They may lack sufficient capital, administrative depth, or patient volume and may be forced to close their doors.

[28] Gaynor, Martin. "The Impact of Hospital Consolidation – Update." *UPDATE* (2012).

The recommendations in this report seek to provide a sound approach to CON and licensure that supports beneficial innovation while mitigating the risks posed by today's delivery system and tomorrow's. As a regulatory tool that *directly* impacts only the supply and distribution of health care resources, CON is not well-suited to addressing most of the risks described above. However, it can be used as a tool to promote access to services and protect the viability of essential providers. Other tools, such as antitrust policies or the emerging certificate of public advantage process, insurance laws, nascent accountable care organization (ACO) certification regulations, grants, and the physician discipline process may provide more effective responses to many of the above risks.

Regional planning can help to monitor the pace and outcomes of change, including those outcomes that are unintended. This type of planning, with feedback loops both to local communities and to Albany, should have a salutary effect on delivery system behavior and provide important guidance for evolving public policy. It will help to ensure that the transformation of the delivery system proceeds in the best interests of all New Yorkers.

ADVANCING THE TRIPLE AIM THROUGH REGIONAL PLANNING

Given regional variation in health system performance, daunting challenges, and dramatic change in the delivery system, regional health planning holds promise as a vehicle for advancing the Triple Aim. The health and health care challenges confronting New York are multi-sectoral and cannot be solved by providers, payers, or consumers alone. They vary by region and locality and demand regional and local solutions. These challenges call for a data-driven, structured effort that brings together diverse stakeholders to assess population health and health system performance in a region and develop consensus-based strategies to address weaknesses. Accordingly, the Council recommends the following framework for regional health planning in New York:

Recommendation #1:

Regional planning can be an effective tool to bring together a broad range of stakeholders to advance the Triple Aim. In this time of rapid change, health planning should be reinvigorated on a regional basis through multi-stakeholder collaboratives to promote better care for individuals, better health for populations and lower per capita costs.

The Council endorses the following principles for regional health planning:

- Regional health planning must be collaborative, and neither regulatory nor bureaucratic.
- Regional health planning must be conducted by entities that:
    - Focus on both health and healthcare, including behavioral health, and coordinate with the local planning process for mental hygiene services;
    - Provide for representation, formal engagement and meaningful participation of all affected stakeholders.
    - Collect, analyze, and display data in an objective manner.
- New York's regional health planning policies should permit diverse governance structures, based on regional circumstances and stakeholder interests, in order to promote stakeholder buy-in.
- The State's responsibilities in relation to regional health planning must include :
    - Oversight of the strategic direction and high-level goals of regional planning;
    - Establishing benchmarks for performance and evaluating outcomes;
    - Encouraging participation in regional planning through policy levers, such as grant awards; and
    - Developing a common data set to support regional planning activities and to permit comparisons among regions.
- Regional health planning should serve to enhance the financial stability of the health care delivery system.

Recommendation #2:

PHHPC recommends the creation of multi-stakeholder Regional Health Improvement Collaboratives (RHICs) to conduct regional planning activities.

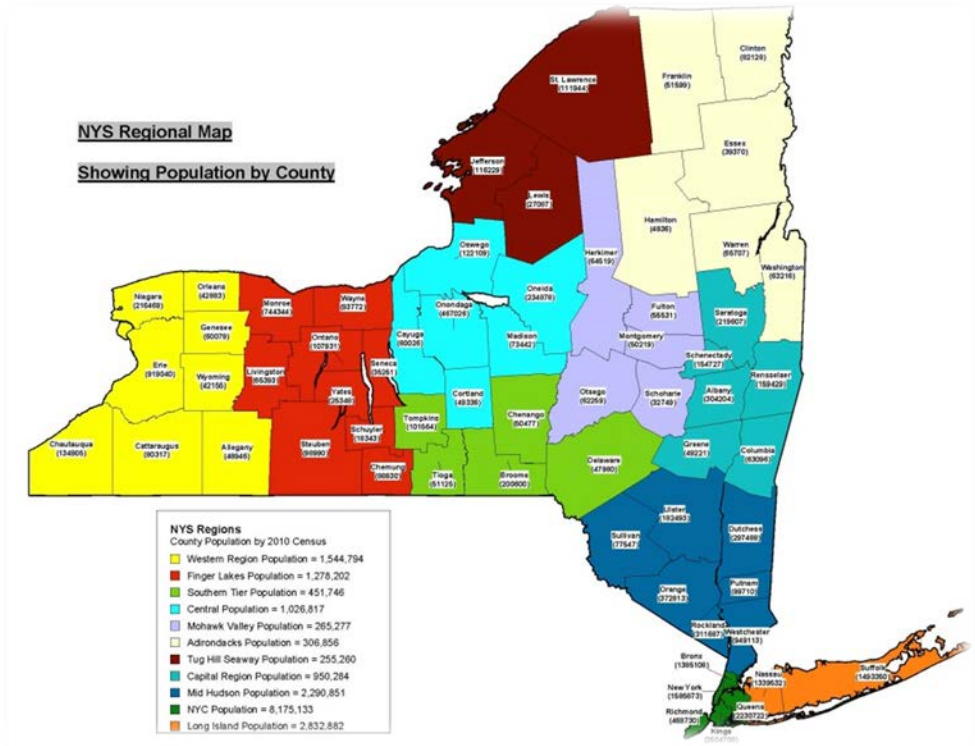
The RHICs should have the following characteristics:

- They should be a neutral and trusted entity. They should not be controlled by any single stakeholder or type of stakeholder. The governance structure of the RHICs should be representative of a variety of stakeholders and sectors that impact, or are impacted by, health and health care issues.
- Key stakeholders that should be actively engaged and included in the governance of a RHIC include: consumers, local public health officials, health and behavioral health care providers across the continuum, payers, business leaders, unions and community-based organizations. Other interested parties that should be engaged include schools and institutions of higher education, local governments, transportation-related entities, and housing-related entities.
- RHICs should be supported, at least in part, by State grants.
- RHICs should have capable executive leadership with sufficient experience and expertise to assume the responsibilities set forth below.

Recommendation #3:

PHHPC recommends the creation of 11 geographic planning regions consistent with the map at Figure 1.

Figure 1. NYS Geographic Planning Regions



- The PHHPC recognizes that no regional map will perfectly reflect all of the factors relevant to health planning. Health care consumers, disease, and public health emergencies will cross regional boundaries.
- The regions pictured on the map take into account existing health planning infrastructure, including local health department collaborations, regional planning organizations, and rural health networks. Although not identical to the Governor's Economic Development Council (EDC) regions, the RHIC regions attempt to minimize the number of EDC regions to which any RHIC would relate.
- Consistent with the RHICs' charge to address both population health and health care issues, and the increasing emphasis on ambulatory care in our evolving health care delivery system, the proposed planning regions are not based exclusively or principally on inpatient referral patterns or migration for high-acuity care.
- Given the permeability of state, county, and regional boundaries, it will be important for regions to engage in sub-regional and inter-regional activities, and to consider interstate issues, in order to optimize the impact of the RHICs.

Recommendation #4:

Each RHIC should advance each dimension of the Triple Aim in its region.

RHICs should convene and actively engage stakeholders, analyze data, and develop a consensus around strategies to promote:

- Better health for populations.
  - RHICs should measure performance of their region and sub-populations within the region against Prevention Agenda 2013 metrics and report on them transparently and publicly; and
  - RHICs should engage in activities to advance at least two Prevention Agenda 2013 priorities selected by community stakeholders based on community needs, commit to improvements in these priority areas in a defined time period, and use evidence-based strategies to achieve measurable objectives. To the extent possible, RHICs should coordinate with and support local health department and hospital planning activities related to the Prevention Agenda 2013.
- Better care. Some examples of activities that might be pursued in this area include:
  - Measurement of health system performance and publication of quality data based on specified metrics;
  - Organizing, leading, and/or supporting regional quality collaboratives;
  - Technical assistance in support of development of patient-centered medical homes (PCMHs);
  - Identifying evidence-based patient and community engagement activities and supporting implementation.
- Lower per capita cost of care. Some examples of appropriate activities include convening, analytics, and technical support for:
  - Analysis of regional experience in health care utilization against benchmarks and identifying specific areas in which the region has higher-than-expected utilization rates;
  - Organizing regional initiatives to reduce preventable utilization of services, such as implementation of evidence-based practices concerning the use of diagnostic imaging, or PQI admissions;
  - Health and health care needs assessments;
  - Organizing and supporting multi-payer, value-based payment and benefit design initiatives;
  - Analysis and publication of quality, cost, and spending data; and
  - Assisting in the creation and operation of collaborations that improve efficiencies in health care delivery and the financial stability of essential providers.

Within each of the dimensions, RHICs will be expected to incorporate strategies to reduce health and health care disparities, whether racial, ethnic, socioeconomic, disability-based, or geographic.

RHICs may also choose to address other health- and health care-related issues. For example, they may analyze and develop strategies to address workforce issues, including recruitment, retention, and training of health care workers. RHICs should work with the Regional Economic Development Councils to address health and health care issues that impact the economy, business and employment.

RHICs may also make recommendations in connection with state grants, including initiatives referenced in the 1115 waiver application. In fact, the State's 1115 waiver amendment repeatedly indicates that preference will be given to applicants that have the support of regional planning entities. RHICs may be consulted concerning regional needs that could be addressed through State grants and/or the development of requests for applications and the criteria that should be applied in making awards. They may also choose to submit letters of support in relation to grant applications from their regions.

This description of potential RHIC activities is not intended to be exhaustive. Stakeholders in a particular region may determine that their RHIC should address a local or regional need or engage in an activity that is not identified in this report.

The Council carefully considered whether review of CON applications might be a suitable activity for a RHIC. It recommends that, unlike the health systems agencies (HSAs) of a former era, CON review should not be a core, or expected, function of the RHICs. They are instead intended to undertake proactive health planning for their respective regions and to stimulate new initiatives to meet identified needs, rather than to serve as part of the state's regulatory process in approving or disapproving specific proposals of one health care provider or another. Under no circumstances should any RHIC serve to delay or hold hostage any CON application coming before the Department or the Council. At the same time, the Council recognizes that a RHIC may have a helpful perspective on matters under consideration by the PHHPC, including a forthcoming CON application. RHICs should be free to submit commentary for the benefit of the Department and the Council, to inform their respective statutory responsibilities.

The Council is also aware that two HSAs remain in New York--the Finger Lakes HSA (FLHSA) and the Central New York HSA -- that have a statutory role in reviewing selected CON applications. In the event that either or both become designated RHICs, the Council understands that they would continue their residual role with respect to CONs.

Recommendation #5:

The PHHPC should consult with the RHICs concerning regional health and health care environments, unmet needs, and effective planning strategies and interventions that could be disseminated statewide to advance the Triple Aim and eliminate health and health care disparities.

ADVANCING THE TRIPLE AIM THROUGH CERTIFICATE OF NEED AND LICENSURE

Purpose and Utility of CON

CON is one of several regulatory tools that can be used to drive health system performance and advance the Triple Aim. Thirty-seven states (including the District of Columbia) have CON programs. They vary in scope -- six states cover only long-term care services, while most, like New York cover a broader array of facilities, equipment and services.[29] Several states with CON programs cover services and equipment regardless of setting – whether they are found in physician practices or licensed facilities. A detailed description of New York's CON program and its history is set forth at Appendix F.

CON programs are based on the assumption that health care markets are too inefficient to produce an optimal quantity and distribution of health care services. In health care markets, unlike typical markets, the suppliers of services have a strong influence over demand, by virtue of ordering services that their patients consume. Patients, unlike consumers of most goods and services, generally lack the expertise, or have the opportunity to become prudent consumers of health care services. Few have the expertise to determine, for example, the medical necessity of a CT scan, or to weigh whether another type of imaging, or none at all, would be more appropriate. And, almost no one is able to shop for quality while experiencing chest pains. In any case, health care services are less sensitive to price than other services. Consumers with health coverage pay for only a fraction of their health care costs, and many consumers view (often rightfully) health care as essential – they are willing to spend more for health care and are unwilling to seek out the provider with bargain basement prices.

CON strives to mitigate these inefficiencies by imposing certain restraints where markets fail. It seeks to limit the supply and guide the distribution of heath care resources, in order to reduce health care costs, improve quality and promote access to necessary services. It exerts downward pressure on costs and spending by curbing the development of excess capacity (especially for supply-sensitive services) that can drive up unnecessary utilization and promote wasteful health care spending.[30] It attempts to consolidate the volume of highly-specialized services and professional expertise among a limited number of facilities in order to promote quality and optimize outcomes.[31] CON also works to channel the development of services where they are needed and to rein in unnecessary capital expenditures.

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[29] American Health Planning Association's 2011 National Directory: State Certificate of Need Programs and Health Planning Agencies (Summary chart is available at http://www.ahpanet.org/matrix_copn.html.)

[30] For purposes of this report, a health care capital project or service is supply-sensitive if the supply of the health care resource in question influences the utilization of that resource, and the level of utilization is driven not by medical theory or evidence, but rather by capacity and payment incentives. For a discussion of "supply-sensitive" care, see Dartmouth Atlas of Health Care, available at http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2937

[31] A health care service is volume-sensitive if a high volume of the service is associated with improved quality or outcomes. Numerous studies have identified a relationship between volume of a specialized service or procedure and outcomes. *See, e.g.* Halm, Ethan A., Clara Lee, and Mark R. Chassin. "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature." *Ann Intern Med* 137.6 (2002): 511-520. Vaughan-Sarrazin, Mary S., et al. "Mortality in Medicare Beneficiaries following Coronary Artery Bypass Graft Surgery in States with and without Certificate of Need Regulation." *JAMA: the Journal of the American Medical Association* 288.15 (2002): 1859-1866.

In addition, CON has been used to protect safety net providers and community hospitals from destabilizing competition that could jeopardize essential services and access. CON has also been used as an all-purpose lever to condition market entry or expansion on actions that support policy goals (such as Medicaid access or charity care). While controversial, this use of CON has been credited with protecting access for low-income individuals.[32]

However, CON is a blunt instrument – an on/off switch – that does not ensure that an approved facility or home care agency will operate efficiently, will be accessible to low-income patients, will realize its projected revenues, or will provide high quality care. It can curb development in saturated markets, but cannot effectively promote development in under-served areas without capital and ongoing operational funding. Nor can it effectively prevent the closure of a service or facility without a source of revenue or workforce to preserve it.

The current CON process exhibits several shortcomings in relation to health care trends and the risks posed by those trends:

- It impacts only supply and distribution of health care services; not demand. It does not affect the health status of populations nor the delivery system failures that may generate preventable utilization and excess spending;
- It does not cover services provided by physician practices that may destabilize essential providers or drive up health care spending;
- It may delay the development of licensed primary care sites that may be needed to address the needs of newly-insured New Yorkers and support new systems of care; and
- Its process for reviewing the character and competence of health care facility and agency operators is misaligned with the growing complexity of health care organizations, the need to develop integrated systems, and the authority exerted by non-established entities.

The recommendations in this report seek to mitigate those shortcomings.

CON's Impact on Cost, Quality and Access

In order to evaluate CON's utility in addressing the risks associated with a health care delivery system in transition, the Health Planning Committee reviewed the literature assessing the effectiveness of CON as a tool to promote appropriate supply, rein in health care spending and improve quality. It concluded that the evidence is equivocal.

Studies conducted by the Dartmouth Atlas on Health Care demonstrate an association between the supply of certain services and health care utilization and spending:

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[32] Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" *National Institute for Health Care Reform. Research Brief 4*, (2011); Campbell, Ellen S., and Gary M. Fournier. "Certificate-of-Need Deregulation and Indigent Hospital Care." *Journal of Health Politics, Policy and Law* 18.4 (1993): 905-925.

- The single most powerful explanation for the variation in how patients are treated is the fact that much of the care they receive is "supply-sensitive"; that is, the frequency with which certain kinds of care are delivered depends in large measure on the supply of medical resources available . . . . Nationally, supply-sensitive care accounts for well over 50% of Medicare spending. . . . Hospitalizations for most medical admissions, ICU stays, physician visits, specialist referrals, diagnostic tests, home health care, and long-term care facilities belong to the "supply-sensitive" category of care. [33]

A recent study conducted by the National Institute of Health Care Reform of health care spending by the automakers in 19 communities nationwide found that the lowest cost communities in the nation were Syracuse and Buffalo. According to the study, differences in the quantity of health care services consumed represented 18 percent of the variation in spending among the communities.[34]

In addition, numerous studies have shown an association between the volume of specialized services performed by a facility or a physician and improved outcomes. CON promotes consolidation of volume and expertise by limiting the number of facilities that are permitted to perform certain procedures. Based on this body of literature, New York has imposed CON controls on cardiac and transplant services. More recent studies are demonstrating a strong volume-quality association for other procedures; esophageal cancer, pancreatic cancer, abdominal aortic aneurysms, pediatric cardiac problems, and AIDS treatments show significantly different mortality rates between high- and low-volume health care providers.[35]

The evidence is inconclusive, however, regarding the effectiveness of CON as a mechanism for reducing supply and associated health care spending or for consolidating volume and improving quality. Given the significant variation among CON programs and health care markets, it has been difficult for researchers to control for the rigor of CON implementation and various market factors that impact costs and quality. Studies evaluating the impact of CON on health care costs and spending are inconsistent.[36] As for the impact

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[33] Wennberg, John E., et al. "Tracking the Care of Patients with Severe Chronic Illness-The Dartmouth Atlas of Health Care 2008." (2008): 10-14 (available at http://www.dartmouthatlas.org/downloads/atlases/2008_Chronic_Care_Atlas.pdf).

[34] White, Chapin. "Health Status and Hospital Prices Key to Regional Variation in Private Health Care Spending." *National Institute for Health Care Reform. Research Brief* 7 (2012).

[35] Halm, Ethan A., Clara Lee, and Mark R. Chassin. "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature." *Ann Intern Med* 137.6 (2002): 511-520.

[36] *E.g.*, Certificate of Need Endorsement by Daimler Chrysler, July 2002; *See also,* Ford Motor Co., CON Study (CY 2000); Statement of General Motors Co. on CON Program in Michigan (2002). Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" *National Institute for Health Care Reform. Research Brief 4*, (2011); Ferrier, Gary D., Hervé Leleu, and Vivian G. Valdmanis. "The Impact of CON Regulation on Hospital Efficiency." *Health Care Management Science* 13.1 (2010): 84-100.; Hellinger, Fred J. "The Effect of Certificate-Of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis." *Am J Manag Care* 15.10 (2009): 737-744. Fric-Shamji, Elana C., and Mohammed F. Shamji, "Impact of US State Government Regulation on Patient Access to Elective Surgical Care," *Clinical & Investigative Medicine*, Vol. 31, No. 5 (October 2008); Conover, Christopher J., and Frank A. Sloan. "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?" *Journal of Health Politics, Policy and Law* 23.3 (1998): 455-481; Conover, Christopher J., and Frank A. Sloan. "Evaluation of Certificate of Need in Michigan." *Center for Health Policy, Law and Management, Duke University, 2003*: Part IV at 39, 45-46, 84, 96. Arnold, J. and Daniel Mendelson. "Evaluation of the Pennsylvania Certificate of Need Program." Lewin-ICF, (1992); Begley, Charles E., Milton Schoeman, and Herbert Traxler. "Factors that may explain Interstate Differences in Certificate-of-Need Decisions." *Health Care Financing Review* 3.4 (1982): 87-94.

of CON on the quality of volume-sensitive services, research provides stronger evidence of the value of CON.[37]

There are few studies of the impact of CON on access, although it is cited as a mechanism for improving and preserving access, particularly for low-income patients.[38] There is some evidence that CON protects access in urban and rural areas by shielding community and safety net hospitals from competition and preventing exodus to suburbs.[39] Observational studies have noted that CON is often used to impose requirements on facilities related to the provision of services to Medicaid beneficiaries and the uninsured.[40] CON also provides an opportunity to prevent decertification of services and beds where they are needed.

When other states have repealed CON laws, the effects on capacity and access have varied based on stringency of CON program, existing saturation in the market, relative spending, the type of facility or service, and demographic trends. Some states reportedly experienced surges in acute care capacity, ambulatory surgery centers, cardiac services, and/or dialysis.[41] Others experienced short-term growth followed by retrenchment or no change in growth rates.[42] The experience of Ohio when it repealed CON for hospitals is noteworthy – 15 hospitals closed, 11 in urban areas, some of which migrated to the suburbs. At the same time, there was significant growth in ambulatory surgery and diagnostic imaging centers.[43]

While difficult to measure in quantitative terms, it is believed that in New York, the sentinel effect of CON, together with actual CON disapprovals, reduces unnecessary capital spending, exerts pressure on providers to locate licensed services and facilities in communities where they are needed, and promotes the consolidation of highly specialized services.[44] In addition, the threat of disapproval (particularly of

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[37] *See* Halm, Ethan A., Clara Lee, and Mark R. Chassin. "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature." *Ann Intern Med* 137.6 (2002): 511-520. Vaughan-Sarrazin, Mary S., et al. "Mortality in Medicare Beneficiaries following Coronary Artery Bypass Graft Surgery in States with and without Certificate-Of-Need Regulation." *JAMA: the Journal of the American Medical Association* 288.15 (2002): 1859-1866. Vaughan-Sarrazin et al. also reported that the "mean patient volume in states with continuous certificate of need regulations was 84% higher than in states without regulations. *But see* DiSesa, Verdi J., et al. "Contemporary Impact of State Certificate-of-Need Regulations for Cardiac Surgery." *Circulation* 114.20 (2006): 2122-2129. The conclusions of the DiSesa study are called into question by its effort to control for "random state effects" which may mask the state regulatory impacts it attempts to evaluate. *Ibid. at 2123-24.* Lorch, S. A., P. Maheshwari, and O. Even-Shoshan. "The Impact of Certificate of Need Programs on Neonatal Intensive Care Units." *Journal of Perinatology: Official Journal of the California Perinatal Association* 32.1 (2012): 39.

[38] Yee, Tracy, et. al, "Health Care Certificate-of-Need Laws: Policy or Politics?" *National Institute for Health Care Reform. Research Brief 4*, (2011)

[39] *Ibid.*; Fric-Shamji, Elana C., and Mohammed F. Shamji, "Impact of US State Government Regulation on Patient Access to Elective Surgical Care," *Clinical & Investigative Medicine*, Vol. 31, No. 5 (October 2008); Ellen S. Campbell and Gary M. Fournier, "Certificate of Need Deregulation and Indigent Hospital Care," *Journal of Health Politics, Policy and Law, no. 4* (Winter 1993).

[40] *Ibid.*

[41] Conover, Christopher J., and Frank A. Sloan. "Evaluation of Certificate of Need in Michigan." *Center for Health Policy, Law and Management, Duke University, 2003*: Part IV at 39, 45-46, 84, 96.

[42] *Ibid.*

[43] *Ibid.;* "Effects of Certificate of Need and its Repeal." State of Washington, Joint Legislative Audit and Review Committee, Jan. 1999: Report 99-1 at 11, 20.

[44] Although relatively few CON applications are officially denied, many that would otherwise be denied are set aside at the request of the applicant when a decision to disapprove appears imminent.

ambulatory surgery centers and other ambulatory care facilities) has induced beneficial collaborations among physician practices, hospitals and FQHCs. In the Rochester area, CON decisions to approve only a portion of the inpatient beds requested by three hospital systems triggered a regional effort to reduce preventable inpatient utilization and strengthen hospitals in outlying areas.

CON and New Models of Care and Payment

CON's role in controlling costs through curbs on supply is predicated in large part on the existence of a payment system that rewards the delivery of greater quantities of care and more complex, capital-intensive care. In the context of payment mechanisms that incentivize health and discourage preventable utilization, the utility of CON as a mechanism to reduce health care spending is questionable. However, value-based and risk-based payments are just beginning to take hold. Even the Medicare ACOs are receiving fee-for-service payments, albeit together with shared savings. Hospitals, in particular, are struggling to manage through this transitional period. Many are still trying to maximize their inpatient census while minimizing readmission penalties. Hospital-sponsored ACOs are still vying for high-end services like cardiac surgery. Thus, in the near term, New York's health care markets remain flawed in ways that justify some controls on supply.

In the longer term, several factors are expected to improve efficiencies in health care markets and arguably lessen the need for CON. The transition away from fee-for-service to value-based and risk-based payments should discourage unnecessary capital investment and supply-driven utilization. New health plan benefit designs are expected to make consumers more value conscious in their health care choices. These changes, together with the availability of cost and quality data through the launch of an all-payer database in New York State and expanded publication of such data have the potential to promote quality and price competition.

While the potential of this transformation is enormous, the Council recognizes that the actual impact of new models on the ground is uncertain. First, the impact of new payment mechanisms may vary by health care sector. Moreover, even if broad penetration of effective, risk-based payments and improved market efficiencies were to be achieved, there may be a long-run role for CON in promoting an appropriate distribution of health care services, if not in curbing supply. It is conceivable that risk-based payment mechanisms may incentivize the development and preservation of health care services only in geographic areas where risk can be spread across large populations that do not have complex and costly needs. Risk-based payments may discourage the delivery of services in high-cost or low-density communities. This concern may be mitigated through adjustments in payments or alternative regulatory mechanisms, such as ACO certification, health plan network requirements, or possibly facility licensure and decertification requirements. However, in the absence of effective alternative requirements, CON may continue to be an appropriate tool.

The recommendations below seek to apply the principles for reform adopted by the PHHPC in June 2012 to support beneficial innovation, while mitigating risks. They promote the Triple Aim by reducing restraints on primary care development, facilitating the creation of integrated systems, and strengthening DOH oversight of governance. They also strive to ensure that CON operates in a cost-effective manner, by eliminating unnecessary or low-value administrative steps, and investing resources where they can have the greatest impact.

Recommendation #6:

PHHPC recommends eliminating CON for primary care facilities, whether D&TCs or hospital extension clinics.

An expansion of primary care is necessary to serve New Yorkers who will be newly-insured under the ACA and to implement the new models of care envisioned under the ACA and the MRT initiatives. Furthermore, primary care does not exhibit the features that typically trigger the need for CON review -- it is not supply-sensitive or volume-sensitive or capital-intensive. The value of imposing a CON review on primary care facilities in light of the need for increased primary care capacity appears limited. Most states appear to have reached this conclusion, as few apply CON to primary care facilities.

Accordingly, PHHPC recommends exempting primary care facilities from CON. In order to qualify for this exemption, applicants would have to employ a physician practicing in the specialty of internal medicine, family medicine, pediatrics, obstetrics or gynecology. They would have to commit to provide one or more of these services on-site. Facilities that provide, or are intended to provide, advanced imaging, radiation therapy, dialysis, or surgery services, however, would not be eligible for this blanket exemption. These services are capital-intensive and, in some cases, supply-sensitive, and require review.

Although exempt from CON, primary care facilities would be required to obtain a license (operating certificate). The licensing process would proceed like the process in States without CON:

- New operators would have to be approved based on character and competence and quality as described in Part IV below.
- Applications by established operators to create new extension sites would also be subject to review based on compliance and the quality of care provided by the operator. A sub-standard operator should not be permitted to expand its operations.
- Physical plants would have to be reviewed for compliance with health care facility construction standards.
- The Council is aware that access to primary care in under-served areas has, on occasion, been threatened when hospital and FQHC acquisitions of physician practices have been delayed by CON and, in particular, by the need to comply with the construction standards. The Council understands that licensed health care facilities receive higher rates of payment from Medicaid and Medicare, in part due to their compliance with these standards. The Council urges the Department to work with stakeholders to create a process by which access to primary care can be preserved when a physician seeks to retire or transfer his/her practice, without compromising patient safety or paying inflated rates for non-compliant facilities.

Recommendation #7:

Projects funded with State Department of Health grants should be exempt from public need review and subject to limited financial review.

Health care facility projects approved in their entirety through a request for applications (RFA) issued by the Department of Health should not be subject to a full-blown CON process, to the extent that regional planning considerations have been incorporated in the RFA. Through the award process, they have been determined to fulfill a public need, and their financial plan has been deemed reasonable. Regional health planning considerations can be captured through the award criteria set forth in the RFA or through endorsements or recommendations submitted by the RHICs along with the applications.

Some financial review may be necessary in relation to issues that were not reviewed as part of the grant award process. These projects will also require a construction application for purposes of physical plant oversight and issuance of an operating certificate, if applicable.

Projects that include components approved through an RFA process and components that were not part of the RFA should not be eligible for this exemption. If a project involves additional elements, a public need and financial evaluation will be necessary to review a project in its entirety.

Recommendation #8:

The Department of Health should enter into a contract with a research institute to advise the Department and the PHHPC concerning emerging medical technologies and services that might be appropriate for CON oversight.

New York State's health care delivery system should be at the forefront of innovation in medical care. However, the Council is concerned about the broad dissemination of capital-intensive, emerging technologies before they have demonstrated their value. Premature adoption of emerging medical technologies may drive up health care spending without improving outcomes. In particular, the Council notes that utilization of advanced imaging technologies has grown dramatically over the past decade and has raised concerns not only about associated costs, but also about unnecessary radiation exposure. Similarly, the use of robotic surgery appears to be growing despite limited evidence concerning its impact on quality, safety and outcomes, in comparison with other modalities.

The Council recognizes that it is difficult for the State to remain current regarding the latest developments in medical technology and to update its regulations as new and expensive technologies emerge. The Council also recognizes that other specialized services, in addition to cardiac services and transplant surgery, might be appropriate for CON review due to a strong volume-quality association. The Council recommends that the Department contract with an academic or research institution to conduct periodic environmental scans and identify emerging, capital-intensive technologies and volume-sensitive services that might be appropriate for CON or, in particular, for the Department's new medical technology demonstration. The Department should consult with the PHHPC concerning the recommendations of the research institute and the adoption of policies in response to those recommendations.

Recommendation #9:

CON for hospital beds should be retained at least in the short run and reconsidered in the next three to five years.

The Health Planning Committee has discussed whether review of public need for hospital beds should be continued, given the growth of payment incentives that discourage admissions. It reviewed data on hospital occupancy and staffed bed rates and noted that in most counties, occupancy rates of certified beds are below 75 percent, and less than 75 percent of the certified beds are staffed. In many counties, less than 50 percent of beds are staffed. These data suggest that hospitals are voluntarily taking beds out of service in response to diminished demand.

The Council has concluded that, in the foreseeable future, payment incentives may eliminate the supply-sensitivity of hospital beds. However, the penetration and impact of new payment mechanisms have yet to be fully realized. As hospitals transition from an inpatient-centered system to a patient-centered one, many are still trying to maximize "heads in beds." Given New York's poor ranking on avoidable hospitalizations and

cost, and its excess inpatient capacity, CON for hospital beds should be retained. This recommendation should be reexamined within the next three to five years.

Recommendation #10:

Consider the use of ACO certification, in lieu of CON for certain facilities, to promote appropriate distribution of facilities and services and Prevention Agenda 2013 goals.

As the delivery system shifts toward integrated systems of care that receive substantial revenues through capitated or risk-based payments, the utility of CON becomes less clear. If providers are to be paid a fixed amount to keep people healthy, for example, the incentive to develop unnecessary capacity will be significantly reduced.

Existing state regulations exempt health care providers operated by HMOs from CON requirements. Arguably, the same rationale that justifies an exemption for HMO-operated facilities could be applied to providers that receive principally risk-based reimbursement and participate in ACOs.

The Health Planning Committee considered the elimination of CON requirements for providers that are participating in ACOs and receiving a majority of their revenue from risk-based payment arrangements. However, the Committee concluded that it would be premature to make such a recommendation at this time. The current crop of Medicare-designated ACOs in New York are being paid on a fee-for-service basis with an additional component of shared savings. It is unclear whether or when true risk-based payment methodologies will take hold (e.g., methodologies that involve both upside and downside risk or capitation) and have the anticipated effects.

The State is developing a certification process for ACOs, which has not yet been implemented. The PHHPC recommends that the Department consult with the Council concerning the ACO certification process. This certification process could be a vehicle for ensuring that essential services are preserved and that population health, access and quality concerns are addressed. Certification should also take into account the risk of inappropriate under-utilization of medically-necessary services. The applicability of CON to such providers should be reconsidered once the ACO certification process is finalized.

Recommendation #11:

Update the CON process for hospice.

The Council recommends that the Department examine its public need methodologies and identify those that require updating. In particular, the hospice need methodology should be updated. The current methodology relies heavily on the incidence of cancer, but it is well-established that hospice care is appropriate for a wide variety of terminal conditions.

New York State is tied with New Jersey for the highest rate of Medicare inpatient days during the last six months of life and has among the lowest rates of hospice use among Medicare beneficiaries nationwide.[45]

[45] "Inpatient Days per Decedent, By Interval Before Death and Level of Care Intensity," "Hospice Days per Decedent During the Last Six Months of Life," The Dartmouth Atlas of Health Care, 2003-2007, available at www.dartmouthatlas.org; *See also* Fisher, Elliot S., et al. "Trends and Variation in End-of-Life Care for Medicare Beneficiaries With Severe Chronic Illness." (2011).

Many factors undoubtedly contribute to the relative under-utilization of hospice in New York – our CON process likely plays a minimal role. Nevertheless, these data suggest the need for interventions to expand access to hospice care. Updating our CON process is one place to start.

Recommendation #12:

Update the CON process for approved pipeline projects.

DOH should take steps to ensure that public need is accurately evaluated when approved projects are in the pipeline. Specifically, providers should not be permitted to retain CONs for extended periods without bringing the approved project to completion and providing the approved services. This practice of "banking" a CON creates an illusion that public need is met and prevents other CON applicants from obtaining the approval necessary to provide needed services.

A firm expiration date of no more than two years for establishment projects and five years for construction projects should be established for CONs. Shorter time periods may be set on a project-specific basis. However, no CON should be on hold for more than five years. If construction is not commenced within five years or an establishment is not finalized within two years, the CON should expire. Once a CON expires, the provider would have to re-apply for, and receive, a CON in order to go forward.

Recommendation # 13:

Update the criteria that trigger the facility licensure requirement and equalize treatment of physician practices and facilities with respect to CON requirements.

Due to advances in medical care and market forces, we are seeing growth in the scope and influence of the physician practice sector – with large multi-specialty practices emerging that include hundreds of physicians and that provide extensive diagnostic and treatment services – including most of the services of a hospital, except for inpatient care and certain highly-specialized procedures. Physician practices are entering into arrangements with corporate entities, such as health insurers, hospitals, medical services organizations, and turn-key radiation oncology enterprises. While these entities do not hold an ownership interest or formal governance role in the practice, they exercise varying degrees of influence over the management and the delivery of care. Physician practices are also playing a leadership role in new care models - two-thirds of the accountable care organizations (ACOs) designated by the federal Centers for Medicare and Medicaid Services (CMS) in New York State are led by physician practices.[46]

Despite the scope and complexity of their services and their close ties to corporate entities, physician practices typically consider themselves exempt from facility licensing requirements and CON. The line between a physician practice and a diagnostic and treatment center that requires a CON and licensure by the Department has grown murky. Because they are exempt from the operating and physical plant standards of a health care facility, those physician practices are often reimbursed at lower rates than licensed facilities.

[46] Burke, *supra* note 21.

Although they have the potential to dominate a health care market and significantly impact access, cost and quality, physician practices are subject to little oversight in comparison with licensed health care facilities. Similarly, medical school and hospital-affiliated faculty practice plans operate ambulatory care sites without a CON or licensure under the Public Health Law.[47] The relatively limited regulatory oversight of facilities that are organized as physician practices may expose the delivery system to unnecessary risks. In addition, certain types of equipment or services raise concerns that could be addressed through CON regardless of setting. For example, there is evidence that high-end diagnostic imaging is supply-sensitive, is over-utilized and poses risks associated excessive exposure to radiation. [48] Yet, only the licensed setting is subject to CON.

The scope and pace of the Council's work did not permit an in-depth analysis of the benefits and burdens of the current rules. However, issues related to corporate ownership or control, and disparate treatment of physician practices and licensed facilities, repeatedly arose in its deliberations.

The Council urges the State to take steps to equalize the treatment of physician practices and licensed facilities under CON and licensure requirements. Some stakeholders suggested that licensed facilities should be exempt from CON for any service or equipment that could be offered by a physician practice, except surgery. Conversely, some Council members suggested that, in order to curb unnecessary spending and utilization, certain physician practice equipment and services should be brought into the CON process.

The Council requests that the Department analyze options and develop a set of recommendations to equalize the treatment of physician practices and licensed facilities under CON and licensure – either by applying CON and licensure to similar services, or exempting similar services from CON and licensure, regardless of setting. The Department's recommendations should be informed by input from stakeholders and:

- Consideration of the relative quality and cost of surgical care, radiation therapy, and imaging services in physician practice and facility settings, including costs attributable to excess utilization due to self-referral patterns.
- Consideration of the impact of physician practice services such as surgery, radiation therapy and imaging on neighboring hospitals, access, disparities and public health.
- Consideration of the effectiveness of local initiatives like the Community Technology Assessment Advisory Board (CTAAB) implemented in the Finger Lakes Region.

The Council requests these recommendations within six months.

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[47] Faculty practice plans are governed by N.Y. Not for Profit Corporation Law §1412.

[48] Nat'l Council on Radiation Protection and Measurements, NCRP Report No. 160, Mar. 2009. Brenner, David J., and Eric J. Hall. "Computed Tomography – An Increasing Source of Radiation Exposure." *New England Journal of Medicine* 357.22 (2007): 2277-2284. Berrington de Gonzalez, Amy, et al. "Projected Cancer Risks from Computed Tomographic Scans Performed in the United States in 2007." *Archives of Internal Medicine* 169.22 (2009): 2071. This trend has been identified even in integrated systems. Smith-Bindman, Rebecca, et al. "Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010." *JAMA: the Journal of the American Medical Association* 307.22 (2012): 2400-2409. A recent study by the GAO found that providers' referrals for MRI and CT scans increased dramatically after they began to self-refer (i.e., after they purchased imaging equipment or joined a practice with equipment). "Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions," GAO, Sept. 2012.

PROMOTING IMPROVEMENTS IN QUALITY AND EFFICIENCY THROUGH GOVERNANCE

New York's process for approving new health care facility and home care agency operators, known as "establishment," strives to promote quality, integrity, and financial stability in health care by assessing the "character and competence" of individuals seeking to operate health care facilities and home care agencies, either as board members or as owners. The character and competence process was developed when health care organizations were simpler – they were typically stand-alone facilities operated by not-for-profits or small groups of individuals. With the increasing integration of health care facilities into systems, interstate expansion of health systems, and the growth of publicly-traded home care and dialysis providers in the State, the establishment process is at times administratively burdensome and not tailored to achieve its intended purpose.

Accordingly, the recommendations below attempt to achieve 3 goals:

- Rationalize the "taint" or disqualification rule to eliminate barriers to integration of systems and recruitment of experienced leadership, while maintaining safeguards to exclude non-compliant and low-quality providers;
- Align the process for reviewing character and competence with the growing complexity of health care organizations; and
- Strengthen the Department's authority to respond, when it becomes apparent that the governing body of a licensed provider is failing to provide quality care or is heading towards financial collapse.

Recommendation #14:

Rationalize "taint" to eliminate barriers to integration and recruitment of experienced governing body members.

Because it is difficult to assess character and competence based on an application, DOH relies, to a large extent, on the absence of negative factors (like professional discipline and exclusion from Medicare or Medicaid) to screen CON applicants. Applicants that have affiliations with health care facilities or agencies are also evaluated based on the compliance record of those facilities. Two or more recurring enforcements (final determinations of non-compliance) that threaten health or welfare within ten years trigger disapproval of the applicant. This statutory bar is colloquially known as a "taint."

The Council recognizes that, as health care organizations grow in complexity and geographic scope, and as they seek to integrate to participate in new models of care and payment, the current approach to disqualification can have unintended consequences. Experienced and capable trustees and owners are needed to lead providers through the delivery system transformation currently under way. As systems grow, and trustees and owners become affiliated with additional entities or acquire more experience, there is an increased likelihood that they will be affiliated with one or more entities that have been the subject of recurring enforcements. Because the current rule mandates disqualification based on two or more recurring enforcements, it discourages the participation of experienced individuals in governance and the development of integrated systems.

In addition, within complex corporate families, screening individuals requires increasing investment of administrative resources by the Department, by applicants, and by agencies in other states that are asked to respond to requests for the compliance history of their affiliated providers. At the same time, reviewing information about individuals who may have no governance or operational responsibilities in relation to the

entity seeking establishment, or about the compliance record of related entities that are several organizational layers removed from the regulated entity, may add little value to the review process and may not be the most effective use of State resources.

As part of Phase 1 of this project, the PHHPC recommended reducing the ten-year look-back to seven years. The Council recommends building on that recommendation by modifying the taint rule to permit greater flexibility, increased attention to quality, and a stronger focus on organizations as opposed to individuals.

Instead of mandating disqualification of a proposed operator whenever an affiliated facility is subject to two identical enforcements that threaten health and welfare within 10 years, New York's establishment policy should disqualify proposed operators based on a pattern of, or multiple, enforcements that evidence a failure in governance and/or systemic weakness. New York's policy should consider quality, as well as non-compliance, using measures and dashboards to be developed by the Office of Quality and Patient Safety. The pattern of non-compliance or poor quality may be demonstrated based on the performance of a single affiliated facility or more than one facility with which the individual is affiliated.

When a proposed owner or trustee presents affiliations with a health care facility or agency that has a pattern of, or multiple, enforcements, or a sub-standard quality record, there should be a presumption of disqualification which may be rebutted in limited circumstances. The presumption may be rebutted based on the individual's role in the organization and actions to address problems, the timing of his or her involvement, recent performance, and extent of his or her involvement in health-related organizations. The affiliations that should be considered should include not only ownership interests or board membership, but also services as the CEO or CFO of a facility or agency.

Compliance and quality reviews should not be limited to individuals. Organizational quality and compliance should be the primary focus when a facility or organization is seeking to acquire another operator or engage in a joint venture and in relation to parent organizations and corporate members of entities seeking establishment.

Recommendation #15:

Streamline character and competence reviews of established not-for-profit corporations.

Not-for-profit corporate structures have become increasingly complex as providers have forged new relationships and diversified their services and markets. One not-for-profit health system, for example, has over 100 trustees on its board. When these large and complex systems seek to merge with or acquire another facility, the character and competence (C&C) review is burdensome and time-consuming. Moreover, the value added by the review of dozens of board members is not clear. As an alternative to DOH review of each board member of an entity already established to operate a health care facility or agency in New York State, under these circumstances, the Council recommends that the Department:

- Require established not-for-profit operators to conduct a C&C review of new board members consistent with DOH regulations at the time of their appointment;
- Require that the operator update the C&C review in the event of any establishment action (e.g., merger, acquisition, joint venture); and
- In lieu of DOH verification of disclosures by board members, require an attestation by the operator regarding the review and verification and the disclosure of any compliance or quality problems.

The Council recognizes that review consistent with DOH standards may be difficult for providers to operationalize, if a more flexible disqualification policy is adopted as described above. Providers will require

guidance from DOH concerning the application of this more flexible policy to particular individuals and organizations with less than perfect track records.

Recommendation #16:

Streamline character and competence reviews of complex proprietary organizations (e.g., publicly-traded, private-equity-owned) and new, complex not-for-profit systems.

Like not-for-profit corporations, proprietary health care organizations in New York State are becoming increasingly complex. Publicly-traded and private-equity-owned, multi-state entities have entered New York's dialysis market and have long been involved in the home care market. In addition, we are seeing the formation of large not-for-profit systems under new parent organizations, sometimes under the leadership of out-of-state systems, with multiple organizational layers and affiliates.

Reviewing individual board members, LLC members, officers, and controlling shareholders and the compliance record of each related entity up and down the corporate family tree is a labor-intensive process that delays the CON process and at times does not appear to add a great deal of value. Instead of reviewing individuals up to the top of the corporate tree, the Committee recommends that the DOH review focus on the individuals involved in the regulated entity and its direct parent (if the direct parent is a holding company, DOH should review a higher level entity).

Entity owners/grandparents and members should be assessed principally based on organizational compliance and competence. DOH should require an attestation from the ultimate parent and any controlling shareholders/members concerning the organizational compliance history and operational track record of the parent, controlling shareholders/members, and related entities; and the character and competence of any natural persons who are controlling owners, directors or officers. The applicant could, with the consent of DOH, opt for an independent, third-party review of its compliance history and track record and the character and competence of its principals, in lieu of the DOH review. DOH would make a recommendation to PHHPC as to character and competence based on the attestation, associated disclosures, and the third-party review or its own review.

Recommendation #17:

Align "passive parent" oversight with powers exerted by parents and promote integrated models of care.

For purposes of this report, a passive parent of a not-for-profit health care facility operator is a member under the Not-for-Profit Corporation Law (NFPCL) that does not exercise any of the active parent powers set forth below. Under the NFPCL, a member has authority to elect and remove some or all of the board members of the established operator; elect and remove officers; adopt, amend or repeal bylaws; amend the certificate of incorporation; and approve any plan to encumber property, dissolve, consolidate or merge the corporation, or dispose of its assets. A member of a not-for-profit corporation is limited in the powers it may exert over a health care facility licensed under Article 28 of the Public Health Law, unless it is established as the operator of the facility.

Specifically, the following powers, known as the active parent powers, may not be exercised by a member, unless the member has received establishment approval:

- appointment or dismissal of hospital management level employees and medical staff, except the election or removal of corporate officers by the members of a not-for-profit corporation;

- approval of hospital operating and capital budgets;
- adoption or approval of hospital operating policies and procedures;
- approval of certificate of need applications filed by or on behalf of the hospital;
- approval of hospital debt necessary to finance the cost of compliance with operational or physical plant standards required by law;
- approval of hospital contracts for management or for clinical services; and
- approval of settlements of administrative proceedings or litigation to which the hospital is party, except approval by the members of a not-for-profit corporation of settlements of litigation that exceed insurance coverage or any applicable self-insurance fund.

Although these powers may not ordinarily be exercised absent establishment approval, the regulations provide a mission/philosophy exception that permits a passive parent to exercise powers for the purpose of requiring the subsidiary (known as the affiliate) to operate in conformity with the affiliate's mission and philosophy.

Passive parent models vary based on the unique circumstances of the organizations involved. In some cases, the same group of individuals serves as the board for the parent entity and each of its affiliates, while in other cases, the boards are overlapping. Some affiliates with passive parent relationships retain their own CEO; others share the CEO of the passive parent.

The Council recognizes that passive parent relationships may benefit the delivery system by offering weak health care facilities access to a stronger administrative infrastructure, by rotating specialists through facilities that lack them, and by lower prices from vendors through bulk purchasing. Passive parent relationships have assisted small, community hospitals in leveraging enhanced rates from health plans. A passive parent relationship may also be a stepping stone to a more fully integrated relationship, as the affiliate cleans up its balance sheet and improves the efficiency and quality of its operations.

However, the Council is concerned about the lack of oversight of passive parent arrangements and the lack of accountability of passive parents for the quality of care and financial stability of their affiliates, despite the significant degree of control they may exert through the board members they appoint and through management or administrative services agreements. Because passive parents are not financially integrated with their affiliates, they lack a stake in the success of the affiliates. They may treat the affiliates as a revenue source and foster dependence on the parent and instability by siphoning off management fees and lucrative clinical cases.

The Council also recognizes the possibility that a passive parent could force the wholesale replacement of an existing board. If the passive parent were a proprietary entity, the not-for-profit mission of the facility could be compromised.

The Council has concluded that some oversight of passive parent arrangements is warranted. However, the Council does not want to discourage beneficial passive parent relationships that may lead to more integrated systems and bring improvements in quality and efficiency. And, the Council recognizes that the powers of a passive parent, although significant, are not as extensive as an active parent. Accordingly, the Council is not recommending a full-blown establishment requirement for passive parents. Instead, the Council recommends that the Department initiate the following abbreviated approval process:

- Prior to the commencement of a passive parent relationship, the established health care facility should be required to submit a notice to the Department identifying the entities involved and

their board members, a copy of the proposed affiliation agreement, and the organizational documents. It should be asked to demonstrate how the proposed arrangement will benefit the health care facility seeking to affiliate, the passive parent, and its system, as well as the broader health care system.

- DOH would have 90 days to recommend disapproval to PHHPC. If no action were taken, the transaction could go forward.
- Grounds for recommending disapproval would be a poor record of compliance, integrity, financial management or quality on the part of the passive parent or its affiliates; or lack of evidence that the passive parent arrangement would benefit the proposed affiliate, as well as the parent and/or existing affiliates.

Approved passive parent relationships would be reviewed every three years. Reviews would be based on the system's compliance record, financial management, quality of care, and evidence that the passive parent arrangement is mutually beneficial for the parent and/or its affiliates. Failure to meet these standards could result in revocation of passive parent approval or other action.

Affiliates with existing passive parents would not be required to seek the Department's approval of current relationships. However, existing relationships would be subject to review every three years. In addition, existing passive parents would be subject to the 90-day review for any new affiliation they seek to initiate.

Recommendation #18:

Improve transparency of major changes in board membership

DOH should create a more structured process for the annual filings required of facilities regarding their board membership. As part of that process, the Department should be notified of any change of 25 percent or more of the members of a facility board within a 12-month period.

This recommendation would improve the Department's ability to monitor changes in control of health facilities. It would also ensure that the Department has updated information concerning the composition of facilities' governing bodies, in the event that compliance, quality of care, or financial issues demand intervention by the Department.

Recommendation #19:

Strengthen DOH authority to respond to failures in governance.

The proposed changes in character and competence reviews (see Recommendations 15 and 16) recognize that these reviews are merely an initial screen based on an application and the absence of disqualifying factors. A perfect character and competence review does not guarantee that the resulting health care facility or home care agency will provide high-quality care. Ongoing monitoring and the authority to intervene in the event of deficient governance are more effective tools in assuring the clinical quality, integrity and financial stability of health care providers.

Under current law, the Department has authority to revoke, limit or suspend operating certificates, and PHHPC has the authority to revoke an establishment. However, in many instances, revoking or otherwise limiting the operating certificate of a provider is an unacceptable strategy, as it would reduce access to

needed health care services in a community. Typically, it would be preferable to bring in a temporary operator or new board members to turn around the facility.

Earlier this year, the Department advanced legislation to permit it to appoint temporary operators of hospitals and D&TCs and to replace board members, under extreme circumstances where health and safety of patients is of concern and financial instability threatens patient care. The PHHPC supports legislation that would permit such interventions under those limited circumstances.

In addition, given the Committee's proposed expansion of the use of applicant attestations to establish character and competence, and the proposed integration of quality considerations into establishment reviews and reviews of applications to expand services or capacity, the Committee recommends using limited-duration operating certificates with greater frequency:

- Where new operators are established;
- Where new models of care are created; and
- Where compliance or quality of care issues are identified.

INCORPORATING QUALITY AND POPULATION HEALTH INTO CON REVIEWS; STREAMLINING FINANCIAL FEASIBILITY REVIEWS; AND RELAXING THE REVENUE SHARING PROHIBITION

The Council has emphasized throughout this redesign process the importance of advancing the Triple Aim. While CON has historically been focused on cost and quality through control of supply of health care resources, the Council finds that health care quality and population health can also be advanced by CON. At the same time, the Council recognizes that CON impacts these dimensions only indirectly.

The Principles for Reform adopted by the Council in June 2012 stated that:

> *CON is one of several regulatory tools that can be used to affect the configuration and operations of healthcare delivery systems. It should be applied only: (i) where it is likely to be cost-effective in comparison with other tools available to achieve desired goals; and (ii) where the goal sought is directly related to the development, reconfiguration, or decertification of health care facilities, programs or services.*

Recommendation #20:

Consider performance on quality benchmarks and relationship to the SHIP, when reviewing applications to expand services or sites.

While we cannot expect CON or licensure to solve our health care quality and population health concerns, the Committee recommends that quality and population health considerations be incorporated into the CON and licensure processes consistent with the principles for reform adopted by the PHHPC in June 2012. Specifically:

- When construction projects involve expansion of capacity or services, ensure that the operator is meeting or exceeding quality benchmarks established by the State.
- Regardless of whether CON is required for a particular construction project, require prior approval of clinical construction projects to assure physical plant safety. This may be accomplished through an architectural review or certification by a licensed architect consistent with the PHHPC's Administrative Streamlining recommendations.
- Require CON and licensure applicants to demonstrate that they have implemented, or plan to implement, a certified electronic health record (EHR) system and connect to the Statewide Health Information Network ("SHIN-NY") to assure health information exchange capacity as condition of CON approval and licensure. The EHR and SHIN-NY requirements may be waived for small construction projects that are subject only to a limited review for compliance with physical plant safety standards. The Council is sensitive to the fact that certain services are highly sensitive and raise heightened confidentiality concerns. For providers of these services uploading data to the SHIN-NY may problematic. The Council recommends that the Department develop a way to comply with these requirements that addresses these concerns.
- Require submission of SPARCs data, consistent with the ACA requirements related to race, ethnicity and disability, as a contingency or condition of CON approval or licensure of projects by existing providers.
- Expand the current public need schedules to solicit information concerning the ways in which projects will help address the priorities and focus areas in the Prevention Agenda 2013.

Recommendation #21:

The Department of Health should pursue a more calibrated approach to financial feasibility reviews.

The Committee recognizes the important role of financial feasibility and cost reviews. However, the Committee recommends a more calibrated approach to financial feasibility reviews that would focus State resources on financially-weak providers, while reducing administrative hurdles for stronger ones. Specifically:

- The Department should conduct ongoing monitoring of the financial status of hospitals and nursing homes, using standardized metrics, to assess their financial performance and respond as appropriate.
- CON applications submitted by financially stable hospitals should be subject to less scrutiny for financial feasibility.
    - In addition, financial reviews should include consideration of the impact of capitation and bundled payments in feasibility submissions. They should also provide greater flexibility in debt structures for high-performing hospitals.

Recommendation #22:

Relax the prohibition on revenue sharing among providers that are not established as co-operators.

The Council has also considered the continuing relevance and utility of the Department's prohibition against the sharing of revenue by established operators with non-established entities. This prohibition was created in order to prevent unlicensed entities from exercising undue influence over established operators. It also arose out of a concern that compensation arrangements based on a percentage of revenue might incentivize contractors to stimulate unnecessary utilization of health care services in order to maximize revenues.

The Council has been advised that this prohibition has prevented contractual arrangements among providers and between providers and vendors in which compensation is based on a percentage of revenues. To comply with the letter of the law, providers and contractors have devised compensation arrangements that entail fixed fees with frequent updates.

Contractual arrangements that involve revenue sharing can create effective incentives to support new collaborative models of care and participation in innovative payment arrangements with payers and purchasers. To promote cost-effective collaborations among providers, the Council recommends that the Department relax its revenue-sharing prohibition with respect to compensation arrangements among providers. Review of the terms of revenue sharing arrangements and limits on the percentage of revenues that may be shared may be necessary, but establishment of participating providers as co-operators should not be required.

Recommendation #23:

The Council recommends that DOH work with stakeholders to review, and update as necessary, the construction and environmental standards and other requirements for health care facilities and agencies to improve the resiliency and sustainability of health care facilities and ensure that patients/residents, staff and facilities are protected in the event of severe weather events, flooding, and other natural disasters.

CONCLUSION

This report, together with the administrative streamlining recommendations adopted in Phase 1, lays the groundwork for a new paradigm for regional planning, CON and licensure in New York State that will support the Triple Aim. Through regional health improvement collaboratives, community stakeholders will develop consensus-based strategies to improve health and health care and reduce costs. The report promotes primary care development by eliminating CON and requiring only licensure for primary care facilities. The report also recognizes the changing nature and roles of physician practices and provides a path for equalizing the regulatory oversight applied to services that are provided in both practice- and facility-based settings. The recommendations remove barriers to integration of systems through revisions to the "establishment" process, while strengthening the Department's ability to oversee passive parents and intervene when governing bodies fail to direct their institutions properly. Finally, the recommendations provide a mechanism for incorporating quality and population health considerations into CON reviews.

The PHHPC expects to revisit CON and licensure policy as the delivery system evolves. The expansion of integrated systems that receive most of their revenues through risk-based payments may call for additional changes in CON and licensure or an entirely new form of regulation in lieu of CON. The transformation of the delivery system may also require changes in law or regulation that are beyond the purview of the PHHPC. For example, the growing acceptance by providers of risk-based payments may demand changes in how the State oversees the transfer of risk to providers, especially oversight of risk transfers between self-insured plans and providers. Regional planning and sound regulatory oversight that supports beneficial innovation, while mitigating risks, will strengthen New York's efforts to achieve better care, better health and lower costs.