MARYLAND HEALTH CARE COMMISSION

Required Under House Bill 800 (2007)
Maryland Health Care Commission – Program Evaluation

Certificate of Need – Update on Implementation of Recommendations:

- 2005 Certificate of Need Task Force
- Comprehensive Evaluation Required by Chapter 702 of 1999

October 1, 2008

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Chair

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Implementation Update: Recommendations of the 2005 Certificate of Need Task Force

	CON Task Force Recommendation	Implementation Progress
Scope of CON Coverage	Increase the capital-expenditure threshold to $10 million for hospitals regulated by the HSCRC and $5 million for other facilities	Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006
	Remove the requirement for a public informational hearing for hospital closures in jurisdictions with more than two hospitals	Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006
	Remove the requirement to obtain a CON exemption for hospital closures in jurisdictions with fewer than three hospitals	Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006
	Expand the business office equipment exemption to include information technology	Implemented through changes to COMAR 10.24.01., effective April 10, 2006
	Remove home-health agency from the definition of health care facility or, alternatively, eliminate home health from the State Health Plan	This recommendation was not approved by full Commission. In 2008, the Commission and Office of Health Care Quality initiated a study to determine how the repeal of CON requirements for home health agencies would be accomplished, how possible adverse effects could be mitigated, and what the fiscal implications would be. The study is scheduled to be completed by the end of 2008.
	Develop a fast-track CON review process for hospital renovation and new construction projects with no new services or for which the hospital agrees not to file a partial rate application for capital	Regular review process now completed more rapidly
	Issue a staff report to allow the Commission to act on a CON application for an unopposed project within 90 days of docketing	Implemented through changes to COMAR 10.24.01., effective April 10, 2006

	CON Task Force Recommendation	Implementation Progress
	Revise determination of non-coverage for hospitals pledging not to increase rates, to deem the request approved if not acted upon within 60 days	Implemented through changes to COMAR 10.24.01., effective October 23, 2006
State Health Plan	Undertake a comprehensive revision of the Plan involving broadly representative technical advisory groups to: eliminate obsolete and duplicative CON review standards; streamline documentation requirements; identify types of projects eligible for review based on a limited set of standards; and be consistent with guiding principles	The Commission updates the State Health Plan on an on-going basis: • A major revision of the State Health Plan chapter (COMAR 10.24.08) regarding nursing homes, home health agencies, and hospice programs was adopted by the Commission effective March 12, 2007. • The State Health Plan for Neonatal Intensive Care Unit Services (COMAR 10.24.18) was updated effective October 23, 2006.
	In updating the Plan, give priority to the Acute Inpatient Services and Ambulatory Surgical Services Chapters; In the Ambulatory Surgical Services Chapter better define "operating room" and "procedure room" to clarify what is permitted in a facility with a single operating room	As a result of revisions to COMAR 10.24.10, effective April 24, 2006, 16 systems standards were eliminated from the Acute Inpatient Services Chapter. Additional changes to the Acute Inpatient Services Chapter, described below, were adopted by the Commission based on the work and recommendations of the Acute Care Work Group. The update of the Ambulatory Surgical Services chapters of the State Health Plan will be initiated by Commission staff in 2009.
	Revisions to the Acute Inpatient Services Chapter should eliminate or substantially modify the following standards to the extent that Staff agrees they are obsolete or redundant: .06A(2) Utilization Review Control Programs; .06A(3) Travel Time; .06A(4) Information Regarding Charges; .06A(5) Charity Care Policy; .06A(6) Compliance with Quality Standards; .06A(7) Transfer and Referral Agreements; .06A(8) Outpatient Services; .06A(9) Interpreters; .06A(10) In-Service Education; .06A(11) Overnight Accommodations; .06A(12) Required Social Services; .06A(19) Minimum Size for Pediatric Unit; .06A(20) Admission to Non-Pediatric Beds; .06A(21) Required Services When Providing Critical Care; .06A(22) Average Length of Stay for Critical	On September 18, 2008, the Commission adopted as emergency regulations an updated forecast of medical-surgical-gynecological-addictions (MSGA) and pediatric service for 2016. These bed need forecasts update the 2010 forecast adopted by the Commission in 2004. The Commission also adopted as proposed permanent regulations a replacement chapter of the State Health Plan for Acute Care Hospital Services (COMAR 10.24.10) at the September 18, 2008 meeting. The replacement chapter includes three general standards; and 16 project

	CON Task Force Recommendation	Implementation Progress
	Care Units; .06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients; .06B(1) Compliance with System Standards; .06B(2)(a) Duplication of Services and Adverse Impact; .06B(4) Burden of Proof Regarding Need; .06B(5) Discussion with Other Providers; .06B(9) Maximum Square Footage; .06C(2) Compliance with System Standards; .06C(3) Conditions for Approval; and, .06C(5) Maximum Square Footage – Renovations.	review standards. The new plan eliminates outdated project review standards and includes new standards regarding the emergency department, size of nursing units, financial feasibility, patient safety, and shell space. For projects involving new or replacement hospital facilities to be located to a new site not within a Priority Funding Area, the plan requires documentation that the proposed site is superior in terms of cost-effectiveness to the alternative site or sites located within a Priority Funding Area. The plan also includes a new methodology that provides for annual updates of the MSGA and pediatric service bed need forecasts with the planning horizon extended from 8 to 10 years.
	Permit hospitals to construct shell space as long as no rate adjustment is sought while the space is unused, and require CON approval of fit-out of space for patient care if such project would be subject to CON review	Implemented through administrative changes in the review of CON applications. The new replacement chapter of State Health Plan on Acute Hospital Services, adopted as proposed permanent regulations on September 18, 2008, includes a project review standard regarding shell space.
	Study alternatives to eliminate the inconsistency between the 140 percent rule for determining licensed acute card bed capacity and the Plan occupancy assumptions	The occupancy threshold governing bed need projections was lowered in revisions to the State Health Plan adopted in 2004. The Commission considered the issue of occupancy thresholds as part of the process of developing the new replacement Acute Care Hospital Services chapter of the State Health Plan and did not recommend further changes. There were, however, several changes adopted to related components of the methodology for forecasting bed need, including increasing the planning horizon from 8 to 10 years, providing an automatic process to calculate minimum and maximum values for discharge rates and length of stay, and providing for annual rather than periodic updates of the bed need forecasts.
CON Review Process	Restructure the process to require two conferences – an application	Implemented through changes to COMAR 10.24.01.,

	CON Task Force Recommendation	Implementation Progress
	review conference and a project status conference – as part of the review of any CON application	effective April 10, 2006
	Modify the CON review process to permit certain changes, addressed in a project status conference, without redocketing of the application	Implemented through changes to COMAR 10.24.01., effective April 10, 2006
	Develop an automated CON application form, require PDF files of CON application documents, develop a standard form for filing requests for Determinations of Non-Coverage, and provide website access to CON filings	For CON modification filings in certain cases, the Commission now requires PDF documents and provides access to those documents via the website. Preliminary design work has been completed on the development of an automated CON application form. Additional steps to automate the CON process are planned.

Source: Maryland Health Care Commission, October 1, 2008.

Implementation Update: Recommendations from the 2001-2002 Analysis and Evaluation of Certificate of Need Regulation in Maryland (Phase I and Phase II Final Reports to the Maryland General Assembly)

Report and Service	Recommendation	Implementation Progress
Phase I: Final Report to the Maryland General Assembly • Obstetric Services	**Recommendation 1.0** The Commission should continue its regulatory oversight of acute inpatient obstetric services through the Certificate of Need program. **Recommendation 1.1** The Commission should modify the need projection, review threshold, and approval policies found in the State Health Plan to permit its consideration of proposed new obstetric services.	The establishment of a new acute inpatient obstetric service continues to be regulated under the CON program in Maryland. The Commission adopted a new chapter of the State Health Plan (COMAR 10.24.12) effective April 15, 2005 for Acute Hospital Inpatient Obstetric Services. The new plan modified the policies governing consideration of a new obstetric service consistent with Recommendation 1.1.
• Cardiac Surgery and Therapeutic Catheterization Services	**Recommendation 2.0** The Commission should continue its regulatory oversight of open heart surgery services through the Certificate of Need program. **Recommendation 2.1** The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care. **Recommendation 2.2** The Commission should use a well-designed research project to investigate cardiac surgical support for specific groups of patients receiving elective angioplasty.	The establishment of new OHS services continues to be regulated under the CON program in Maryland. The Commission established an Advisory Committee on Outcome Assessment in Cardiovascular Care in 2002. The Advisory Committee and its subcommittees completed their work in 2005. The cardiac services Chapter of the State Health Plan effective March 15, 2004 permits research waiver applications for a study of the safety and efficacy of non-primary PCI in hospitals without on-site cardiac surgery. A research proposal was

Report and Service	Recommendation	Implementation Progress
		submitted for review in 2005 and subsequently withdrawn prior to Commission action. A revised research proposal was submitted in 2006. After review by a Research Proposal Review Committee, the revised proposal was accepted by the Commission in April 2007. On October 22,, 2007, regulations became effective that guide the submission of research waiver applications to participate in a research project conducted by the Atlantic C-PORT project. The Commission awarded 4 non-primary percutaneous coronary intervention research waivers in the metropolitan Regional Service Areas in September 2008, and took no action on 3 applications pending receipt and review of waiver applications from the Western Maryland Regional Service Area.
	Recommendation 2.3 The Commission will continue to coordinate its planning and regulatory activities with other entities for the purpose of promoting affordable, accessible, high quality care for all residents of the state. The Maryland Health Care Commission and Health Services Cost Review Commission should monitor changes in market demand and referral patterns as a result of new or expanded open heart surgery services that may affect Maryland's Medicare waiver.	The Commission coordinates its planning and regulatory activities on an on-going basis.
	Recommendation 2.4 The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission. The Commission should conduct a study before seeking the required statutory change.	As a condition of issuing a CON to establish a new OHS program, the Commission requires the program to achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. This condition has been applied in the approval of two OHS programs: Sacred Heart Hospital and Suburban Hospital. The Commission has not obtained authority to revoke the certification of an existing OHS program that was approved prior to 1997. In terms of the minimum volume requirement, Prince George's

Report and Service	Recommendation	Implementation Progress
		Hospital Center is the only program not meeting minimum volume requirements.
• Home Health	**Recommendation 3.0** The Commission should continue its regulatory oversight of home health agencies through the Certificate of Need program. **Recommendation 3.1** The Commission will support efforts to reorganize the current statutory framework for licensure of home-based health care services to provide consistent and improved oversight for both home health agencies and residential service agencies. **Recommendation 3.2** The Commission will monitor the effectiveness of Certificate of Need oversight for home health agencies in light of the changing environment and periodically assess whether Certificate of Need regulation is still needed.	The establishment of a new home health agency continues to require CON approval in Maryland. The Commission participates in work groups established by the Office of Health Care Quality (OHCQ) to examine licensure for home health and residential service agencies. OHCQ has begun collecting data for residential service agencies. The Commission monitors the impact of the CON program on the availability of home health agency services on an on-going basis by collecting annual statistics on utilization, consulting with federal and state agencies, and updating State Health Plan need projections and planning policies. The Commission's 2006 CON Task Force recommended removing home health agencies from the CON program. Following consideration of the CON Task Force recommendations and public comments, the Commission voted not to seek a statutory change removing home health agencies from the CON program.
• Hospice Services	**Recommendation 4.0** The Commission should continue its regulatory oversight of hospice services through the Certificate of Need program.	The establishment of a new hospice program continues to be regulated under the CON program in Maryland.
• Nursing Home Services	**Recommendation 5.0** The Commission should continue its regulatory oversight of nursing home services through the Certificate of Need program.	Nursing homes continue to be regulated under the CON program in Maryland. The capital expenditure threshold was modified by Chapter 541 of 2006.

Report and Service	Recommendation	Implementation Progress
		Adjusted for inflation, the current capital expenditure applicable to nursing home projects is $5,250,000.
Phase II: Final Report to the Maryland General Assembly • Acute Inpatient Services (Medical-Surgical and Pediatric)	**Recommendation 1.0** The Commission should continue its regulatory oversight of acute inpatient medical-surgical and pediatric services through the Certificate of Need program. **Recommendation 1.1** The Commission recommends to the General Assembly that the current capital expenditure threshold in statute of $1,250,000 be increased to $2,500,000 for acute care hospitals.	Acute inpatient hospital services continue to be regulated under the CON program in Maryland. Based on the recommendations of the CON Task Force, the recommended increase in the capital expenditure was modified from $2,500,000 to $10,000,000. This change in the capital expenditure threshold was implemented by Chapter 541 of 2006. Adjusted for inflation, the current capital expenditure applicable to hospital projects is $10,500,000.
• Organ Transplant , NICU, Burn Care Services	**Recommendation 2.0** The Commission should continue its regulatory oversight of organ transplant surgery, neonatal intensive care (NICU), and burn care services through the Certificate of Need program.	Organ transplant, neonatal intensive care unit (NICU), and burn care services continue to be regulated under the CON program in Maryland.
• Rehabilitation and Chronic Hospital Services	**Recommendation 3.0** The Commission should continue its regulatory oversight of inpatient rehabilitation and chronic hospital services. **Recommendation 3.1** The Commission should support efforts to improve data collection regarding rehabilitation and chronic hospital services to strengthen the ability to examine need and quality issues.	Special hospital rehabilitation and chronic services continue to be regulated under the CON program in Maryland. The Commission has worked with the Health Services Cost Review Commission to incorporate a patient-level data set for hospital-based rehabilitation and chronic hospital care programs.

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		The rehabilitation data set was implemented in 2003. Regulations regarding the chronic hospital data set were revised in 2005 to collect patient-level chronic hospital data.
• Ambulatory Surgery Services	**Recommendation 4.0** On an interim basis, the Commission should make no changes in ambulatory surgical facilities CON policy. However, a research agenda should be developed to clarify the likely impact of policy alternatives. (See Recommendation 4-4). **Recommendation 4.1** Revisions to the MHCC Ambulatory Surgical Facility Survey should be initiated for the 2001 survey cycle, with appropriate consultation and coordination with the affected providers, to address data deficiencies. **Recommendation 4.2** In cooperation with the Department of Health and Mental Hygiene's (the Department) Office of Health Care Quality (OHCQ), research should be undertaken to define the universe of facilities in Maryland which serve as settings for invasive procedures but are not required to obtain licensure under current law and regulation. A white paper outlining the costs and benefits of expanding the scope of freestanding ambulatory surgical facility (FASF) licensure, based on this research, should be developed and distributed for review and comment. MHCC and OHCQ should consider the research and comments and formulate recommendations to the Department concerning the appropriate scope of FASF licensure. **Recommendation 4.3** A process should be initiated to develop a consensus among MHCC, OHCQ, and the regulated industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure.	The establishment of two operating room ambulatory surgical facilities continues to be regulated under the CON program in Maryland. The Ambulatory Surgical Services Survey was modified over the period 2001-2003 to collect: more detailed information on the characteristics of operating and procedure rooms; cases performed by room type, specialty, and surgical minutes; and, a breakdown of net revenue by payer source. The Commission plans to develop a new chapter of the State Health Plan on surgical services that will address issues related to ambulatory surgery. The Commission uses American Institute of Architects (AIA) guidelines to classify operating and procedure rooms. For purposes of CON regulation and determinations of coverage, an operating room is a sterile room for open surgical procedures. Non-sterile rooms, referred to as procedure rooms, in which closed surgical procedures are performed

Report and Service	Recommendation	Implementation Progress
		are not regulated under CON.
	Recommendation 4.4 Research should be conducted to clarify the appropriate direction of CON policy reform with respect to ambulatory surgical facilities. Three areas of research focus are recommended: • A detailed comparative analysis of the ambulatory surgical services delivery system and the regulatory policies that have shaped those systems in a group of selected states; • An in-depth analysis of the charge and cost structure of a sample of Maryland FASFs identifying the relationship between costs and charges and characteristics such as range of specialties, type of specialties, volume of procedures, and competitiveness within market service areas; • A review and analysis of the implications for quality of care of Maryland policies promoting the establishment and operation of low volume, physician-office based surgical facilities.	While Commission staff explored strategies to obtain support for a research study regarding ambulatory surgical services, this effort did not identify funding sources. The Commission intends to develop a new State Health Plan chapter on surgical services that will address issues related to ambulatory surgery. Work on this chapter will explore the issues outlined in this recommendation.
• Inpatient Psychiatric Services	**Recommendation 5.0** The Commission recommends that Maryland continue to regulate the establishment of inpatient psychiatric facilities, services, and bed capacity through the Certificate of Need review process. **Recommendation 5.1** The Commission recommends that standards for minimum geographic and financial access to inpatient psychiatric services be adopted in the revised State Health Plan for Psychiatric Services, and that consideration be given to referencing these standards in any future clarification of statute governing the closure of hospitals or essential medical services.	Inpatient psychiatric services continue to be regulated under the CON program in Maryland. The Commission is working with the Mental Health Transformation Project to develop a Plan to Guide the Future Mental Health Services Continuum in Maryland. The 2007 Joint Chairmen's Report[1] directed the Commission to develop a plan to guide the future mental health service continuum needed

[1] Chairmen of the Senate Budget and Taxation Committee and House Committee on Appropriations, *Report on the State Operating Budget (HB 50) and the State Capital Budget (HB 51) and Related Recommendations*, Joint Chairmen's Report, Annapolis, Maryland, 2007 Session, p. 97-98.

Report and Service	Recommendation	Implementation Progress
	Recommendation 5.2 The Commission will change the State Health Plan's current requirement for a separate Certificate of Need approval for each additional category of inpatient psychiatric service, to require an exemption from CON and to establish specific standards to met for each additional category. A statutory change may be needed, in order to clarify that, for an existing adult psychiatric service in a general hospital, the addition of child or adolescent psychiatric services does not constitute a "new" medical service, requiring CON approval.	in Maryland. The Plan will include a statewide mental health needs assessment of the demand for: • Inpatient hospital psychiatric services (in State-run psychiatric, private psychiatric and acute general hospitals); and • Community-based services and programs needed to prevent or divert patients from requiring inpatient mental health services, including services provided in hospital emergency departments In 2008, the Commission appointed a 28-member Task Force. To date, the Task Force has held five meetings. The Commission requested and received an extension to December 1, 2008 in the due date of the report required by the Joint Chairmen's Report. The findings and recommendations developed as part of this Task Force will be used to update relevant chapters of the Maryland Health Care Commission's State Health Plan and to inform the annual State Mental Health Plan prepared by the Mental Hygiene Administration in the Department of Health and Mental Hygiene.
• Inpatient Psychiatric Services and Residential Treatment Centers for Children and Adolescents	**Recommendation 6.0** The Commission should continue its regulatory over-sight of child and adolescent inpatient psychiatric and residential treatment center ("RTC") services through the Certificate of Need review process. **Recommendation 6.1** The Commission should modify the State Health Plan's current requirement for a separate Certificate of Need for each additional category of inpatient psychiatric service, to require an exemption from CON, based on clinical and program standards for the proposed new service to be established in the State Health Plan	Residential treatment services continue to be regulated under the CON program in Maryland. This recommendation has not been implemented.

Report and Service	Recommendation	Implementation Progress
	for each category of inpatient psychiatric service. This change is particularly important to expanding access to inpatient psychiatric beds dedicated to the care and children and adolescents, many of which have been closed by private psychiatric facilities over the past decade. **Recommendation 6.2** The Commission should support efforts to establish an on-going comprehensive data system and bed registry for RTCs. The Commission, in partnership with the Governor's Office of Children, Youth, and Families and the Mental Hygiene Administration, should make recommendations to conduct a study on the scope, content, and ongoing administration of this database.	This recommendation has not been implemented. The Governor's Office of Children, Youth, and Families was discontinued and later re-established as the Office of Children. The Multi-Agency Review Team (MART) maintains complete data on the most difficult to place, treatment-resistant RTC patients.
• Intermediate Care Facilities for Addictions Treatment	**Recommendation 7.0** The Commission should continue to regulate the creation of new intermediate care facilities for addictions treatment, and to expand bed capacity at existing facilities.	Intermediate Care Facilities for Addictions Treatment continue to be regulated under the CON program in Maryland.
• Intermediate Care Facilities for the Developmentally Disabled	**Recommendation 8.0** The Commission should continue to regulate intermediate care facilities for the developmentally disabled through Certificate of Need review, but should also develop a State Health Plan section whose rules and definitions afford procedural flexibility to any changes to facility and bed capacity proposed	Intermediate Care Facilities for the Developmentally Disabled continue to be regulated under the CON program in Maryland. A State Health Plan chapter has not been developed.

Source: Maryland Health Care Commission, October 1, 2008.

Report of the
Certificate of Need Task Force

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I. Introduction

Purpose of the CON Task Force

The goal of the CON Task Force is to enhance the credibility and integrity of the Certificate of Need program in a dynamic and evolving health care system, by conducting a stakeholder driven review, using a combination of a Task Force and public comment process, to gain insight and make recommendations to enhance and improve the program. The objectives of the CON Task Force are to:

- Review and recommend modifications in the scope of services and facilities regulated under the Certificate of Need program;
- Review and recommend enhancements in the Certificate of Need application review process; and
- Review and recommend enhancements in the monitoring of Certificate of Need projects under development.

CON Task Force Composition

The CON Task Force was established by Stephen J. Salamon, Chairman of the Maryland Health Care Commission. The 24-member Task Force is chaired by Commissioner Robert E. Nicolay. Commissioners Robert E. Moffit, Ph.D. and Larry Ginsburg also serve on the Task Force. Members of the Task Force include representatives of the Maryland Hospital Association, Med-Chi, CareFirst BlueCross BlueShield, Health Facilities Association of Maryland, LifeSpan, Hospice Network of Maryland, Maryland Ambulatory Surgical Association, and other interested organizations, mostly representing providers. (Appendix A provides a list of CON Task Force members).

II. Recommendations of the CON Task Force

Principles to Guide the CON Program

Maryland's Certificate of Need program should:

- respond to its residents' needs for health care services, including hospital, long term care, ambulatory surgery, and specialized services;
- promote the quality and safety of these services;
- promote improved access to these services, including addressing the needs of underserved populations and both the ethnic and racial disparities in health care which presently exist; and
- promote the affordability of health care available to Maryland residents.

Certificate of Need should apply in situations where market forces are likely to result in:

- significantly higher or unnecessary costs to the system;
- decreased access to care by vulnerable populations or less populous regions of the state; or
- a diminution of the quality or safety of patient care.

The Certificate of Need program should be:

- procedurally clear, consistent, and timely;
- flexible enough to accommodate unique situations, whether of provider mission, geography and demographics, or technological advances; and
- specific to Maryland's unique policy and regulatory framework.

The State Health Plan standards, review criteria, and associated data used to conduct Certificate of Need reviews should be kept current, and regularly updated.

Scope of CON Coverage

Background and Issues

- ***Capital Expenditure Review Threshold***

Under Maryland health planning law, a CON is required before: a new health care facility is built, developed, or established; an existing health care facility is moved to another site, subject to some limitations; the bed capacity is changed, subject to several limitations; the type or scope of any health care service offered by a health care facility is changed. In addition, any health care facility that makes

a capital expenditure that exceeds the threshold for capital expenditures is required to obtain a CON. The current capital expenditure review threshold is $1,650,000.[1]

The capital expenditure threshold functions as a trigger for CON review in conjunction with the other requirements of the law. For example, if an action would otherwise require a CON, then that requirement would apply regardless of whether the capital expenditure was below the review threshold. In the case of acute care hospitals, the capital expenditure threshold functions as a trigger in conjunction with provisions in the statute that give hospitals the ability to undertake certain types of projects above the threshold without obtaining a CON, provided the project does not require, over the entire period or schedule of debt service associated with the project, a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs. The ability to avoid CON review for over-threshold capital expenditures by "taking the pledge" not to increase rates applies only to hospitals.

Because of differences in the scope of CON programs nationally, comparative data on capital expenditure thresholds is limited. Based on available data from the American Health Planning Association, Maryland's health facility capital expenditure review thresholds have generally been near the national norm over the last decade. In 1993, the Maryland threshold ($1.25 million) was substantially higher than the national median and mode, both $1.0 million. In 1996, the Maryland threshold was roughly equal to the national median and still higher than the mode. Maryland is one of six states with CON programs that index their capital expenditure thresholds. By 2004, the Maryland threshold ($1.6 million), though indexed, was lower than both the national median ($2.0) and mode ($2.0 million) threshold values in comparable CON states.

The Task Force received comments from 11 organizations supporting an increase in the capital expenditure threshold for CON review. The comments recommended an increase in the capital expenditure threshold ranging from $5.0 to $10.0 million. There was also a recommendation to base the threshold on a percentage of revenue rather than have a fixed dollar threshold. In suggesting that the capital expenditure threshold be increased, most commenters believed that this would decrease the number of projects requiring CON review.

- ***Covered Facilities and Services***

Under Health-General Article §19-120, a CON is required before a new health care facility (service) is built, developed, or established:

- Hospitals
- Nursing homes
- Ambulatory surgical facilities (two or more operating rooms)
- Residential treatment centers
- Intermediate care facilities

[1] The former Health Resources Planning Commission's original enabling statute (Ch. 108, Acts of 1982) set the capital review threshold at $600,000; this was amended in 1988 (Chs. 688 and 767, Acts of 1988) to $1,250,000. Beginning in 1995, the capital expenditure threshold was indexed annually to consider inflation. In a revision to CON procedural regulations effective November 6, 1995, the definition of "threshold for capital expenditures" was expanded to add the phrase "for 1995, after that to be adjusted annually by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest $50,000."

- Home health and hospice agencies
- Specialized health services (OHS, organ transplant surgery, NICU, and burn care)

In addition to covering the development of certain new health facilities and services, the Maryland CON statute also has provisions applying to closures. Under current law, there is a requirement for a public informational hearing for hospital closures in jurisdictions with more than two hospitals and the requirement for an exemption from CON review for hospital closures in jurisdictions with fewer than three hospitals.

While Maryland law provides that a CON is not required before a health care facility makes a capital expenditure for business or office equipment that is not related to patient care, the Task Force received several comments noting the need to clarify the application of this provision to health information system technology.

The HSCRC plays a pivotal role in the Commission's oversight of acute care hospitals under the Certificate of Need program. For all acute care hospital reviews conducted under the Certificate of Need program, the Commission consults with HSCRC concerning the financial feasibility of the proposed project. Under a 1988 change to the health planning law, certain hospital capital projects do not require CON review if the hospital assures HSCRC that the project will not raise rates more than $1.5 million during the entire period of debt service related to the project (the "Pledge").

Task Force Recommendations

The Task Force discussed elimination or modification of CON coverage of hospice, obstetric, open heart surgery, organ transplant, burn care, and neonatal intensive care unit (NICU) services. No change in the scope of regulation for these services was recommended by the Task Force.

1. The Task Force recommends an increase in the statutory capital expenditure review threshold from $1.25 to $10.0 million for hospitals regulated by the HSCRC and to $5.0 million for all other facilities (maintain the annual adjustment for inflation).

2. The Task Force recommends the following changes:

    - Remove the requirement for a public informational hearing for hospital closures in jurisdictions with more than two hospitals; remove the requirement to obtain an exemption from CON review for hospital closures in jurisdictions with fewer than three hospitals;

    - Expand the existing business office equipment exemption to include health information technology/medical information systems; and

    - Remove home health agency from the definition of "health care facility" or, alternatively, eliminate from the State Health Plan the home health agency need methodology and/or projections.

By a vote of 8 to 7, the Task Force recommended removing home health services from CON review based on a number of considerations, including the limited scope of home health agency CON regulation and ability of the Medicare program to control costs and establish and enforce conditions of participation. Because there was an acknowledgement that there was no general consensus by the Task Force on this issue, an alternative motion was made, approved unanimously by the Task Force, that if the Commission does not support deregulation of home health services from CON review, then the Commission should revise the State Health Plan to eliminate the State Health Plan home health agency need methodology and/or projections, and focus the review of potential new applications on standards such as the charity care requirement and Medicaid participation.

3. The Task Force recommends the development of a streamlined ("Fast Track") CON review process for hospital renovation and new construction projects with no new services or beds for which the hospital agrees not to file a partial rate application for capital.

4. The Task Force recommends the issuance of a Staff Report so that the Commission can act on the application within 90 days of docketing for projects with no opposition from interested parties. Staff should report to the Commission on the status of all projects where a Staff Report is not issued for Commission action within 90 days of docketing.

5. For hospitals taking the "pledge" not to increase rates, the Task Force recommends revising Determination of Non-Coverage requirements to deem the request approved if not acted upon by the Commission within 60 days

State Health Plan

Background and Issues

Under Health-General Article §19-118, the Commission is required at least every five years to adopt a State Health Plan. The plan shall include: the methodologies, standards, and criteria for certificate of need review; and, priority for conversion of acute capacity to alternative uses where appropriate. The current State Health Plan is organized in 10 chapters:

COMAR 10.24.07	Overview, Psychiatric Services
COMAR 10.24.08	Long Term Care Services
COMAR 10.24.09	Specialized Health Care Services-Acute Inpatient Rehabilitation Services
COMAR 10.24.10	Acute Inpatient Services
COMAR 10.24.11	Ambulatory Surgical Services
COMAR 10.24.12	Acute Hospital Inpatient Obstetric Services
COMAR 10.24.14	Alcoholism and Drug Abuse Intermediate Care Facility Treatment Services
COMAR 10.24.15	Specialized Health Care Services-Organ Transplant Services
COMAR 10.24.17	Specialized Health Care Services-Cardiac Surgery and Percutaneous Coronary Intervention (PCI) Services

Each chapter of the State Health Plan is incorporated by reference in the Code of Maryland Regulations (COMAR).

The plan development process used by the Commission has typically involved advisory groups and extensive public comment and review prior to formal adoption of a plan chapter. In the most recent update of the cardiac services chapter of the State Health Plan, for example, the Commission considered the findings and recommendations of an Advisory Committee on Outcome Assessment in Cardiovascular Care and its subcommittees. To assist in the recent update of the State Health Plan acute care bed need methodology and bed need forecasts for medical-surgical-gynecological-addictions (MSGA) and pediatric services, the Commission formed an Acute Care Hospital Work Group composed of representatives of Maryland hospitals. The planning process used by the Commission also involves extensive data collection and analysis and the preparation of issue and statistical briefs to track key trends in health services utilization. Data sets used to support preparation of the State Health Plan include the HSCRC data on inpatient, ambulatory surgery, and emergency department use as well as the Commission's Maryland Freestanding Ambulatory Surgery Survey, Maryland Hospice Survey, and the Maryland Long Term Care Survey.

The Task Force received a number of comments regarding the importance of an updated State Health Plan in guiding the CON review process. Many of these comments specifically addressed the need to update the Acute Inpatient Services Chapter of the State Health Plan. Although the Commission historically reviewed few hospital CON proposals, this pattern changed a few years ago as hospital utilization increased and financing became more favorable. CON proposals from acute care hospitals now account for the largest volume of the Commission's CON workload. The Task Force also recommends that review and revision of the Ambulatory Surgical Services Chapter of the State Health Plan be a priority. The Task Force also discussed emergency department services. Although establishing a new chapter of the State Health Plan on emergency department services was not recommended, the Task Force recognized the need to incorporate review standards regarding emergency department services in the Acute Inpatient Services Chapter of the State Health Plan.

The Task Force also received comments regarding the average annual occupancy rate scale currently used in the State Health Plan to forecast the need for medical/surgical/gynecology/addictions (MSGA) beds, including the recommendation to use a single average annual occupancy rate standard of 71.4%. This latter standard (often referred to as the "140% rule" – 100/140 = 71.4%) is used by the Department of Health and Mental Hygiene to establish the total number of licensed acute care beds in hospitals. Maryland's hospital licensure law was amended, effective in 2000, to peg maximum licensed acute care bed capacity to the average daily census of acute care patients reported by hospitals. On July 1 of each year, hospital licenses are revised to reflect that the hospital is licensed (and, thus, may legally operate) a total number of acute care beds equal to 140% of the average daily census of acute care patients reported by that hospital for the twelve month period ending on March 31 of that same year The CON law was also amended to allow hospitals to construct acute care bed capacity equal to their current licensed capacity without reference to any need standards of the State Health Plan. This law had the effect of eliminating over 2,700 beds from hospital licenses

when it went into effect. Currently, Maryland hospitals report that, in the aggregate, they have physical capacity for 967 more acute care beds than are licensed. Twelve of the state's 47 hospitals (26%) report having less physical capacity for acute care beds than is currently licensed.

Task Force Recommendations

1. Because of its importance in guiding the CON review process, the Task Force recommends that the Commission undertake a comprehensive revision of the State Health Plan. The update and revision of the State Health Plan should involve broadly representative technical advisory groups, including consumers and representatives of interested public and private organizations, to obtain expertise on the availability, access, cost, and quality of services. The review of each chapter of the State Health Plan should:

    - Eliminate obsolete and duplicative CON review standards;
    - Streamline documentation requirements;
    - Identify those types of projects eligible for review based on a limited set of standards; and
    - Be consistent with the guiding principles.

2. In updating the State Health Plan, priority should be given to revision of the Acute Inpatient Services and Ambulatory Surgical Services chapters:

    Acute Inpatient Services (COMAR 10.24.10)

    - The revision of the Acute Inpatient Services chapter of the State Health Plan should eliminate or substantially modify the following standards to the extent that they are obsolete and redundant, including: .06A(2) Utilization Review Control Programs; .06A(3) Travel Time; .06A(4) Information Regarding Charges; .06A(5) Charity Care Policy; .06A(6) Compliance with Quality Standards; .06A(7) Transfer and Referral Agreements; .06A(8) Outpatient Services; .06A(9) Interpreters; .06A(10) In-Service Education; .06A(11) Overnight Accommodations; .06A(12)Required Social Services; .06A(19) Minimum Size for Pediatric Unit; .06A(20) Admission to Non-Pediatric Beds; .06A(21) Required Services When Providing Critical Care; .06A(22)Average Length of Stay for Critical Care Units; .06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients; .06B(1) Compliance with System Standards; .06B(2)(a) Duplication of Services and Adverse Impact; .06B(4) Burden of Proof Regarding Need; .06B(5)Discussion with Other Providers; .06B(9) Maximum Square Footage; .06C(2) Compliance with System Standards; .06C(3) Conditions for Approval; and, .06C(5) Maximum Square Footage-Renovations. The Task Force recommends that Commission staff move expeditiously to draft proposed

regulations eliminating those standards that it agrees are obsolete or redundant and that remaining issues regarding the State Health Plan standards be considered by a technical advisory group.

- The revision should add policies to the Acute Inpatient Services Chapter of the State Health Plan addressing shell space. The policies should permit the development of shell space provided that the hospital does not seek a rate adjustment while the space is unused. In order to fit out and finish the shell space for patient care, CON approval should be required if such fit out and finishing constitutes a project subject to CON review and approval.

Ambulatory Surgical Services (COMAR 10.24.11)

- The Ambulatory Surgical Services Chapter should better define the terms "operating room" and "procedure room" to clarify what is permitted in a CON-exempt facility with a single operating room.

3. The Task Force recommends that the Commission study alternatives to eliminate the inconsistency between the 140% rule for establishing licensed acute care bed capacity and the State Health Plan occupancy assumptions. A technical advisory group should be formed by the Commission with representatives from the Maryland Hospital Association, major payers, and other interested organizations.

CON Review Process

Background and Issues

The current procedural regulations that govern the CON process (COMAR 10.24.01.08C Completeness Review and Docketing) provide that:

(1) Staff has 10 days in which to conduct a "completeness" review;

(2) Applicants have 10 days in which to respond to staff's questions generated during the completeness review;

(3) Completed applications are to be docketed – applications lacking necessary information can be dismissed and returned;

(4) 10 day extensions to supply required information can be approved by staff (only with consent of all applicants in comparative reviews); and

(5) Staff may request additional supplementary information at any time after docketing.

Applicants frequently make changes to Certificate of Need applications after docketing, sometimes triggering a "re-docketing" of the application pursuant to COMAR 10.24.01.08E.

Only "modifications" require re-docketing – changes that do not involve Certificate of Need regulated facilities or services do not constitute "modifications" requiring re-docketing. Applicants may:

(1) Modify applications at any time up until 45 days after docketing;

(2) In comparative reviews, modify an application only with consent of all the applicants after the 45th day; and

(3) In non-comparative reviews, (a) reduce costs, (b) reduce annual projected revenue, (c) reduce beds and services or (d) make changes to respond to the changes in the State Health Plan at any time (only with consent of other applicants in comparative reviews).

Re-docketing permits public notice of and response to the changed application. Consequently re-docketing also extends the Commission's time to approve or deny an application.

The Task Force received a number of comments regarding various components of the CON review process, including completeness review, requests for additional information, and re-docketing rules. Comments received regarding completeness review fall into four general categories, including what specific information is required for the Commission to find an application complete in order to initiate the review, the length of time that should be permitted for the Commission to conduct completeness review, the length of time that applicants should be permitted to respond to completeness review, and the role of interested parties in completeness review. Comments were also received concerning the delay caused by the requirement for re-docketing for an applicant that makes certain changes to an application. Taken together these comments raise issues about the structure and timeliness of the project review process.

Task Force Recommendations

The Task Force reviewed the regulations governing designation of interested parties in CON reviews and recommended no changes. The Task Force also considered the advantages and disadvantages of eliminating the review schedule and recommended that the schedule be retained. In reviewing the CON review process, the Task Force made the following recommendations:

1. The review process should be restructured to require two conferences as a standard feature of the review of any CON application:

   Application Review Conference

   - The format of this Application Review Conference (ARC) should be a walk-through of the application and its appendices with staff providing the applicant with its views on the completeness of each question or information requirement outlined in the application;
   - The conference will serve to formulate the written completeness review questions with input from both staff and the applicant; and

- Because of the conference, the completeness questions, prepared by staff and given to the applicant within a reasonably short period after the ARC, will be fewer and limited to more substantive issues which could not be fully addressed at the conference or which require development of information or analyses by the applicant; and better understood by the applicant because of the applicant's participation in framing the questions at the ARC.

Project Status Conference

- A Project Status Conference (PSC) will be held to address those standards and review criteria which present a problem for approval of the project. Prior to this meeting, the Reviewer or staff will send a memorandum to the applicant and interested parties outlining the areas of concern so that the applicant can have appropriate persons attend the PSC.
- The PSC will be structured to allow the applicant and interested parties to ask questions about the status of the project and provide comment regarding the identified issues;
- A written summary of the PSC will be prepared for the record, along with a statement of applicant revisions to the Summary, if desired by the applicant;
- Following the PSC, the applicant will have an appropriate period of time to make changes, if desired, to the project, which cure the problems or deficiencies identified at the PSC, without the requirement for re-docketing. Each interested party will have a 10 day period in which to file comments on changes to the project.

This recommendation is intended to allow for more expeditious processing of projects that contain a number of distinct elements, some of which conform to the State Health Plan and should be allowed to go forward quickly and other elements that do not conform, but, if modified or eliminated, make approval of the entire project feasible. Given the multi-faceted nature of many projects and the fact that such projects can be modified in ways that improve compatibility with the State Health Plan and CON law, without compromising feasibility, this recommendation aims to make the project review process more collaborative.

2. The Task Force recommends modifying the review process by allowing for changes in a project, addressed in the Project Status Conference, that bring it in closer conformance with the State Health Plan, based on staff or the Reviewer's analysis, without penalizing such changes by adding more process or time to the review through re-docketing.

This recommendation is also designed to streamline the review process. In combination with the recommendation hold an Application Review Conference and Project Status Conference, the ability to allow changes to projects without requiring re-docketing will shorten the review process.

3. The Task Force recommends that hospitals be permitted to construct shell space so long as no rate adjustment associated with the capital cost of the shell space is sought by the hospital while the space remains vacant.

4. The Task Force recommends developing an automated CON application form; requiring PDF files of CON application documents; developing a standard form for filing requests for Determinations of Non-Coverage; and, providing website access to CON filings.

   To streamline the application process and facilitate access to key documents, the Task Force believes that the Commission should take steps to automate the application process for CON reviews. The Task Force also believes that developing a standard filing format for Determinations of Non-Coverage would reduce the need to request additional information and streamline the process.

III. Summary of CON Task Force Recommendations

- **Summary of CON Task Force Recommendations and Type Recommended Change Required for Implementation: Scope of Coverage, State Health Plan, and CON Review Process**

Recommendation	Statutory Change	Regulatory Change	Administrative Change
SCOPE OF CON COVERAGE			
1. Increase the capital expenditure review threshold from $1.25 to $10.0 million for hospitals regulated by HSCRC; and, from $1.25 to $5.0 million for all other facilities.	§19-120	COMAR 10.24.01	
2. The Task Force recommends the following changes:			
• Remove requirement for public informational hearing for hospital closures in jurisdictions with more than two hospitals; remove requirement to obtain an exemption from CON review for hospital closures in jurisdictions with fewer than three hospitals	§19-120(l)(1)(ii) §19-120(l)(2)(i)	COMAR 10.24.01	
• Expand the existing business office equipment exemption to include health information technology/medical information systems		COMAR 10.24.01	
• Remove home health agency from the definition of "health care facility" or, alternatively, eliminate from the State Health Plan the home health agency need methodology and/or projections.	§19-114(d); §19-120(j)(2)(iii)3	COMAR 10.24.01; COMAR 10.24.08	
3. Develop streamlined ("Fast Track") CON review process for hospital renovation and new construction projects with no new services or for which the hospital agrees not to file a partial rate application for capital.		COMAR 10.24.01; COMAR 10.24.10	
4. The Task Force recommends the issuance of a Staff Report so that the Commission can act on the application within 90 days of docketing for projects with no opposition from interested parties. Staff should report to the Commission on the status of all projects where a Staff		COMAR 10.24.01	

Recommendation	Statutory Change	Regulatory Change	Administrative Change
Report is not issued for Commission action within 90 days of docketing. 5. Revise Determination of Non-Coverage requirements for hospitals taking the "pledge" not to increase rates to deem the request approved if not acted upon by the Commission within 60 days	§19-120(k)(5)(viii)	COMAR 10.24.01	
STATE HEALTH PLAN 1. Because of its importance in guiding the CON review process, the Task Force recommends that the Commission undertake a comprehensive revision of the State Health Plan. The update and revision of the State Health Plan should involve broadly representative technical advisory groups, including consumers and representatives of interested public and private organizations, to obtain expertise on factors influencing the availability, access, cost, and quality of services. The review of each chapter of the State Health Plan should: • Eliminate obsolete and duplicative CON review standards; • Streamline documentation requirements; • Identify those types of projects eligible for review based on a limited set of standards; and • Be consistent with the guiding principles. 2. In updating the State Health Plan, priority should be given to revision of the Acute Inpatient Services and Ambulatory Surgical Services chapters: ***Acute Inpatient Services (COMAR 10.24.10)*** • The revision of the Acute Inpatient Services chapter of the State Health Plan should eliminate or substantially modify the following standards to the extent that they are obsolete and redundant, including: .06A(2) Utilization Review Control Programs; .06A(3) Travel Time; .06A(4) Information Regarding Charges; .06A(5) Charity Care Policy; .06A(6)		COMAR 10.24.07-12; 10.24.14-15; 10.24.17-18 COMAR 10.24.10	Form technical advisory group

Recommendation	Statutory Change	Regulatory Change	Administrative Change
Compliance with Quality Standards; .06A(7) Transfer and Referral Agreements; .06A(8) Outpatient Services; .06A(9) Interpreters; .06A(10) In-Service Education; .06A(11) Overnight Accommodations; .06A(12)Required Social Services; .06A(19) Minimum Size for Pediatric Unit; .06A(20) Admission to Non-Pediatric Beds; .06A(21) Required Services When Providing Critical Care; .06A(22)Average Length of Stay for Critical Care Units; .06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients; .06B(1) Compliance with System Standards; .06B(2)(a) Duplication of Services and Adverse Impact; .06B(4) Burden of Proof Regarding Need; .06B(5)Discussion with Other Providers; .06B(9) Maximum Square Footage; .06C(2) Compliance with System Standards; .06C(3) Conditions for Approval; and, .06C(5) Maximum Square Footage-Renovations. The Task Force recommends that Commission staff move expeditiously to draft proposed regulations eliminating those standards that it agrees are obsolete or redundant and that remaining issues regarding the State Health Plan standards be considered by a technical advisory group. • The revision should add policies to the Acute Inpatient Services Chapter of the State Health Plan addressing shell space. The policies should permit the development of shell space provided that the hospital does not seek a rate adjustment while the space is unused. In order to fit out and finish the shell space for patient care, CON approval should be required if such fit out and finishing constitutes a project subject to CON review and approval. ***Ambulatory Surgical Services (COMAR 10.24.11)*** • The Ambulatory Surgical Services Chapter should better define the terms "operating room" and "procedure room" to clarify what is permitted in a CON-exempt facility with a single operating room.		COMAR 10.24.12	Form technical advisory group

Recommendation	Statutory Change	Regulatory Change	Administrative Change
3. The Task Force recommends that the Commission study alternatives to eliminate the inconsistency between the 140% rule for establishing licensed acute care bed capacity and the State Health Plan occupancy assumptions. A technical advisory group should be formed by the Commission with representatives from the Maryland Hospital Association, major payers, and other interested organizations.			Form technical advisory group
CERTIFICATE OF NEED REVIEW PROCESS 1. The review process should be restructured to require two conferences as a standard feature of the review of any CON application: *Application Review Conference(ARC)* • The format of this conference should be a walk-through of the application and its appendices with staff providing the applicant with its views on the completeness of each question or information requirement outlined in the application; • The conference will serve to formulate the written completeness review questions with input from both staff and the applicant; and • Because of the conference, the completeness questions, prepared by staff and given to the applicant within a reasonably short period after the ARC, will be fewer and limited to more substantive issues which could not be fully addressed at the conference or which require development of information or		COMAR 10.24.01	

Recommendation	Statutory Change	Regulatory Change	Administrative Change
analyses by the applicant; and better understood by the applicant because of the applicant's participation in framing the questions at the ARC. *Project Status Conference(PSC)* • A Project Status Conference will be held to address those standards and review criteria which present a problem for approval of the project. Prior to this meeting, the Reviewer or staff will send a memorandum to the applicant and interested parties outlining the areas of concern so that the applicant can have appropriate persons attend the PSC. • The PSC will be structured to allow the applicant and interested parties to ask questions about the status of the project and provide comment regarding the identified issues; • A written summary of the PSC will be prepared for the record, along with a statement of applicant revisions to the Summary, if desired by the applicant; • Following the PSC, the applicant will have an appropriate period of time to make changes, if desired, to the project, which cure the problems or deficiencies identified at the PSC, without the requirement for re-docketing. Each interested party will have a 10 day period in which to file comments on changes to the project. 2. The Task Force recommends modifying the review process by allowing for changes in a project, addressed in the PSC, that bring it in closer conformance with the State Health Plan, based on staff or the Reviewer's analysis, without penalizing such changes by adding more process or time to the review through redocketing. 3. The Task Force recommends that hospitals be permitted to construct shell space so long as no rate adjustment associated with the capital cost of the shell space is sought by the hospital while the space remains vacant.		COMAR 10.24.01	

Recommendation	Statutory Change	Regulatory Change	Administrative Change
4. The Task Force recommends developing an automated CON application form; requiring PDF files of CON application documents; developing a standard form for filing requests for Determinations of Non-Coverage; providing website access to CON filings.		COMAR 10.24.01	Prepare automated application forms for CON review and Determinations of Non-Coverage; design CON website; revise CON database.

• Summary of Issues Reviewed by the CON Task Force With No Change Recommended at This Time

Issues Reviewed	No Change Recommended at this Time
Scope of CON Coverage	• Open Heart Surgery Services • Neonatal Intensive Care Unit Services • Organ Transplant Surgery Services • Burn Care Services • Hospice Services • Obstetric Services
State Health Plan	• Scope of the State Health Plan
CON Review Process	• Qualification of Interested Parties • CON Review Schedule

Appendix A

Certificate of Need Task Force Members

Maryland Health Care Commission
Certificate of Need Task Force[2]

Chairman

Commissioner Robert E. Nicolay, CPA
Retired, ExxonMobil Corporation

Members

Alan Bedrick, M.D.
Maryland Chapter of the American Academy of Pediatrics
Department of Pediatrics
Franklin Square Hospital
Baltimore, Maryland

Albert L. Blumberg, M.D., F.A.C.R.
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Lynn Bonde
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Patricia M.C. Brown, Esquire
Senior Counsel
Johns Hopkins Health System Corporation
Baltimore, Maryland

William L. Chester, M.D.
First Colonies Anesthesiology Associates
Rockville, Maryland

Annice Cody
Vice President, Planning and Marketing
Holy Cross Hospital
Silver Spring, Maryland

Hal Cohen
Health Care Consultant
Baltimore, Maryland

[2] Terri Twilley, M.S., R.N. served as a member of the Task Force from May to July 2005.

Commissioner Larry Ginsburg[3]
Assistant to the President
SEIU

Natalie Holland
Genesis Health Care
Towson, Maryland

Carlessia A. Hussein, Dr.P.H.
Department of Health and Mental Hygiene
Office of Minority Health and
Health Disparities
Baltimore, MD

Adam Kane, Esquire
Director of Government Affairs
Erickson Retirement Communities
Baltimore, Maryland

Michelle Mahan
Vice President and CFO
St. Joseph Medical Center
Towson, Maryland 21204

Henry Meilman, M.D.
Chief, Cardiac Catheterization Laboratory
Union Memorial Hospital
Baltimore, Maryland

Commissioner Robert E. Moffit, Ph.D.
Heritage Foundation

Anil K. Narang, D.O.
Diagnostic Medical Imaging, P.A.
Silver Spring, Maryland

Lawrence Pinkner, M.D.
Maryland Ambulatory Surgery Association
Owings Mills, Maryland

Frank Pommett, Jr.
Senior Vice President, Operations and Executive Director
Sacred Heart Hospital
Cumberland, Maryland

[3] Commissioner Larry Ginsburg served as a member of the Task Force from May to September 2005.

Barry F. Rosen, Esquire
Gordon, Feinblatt, Rothman, Hoffberger, Hollander, LLC
Baltimore, Maryland

Christine M. Stefanides, RN, CHE
President and CEO
Civista Medical Center
LaPlata, Maryland

Joel Suldan, Esquire
Vice President and General Counsel
LifeBridge Health
Baltimore, Maryland

Jack Tranter, Esquire
Gallagher, Evelius & Jones
Baltimore, Maryland

Elizabeth Weglein, CEO
Elizabeth Cooney Personnel Agency, Inc.
Baltimore, Maryland

Douglas H. Wilson, Ph.D.
Director, Planning and Business Development
Peninsula Regional Health System
Salisbury, Maryland

Appendix B

CON Task Force Meeting Minutes

Summary of the Meeting of the CON Task Force

May 26, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present

Robert E. Nicolay, CPA, Chairman
Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Hal Cohen
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Henry Meilman, M.D.
Anil K. Narang, D.O.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Christine M. Stefanides, RN, CHE
Joel Suldan, Esquire
Jack Tranter, Esquire
Terri Twilley, MS, RN

Task Force Members Absent

Commissioner Robert Moffit, Ph.D.
Douglas H. Wilson, Ph.D.

Members of the Public Present

Andrew Cohen, AGC and Associates
Miles Cole, Maryland Department of Business and Economic Development
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver

Sean Flanagan, St. Joseph Medical Center
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Donna Jacobs, University of Maryland Medical System
Anne Langley, Johns Hopkins Health System
Vanessa Purnell, MedStar Health
Pegeen Townsend, MHA: Association of Maryland Hospitals & Health Systems

1. Call to Order and Introductions

Chairman Robert E. Nicolay called the meeting to order at 1:05 p.m. He welcomed the members of the Task Force and members of the public in attendance. At Chairman Nicolay's request, the Task Force members introduced themselves. Pamela Barclay, Interim Executive Director, introduced members of the Commission's staff. Chairman Nicolay noted that the Task Force has an ambitious schedule of meetings through the middle of August and that the Commission's staff will work closely with the Task Force. He emphasized that members of the public are welcome at each meeting.

2. Overview of Task Force Objectives, Report Development Process, and Timetable

Chairman Nicolay provided an overview of the objectives and timetable. The purpose of the Task Force is to enhance the credibility and integrity of the Certificate of Need program by conducting a stakeholder driven review, using a combination of the broadly representative Task Force and a public comment process to gain insight and make recommendations to enhance and improve the program. The objectives of the Task Force: review and recommend modifications in the scope of services and facilities regulated under the Certificate of Need program; review and recommend enhancements in the CON review process; and review and recommend enhancements in the monitoring of CON projects under development.

Chairman Nicolay announced that the Task Force will convene a Public Forum to solicit recommendations on the CON program on Tuesday, June 7, 2005 from 10:00 a.m. to 1:00 p.m. at the offices of the Commission. The Public Forum will provide an opportunity for the Task Force to receive comments from stakeholders and members of the public. The Task Force will develop a report summarizing the findings and recommendations for presentation to the full Commission. The Commission will review the Task Force report and release it for public comment in September; followed by an evaluation of public comments received and modifications to the Final Recommendations in October. The Commission will take Final Action on the Task Force recommendations in November and, in December, will develop and approve an implementation plan with recommendations regarding modifications to administrative, regulatory, and statutory provisions.

3. Discussion of the June 7, 2005 Public Forum

Chairman Nicolay noted that the Public Forum has been well publicized. Staff has sent out nearly 700 notices regarding the forum. Speakers will sign in on the morning of the Forum and then the Task Force will determine the length of time allotted to the speakers based on the number of presenters requesting to speak. Following the Public Forum, the Commission will continue to receive written testimony through June 10th. The staff will subsequently summarize all testimony for presentation to the Task Force at its June 23rd meeting.

4. Background: Maryland Certificate of Need Program

Ms. Barclay presented a background briefing on Maryland's Certificate of Need program. Key components of her presentation included a discussion of the scope of the CON program. A CON is required before a new health care facility/service is built, developed, or established by hospitals; nursing homes; ambulatory surgical facilities with two or more operating rooms; residential treatment centers; intermediate care facilities (substance abuse and developmental disabilities); Medicare-certified home health agencies; and hospice agencies. A CON is also required for certain patient-care related capital expenditure projects that involve a health care facility (e.g., construction and/or renovation) above the current threshold of $1,650,000. Additionally, a CON is required before a new, highly specialized service such as Open Heart Surgery, Organ Transplant Surgery, Neonatal Intensive Care (NICU), or Burn Care is developed by a hospital.

A CON is not required for hospital capital expenditures over the threshold if no rate increase is pledged (for certain eligible projects); conversion of an existing hospital to a limited service hospital; closure of a hospital or medical service provided by a hospital; assisted living facilities; major medical equipment (e.g., CT scanners, linear accelerators, catheterization laboratories); kidney dialysis centers; capital expenditures to acquire health care facilities; or waiver beds for non-hospital facilities.

Ms. Barclay discussed the levels of CON review. Determinations of non-coverage are initiated by a letter to the Commission regarding acquisitions, waiver beds, one operating room, or hospital capital projects eligible for the "pledge" not to increase rates. In these circumstances, the determination is made by the Commission's Executive Director within thirty days of the applicant's request. Exemptions from CON Review are initiated by an applicant's Request for Exemption from CON Review in circumstances such as a merger or consolidation of two or more hospitals or other health care facilities, or the closure of a hospital in jurisdictions with fewer than three hospitals. Decisions are made by the Commission upon the analysis and recommendation of staff within forty-five days of the notice. There are no interested parties permitted in applications for determination on non-coverage or exemption from CON Review. A CON Review is initiated by an applicant's writing a Letter of Intent, followed by a CON application within sixty days, for a new health care facility or capital expenditures above the threshold. The Commission makes decisions on applications for CON following a staff recommendation in instances that are uncontested, or following a Commissioner-

Reviewer's recommendation when there are interested parties in either a contested or comparative review. The time frames for decisions made in these circumstances are from ninety days to 150 days when an Evidentiary Hearing is held.

Ms. Barclay discussed a statistical breakdown of the types of CON decisions by level of review from 2000 through 2004 and an estimation for 2005. During that time, Commission decisions for CON approvals, denials, and modifications have ranted from a low of 8 decisions in 2001 to a estimate of 37 decisions in 2005. Further, the costs of acute general and special hospital projects approved or reviewed by the CON program has increased from $500 million during 1991-93 to approaching $3 billion for 2003-2005.

Key trends in health care facility projects include increased numbers of treatment beds and observation/admission units in emergency departments; larger and increased numbers of operating rooms; increased numbers of intensive care unit and medical/surgical beds, conversion to private rooms and replacement of hospital facilities; addition of new rehabilitation and obstetrics services; closure of subacute, psychiatric, and obstetrics services; and the addition of patient safety protocols such as new information systems technology (e.g., computerized physician order entry) for acute care hospitals. Key trends in nursing homes include replacement facilities, conversion to private rooms, and the redevelopment of off-line capacity as bed needs increase. Ambulatory surgery facilities' capacity is increasing through the addition of operating rooms and hospital-affiliated free standing ambulatory surgical facilities. Trends in specialized health care services include applications for new services in primary and elective angioplasty and neonatal intensive care units.

The Certificate of Need Review Criteria set forth in COMAR 10.24.01.08G(3)(a)-(f) require the Commission to consider State Health Plan standards, policies, and projections; demonstrated or projected need for the new facility or service; the availability of more cost-effective alternatives; the viability of the project with respect to the availability of financial and non-financial resources (community support and available staff, and other resources necessary to sustain the project); compliance with the conditions of previous CONS; and the impact on existing providers. The State Health Plan ensures that rational, planned growth in capacity is based on community need and benefit and that projects are reviewed based on an objective measure of quality, geographic and financial access, and affordability. Further, the development of the State Health Plan assures and public process and the coordination of policy among the Commission, Office of Health Care Quality, Medicaid, the Health Services Cost Review Commission and the Department of Aging.

Ms. Barclay presented a summary of the evolution of the CON program including changes in process and coverage. In 1985, Health Care Cost Containment legislation deregulated major medical equipment and established the exemption from CON for certain projects in statute. In 1986, changes in CON regulation were made for ambulatory surgical facilities. In 1988, changes in CON regulation for hospital capital expenditures included the deregulation of hospital capital expenditures provided that there was no rate increase ("the Pledge"); the capital review threshold was raised from

$600,000 to $1,250,000; and CON was explicitly required to establish open heart surgical programs, organ transplant surgery, burn, or NICU services. The HealthCare Reform Act of 1995 created further changes in the CON regulation of ambulatory surgical facilities and changes in the CON process. The Hospital Cost Containment and Capacity Act in 1999 included changes in hospital closure rules, the elimination of waiver beds for acute care hospitals, the annual calculation of licensed acute care hospital beds as 140% of the average daily census; and the spousal carve-out provision permitting direct admission to a continuing care retirement community. Further changes in the CON regulation of CCRCs were adopted in 2000 with the CON-excluded beds at CCRC nursing homes raised from 20 to 24% for some CCRCs and limited direct admissions to CCRC nursing homes permitted.

Ms. Barclay discussed a comparative profile of Maryland and of CON programs in the United States as of February 2004 and capital expenditure review thresholds for state CON programs in 2004. She pointed out distinctive aspects of Maryland's CON program. Maryland's planning based approach to regulation includes one of the most extensive data collection and analysis support structures in the nation with extensive consultation with health services providers through advisory committees such as the recently convened Technical Advisory Committee on Outcome Assessment in Cardiovascular Care and its three subcommittees. Maryland's use of waivers and pilot projects to study implications in a dynamic, rapidly changing environment is also unique. As many as 22 other states regulate major medical equipment while Maryland excludes it from regulation but does include home health and hospice services. Maryland's unique approach to outpatient surgery and its linkage to and work with the Health Services Cost Review Commission also sets it apart from other states.

Chairman Nicolay thanked Ms. Barclay for her presentation and asked if Task Force members had any questions. Joel Suldan asked for further information regarding the actual time taken for CON reviews. Ms. Barclay said that staff will provide that information. Barry Rosen asked whether there has been consideration of triggering a CON review based upon the percent of revenue of the CON applicant, rather than the capital expenditure threshold. Ms. Barclay said that staff will research that issue. Albert L. Blumberg, M.D., F.A.C.R. asked if Maryland's CON program was created in the early 1970's. Susan Panek, Chief of CON, replied that it was created in 1968.

5. Future Meeting Schedule

June 7, 2005: Public Forum, 10:00 a.m.

June 23, 2005: Task Force Meeting, 1:00 p.m.

July 14, 2005: Task Force Meeting, 1:00 p.m.

July 28, 2005: Task Force Meeting, 1:00 p.m.

August 11, 2005: Task Force Meeting, 1:00 p.m.

6. Other Business

William Chester, M.D. asked if surrogates could attend meetings in the absence of task force members. Chairman Nicolay responded that surrogates would be acceptable as long as the Commission was notified in advance. Dr. Chester asked if email correspondence was permissible and Chairman Nicolay replied that email correspondence would not be a problem. Frank Pommett, Jr. asked if staff will be making comments to the Task Force. The Chairman replied the Commission does not want the review to be staff-driven, but that staff comment would be solicited and considered. Joel Suldan suggested that staff make recommendations regarding what services need to be regulated. He wanted further information regarding why some services are regulated and others are not. The Chairman said that these questions will be considered. Adam Kane requested that task force members be given a copy of the State Health Plan. Chairman Nicolay said that copies of the State Health Plan will be provided to all members of the task force. Terri Twilley asked whether the task force will be looking at CON activity in other states, for example, in Vermont with regard to home health care and fair trade issues. Chairman Nicolay said that the task force would be looking at input from everyone.

7. Adjournment

Chairman Nicolay said that he is looking forward to working with everyone and thanked them for coming. The meeting was adjourned at 2:07 p.m.

Summary of the CON Task Force Public Forum

June 7, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members and Commissioners Present

Commission Chairman Stephen J. Salamon
Commissioner Robert E. Nicolay, Task Force Chairman
Commissioner Larry Ginsburg
Commissioner Robert Moffit, Ph.D.
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Hal Cohen
Natalie Holland
Carlessia A. Hussein, DrPH
Michelle Mahan
Henry Meilman, M.D.
Anil K. Narang, D.O.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Christine M. Stefanides, RN, CHE
Joel Suldan, Esquire
Jack Tranter, Esquire
Terri Twilley, MS, RN
Douglas H. Wilson, Ph.D.

Task Force Members Absent

Adam Kane, Esquire

Public Testimony

Erwin Abrams, Hospice Network of Maryland
Mara Benner, Maryland National Capital Homecare Association
Thomas Firey, Maryland Public Policy Institute
Sean Flanagan, St. Joseph Medical Center
Andrea Hyatt, Maryland Ambulatory Surgical Association
Donna Jacobs, University of Maryland Medical Systems
Deron Johnson, Maryland Ambulatory Surgical Association
Robert Johnson, Jewish Social Service Agency
Danna Kauffman, Mid-Atlantic LifeSpan
Lawrence Merlis, President and CEO, Greater Baltimore Medical Center
Frank Monius, Maryland Hospital Association
Sam Moskowitz, Mercy Health Services
Cal Pierson, President, Maryland Hospital Association
Nicole Price, SEIU, District 1199 E-DC
Andrew Solberg, A.L.S. Healthcare Consultant Services
Howard Sollins, Health Facilities Association of Maryland
Sue Ellen Stuart, Gentiva Health Services
Elizabeth Weglein, Maryland National Capital Home Care Association

Members of the Public Present

Vanessa Aburn, Union Memorial Hospital
Regina Bodnar, Greater Baltimore Medical Center
Clarence Brewton, MedStar Health
Amy Carle, Maryland Ambulatory Surgical Association
Andrew Cohen, AGC and Associates
Miles Cole, Maryland Department of Business and Economic Development
Karlene Conrad, Community Hospices
Richard Coughlan, Cohen, Rutherford + Knight
Sylonda Davis, University of Maryland Medical Center
Ron DeCesare, Professional Healthcare Resources
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver
Sean Flanagan, St. Joseph Medical Center
Craig Flury, Flury & Associates, Inc.
Greg Floberg, Hospice of Charles County
Valerie Fox, Stella Maris
Myrtle R. Gomez, Nursing Enterprises
Bruce Goodman, Community Home Health of Maryland
Christopher Hall, Adventist Healthcare
James Hamill, Washington County Health System
Marie Harkowa, Shore Home Care Hospice
Wynee Hawk, Greater Baltimore Medical Center
James Hursey, Greater Baltimore Medical Center
Donna Jacobs, University of Maryland Medical System

Deron Johnson, Law Office of J. William Pitcher
Brian Kahan
Danna Kauffman, Mid-Atlantic LifeSpan
Eileen Lacijan, Hospice of Queen Anne's
Anne Langley, Johns Hopkins Health System
Angela Lavin, Funk & Bolton, P.A
Richard McAlee, Esquire, Southern Maryland Hospital
Michael S. McHale, Community Hospices
Shawn McNamara, Upper Chesapeake/St. Joe's Home Care
Denise Matricciani, Maryland Hospital Association
Lawrence Merlis, Greater Baltimore Medical Center
Joe Meyers, St. Agnes Health Care
Amy Millar
Ann Mitchell, Montgomery Hospice
Frank Monius, Maryland Hospital Association
Sam Moskowitz, Mercy Health Services
Alice Neily, Hospice Network of Maryland
Nicole Price, SEIU, District 1199 E-DC
Vanessa Purnell, MedStar Health
Barbara Ray, Hospice Caring, Inc.
Debbie Reeder, Chester River Home Care and Hospice, Hospice Network of Maryland
Cori Rehus, St. Agnes Health Care
Laura Resh, Carroll Hospital Center
Michele Rice, Potomac Home Health Care
Bill Salganik, Baltimore Sun
Sue Lyn Schramm, Montgomery Hospices
Rajesh Shah, Harvard University Law School
Robin Shaivitz, Alexander & Cleaver
Eric Slechter, Franklin Square Hospital
Andrew L. Solberg, A.L.S. Healthcare Consultant Services
Sue Ellen Stuart, Gentiva Health Services
Judy Weiland, Mercy Health Services
Paula S. Widerlite, Adventist HealthCare
Georgia Wilkison, Hospice of Queen Anne's

Call to Order and Introductory Remarks

Chairman Robert E. Nicolay called the meeting to order at 10:12 a.m., welcoming the members of the Task Force and members of the public in attendance. Chairman Nicolay explained that the Task Force convened this Public Forum to receive and consider comments on Maryland's Certificate of Need Program, with particular focus on the three areas of the Task Force's charge: to propose modifications to the procedures, services, and facilities that are covered under the program, enhancements to the application process, and enhancements to the monitoring of Certificate of Need-approved projects under development. The Chairman noted that the members of the Task

Force represent a broad cross section of Maryland's health care community, and that the Commission is grateful for their participation.

Chairman Nicolay introduced Commission Chairman Stephen J. Salamon, who was instrumental in the creation of the Certificate of Need Task Force. Chairman Salamon welcomed everyone on behalf of the entire Commission, and thanked the Commissioners who had given their time to serve on the Task Force, as well as the other members, whom he appointed in order to bring broad geographic representation and a wide range of expertise and experience to this effort. He thanked the Commission's staff, as well as the stakeholders and other members of the public for their participation. Chairman Salamon stated that the objective of the Task Force is to examine the Certificate of Need program and the health care services under its authority, as established in Maryland law, through a "stakeholder-driven" process. He emphasized the importance to the Commission of this active participation by stakeholders in the health care system.

Chairman Nicolay then briefly described the work plan for the Task Force, which will meet during the months of June, July, and August to analyze today's public testimony and any written comments received by 4:30 p.m. on Friday, June 10, 2005. The Task Force will present recommendations to the full Commission at its September meeting. Between September and December of 2005, any recommendations requiring regulatory changes will come to the Commission as proposed regulations, which will afford an additional period of public comment. Any statutory changes needed to accomplish changes to the Certificate of Need program recommended by the Task Force and adopted by the Commission could be proposed to the 2006 session of the General Assembly.

Chairman Nicolay explained that the Public Forum was scheduled for three hours, until 1:00 p.m., and that he would use the full time allotted, and allow more time, if needed, in order to be able to hear from any person or organization present that wanted to address the Task Force. Consequently, he would place no time limits on testimony, and expected that Task Force members would ask questions for clarification or further information during each person's testimony.

Public Forum Comments

1. **Lawrence Merlis, President and CEO of Greater Baltimore Medical Center**

Mr. Merlis presented the recommendations of the Greater Baltimore Medical Center ("GBMC") on the scope of services and facilities regulated under Certificate of Need, which proceed from the belief that sophisticated and large medical centers should be able to provide a full array of services to their patients and the communities that they serve. GBMC believes that, as currently structured, Maryland's Certificate of Need program prevents it from accomplishing that objective. Despite "tremendous advances in clinical care and clinical technology" over the past twenty years, Mr. Merlis, said, the

scope of medical services covered by CON regulation has remained basically unchanged. GBMC recognizes the important role of Certificate of Need in the review and analysis of large capital construction projects proposed by hospitals -- issues related to increases in hospital costs and charges, and their effect on the Medicare waiver – as well as by other inpatient health care facilities.

However, Mr. Merlis argued, for clinical services, the Certificate of Need program has failed to recognize the significant changes in clinical practice and technology over the past twenty years, thereby creating an unequal dichotomy in which certain clinical services remain very tightly regulated, while equally sophisticated and, in some cases, more complex clinical services may be developed without Certificate of Need, with positive clinical outcomes and effective cost control. As examples, Mr. Merlis cited GBMC's interventional radiology program, which has treated over 2,000 patients with an "invasive, diagnostic, and therapeutic catheter-based" method; its vascular surgery program, in which surgeons insert aortic stents and grafts as well as carotid stents into many patients; and related neurosurgical and spine centers: in these services, physicians employ complex technologies in the kidney, the liver, and other major organs, but they are prevented from performing the same kinds of procedures on the heart by Certificate of Need regulation.

To address this inconsistency of regulatory authority, GBMC believes that the Commission should comprehensively evaluate the entire range of highly technological and complex clinical services – now standard practice at sophisticated community hospitals – to establish a consistent regulatory framework that achieves what is best for the residents of Maryland. Mr. Merlis stated GBMC's belief that not market dominance, not politics, and not the retention of a franchise granted by Certificate of Need should determine where quality services may be provided, and that a commitment to clinical excellence and ongoing compliance should become the focus of health care regulation.

Mr. Merlis stated that across the country, CON is being challenged in light of these medical changes and advances, and is being re-examined, he believes, because of the demands of the patients and the population for greater choice and access. GBMC believes that, for these specialized clinical procedures, a better regulatory process would be licensure, with standards developed by professional organizations, which would provide appropriate regulatory oversight, and a standard of entry and ongoing monitoring of care and quality. Licensure, he stated, would provide and create a proven method to lower costs with market competition, and would improve access and choice.

Mr. Merlis observed that, across the country, states are making changes in their Certificate of Need regulation of health care facilities: 13 states have repealed Certificate of Need, another 14 states are changing the applicability of Certificate of Need, and others, such as Illinois and Michigan, are examining the future role of Certificate of Need in regulating their health care systems. This re-evaluation of Certificate of Need as anti-competitive is consistent, he said, with the 2004 report by the Department of Justice and the Federal Trade Commission, entitled *Improving Health Care: A Dose of Competition*, which concluded that, while "CON programs are intended to control health care costs,

there is considerable evidence that they can actually drive up prices by fostering anti-competitive barriers to entry." Consistent with this view, GBMC believes that Certificate of Need programs favor market incumbents, increase costs, as well as impose a barrier to entry that hinders a thriving marketplace. Mr. Merlis provided a copy of the Executive Summary of the FTC/DOJ report for the staff to provide to the members of the Task Force.

In conclusion, Mr. Merlis said that the focus of regulatory policy should always be to provide for the benefit and needs of our patients and our communities. GBMC believes that the Commission and this Task Force need to consider options that create appropriate competition but, at the same time, address the concerns of quality and access and costs. He hoped that there will be a meaningful discussion through this process to evaluate regulation and evaluate the effectiveness of Certificate of Need, consider the elimination of Certificate of Need, as appropriate, and to implement other types of regulation, such as licensure.

2. Andrea Hyatt and Deron Johnson, Maryland Ambulatory Surgical Association

Mr. Johnson noted that the Maryland Ambulatory Surgical Association ("MASA"), which represents single and multi-specialty surgical centers across the state, supports the CON process as it is today for ambulatory surgery, and does not support any changes to it. Mr. Johnson also stated the position of MASA in favor of tighter definitions of what constitutes an operating room and a procedure room, in terms of their appropriate use, and the types of equipment and physical environment in each type of room. The current State Health plan for ambulatory surgical services contains a definition of several kinds of operating rooms, but not of procedure rooms. Mr. Johnson said that MASA does not have, at this point, any comments on the Certificate of Need review process or project monitoring, but will be following the Task Force deliberations and will comment as appropriate. For now, MASA believes that CON is "working fine."

Andrea Hyatt, administrator of the Dulaney Eye Center in Towson, Maryland, said that she supports Mr. Johnson's comments. She explained that there is considerable uncertainty among providers of freestanding ambulatory surgical services about the physical environment and scope of services permissible in operating rooms versus those in procedure rooms, and that the various levels of approval, licensure, and certification – between the Commission, the Office of Health Care Quality, and the Centers for Medicare and Medicaid services ("CMS") – contribute to this uncertainty. She noted that there are clear definitions available from the Guidelines for Health Care Facilities publication by the American Institute for Architects ("AIA") as well as from the various accreditation bodies for ambulatory surgery centers. Task Force member Dr. Albert L. Blumberg asked Ms. Hyatt what the disadvantage to her members would be if CON went away for ambulatory surgery. Ms. Hyatt replied that if CON went away totally, it would have an undesired effect not on just ambulatory surgery centers, but on all facilities that offer surgical procedures, citing a current crisis caused by a shortage of anesthesia providers. Ms. Hyatt noted the difficulty in obtaining sufficient staff to safely cover

operating rooms in every setting, whether in a hospital or an ambulatory surgery center. Without some limitation on entry into this market, these existing shortages would become more critical, and ambulatory surgical providers more stressed than currently is the case.

3. Cal Pierson, Maryland Hospital Association

Mr. Pierson, President of the Association of Maryland Hospitals and Health Systems (MHA), noted that his organization initiated its own study of the Certificate of Need program earlier this year, and has provided copies of the resulting report to the members of the Task Force. On behalf of MHA's 69 acute and specialty care member institutions, Mr. Pierson stated that Maryland hospitals have consistently supported an effective and rational CON process. Periodic comprehensive reviews such as this one have been very important to improve the process over time. MHA endorses the Certificate of Need program, he said, but believes strongly that changes can be incorporated which would streamline it and further facilitate and enhance the process. The creation of this Task Force represents a timely opportunity to "learn from our past experiences and to consider new ideas and approaches for the future."

In January 2005, MHA convened its Certificate of Need Work Group, comprised of hospital representatives and subject matter experts, to review the CON process as well as the State Health Plan, in order to identify areas of improvement. They also talked with their members, to learn about their individual experiences with the CON process.

MHA's first recommendation is to update the State Health Plan (SHP) and keep it current. MHA believes that many of the current system standards are obsolete or redundant, and should be repealed, and replaced by others more current and regularly revisited, such as the American Institute of Architects (AIA) guidelines for square footage in hospital construction.

MHA also recommends that the Commission eliminate the use of standards that are not formally adopted as regulation, in the State Health Plan. Only standards promulgated and detailed in the SHP should be used in the CON review process. Mr. Pierson stated MHA's view that the health planning and CON process has strayed from this "accepted" process of applying in Certificate of Need review only those standards formally adopted in the Plan. As a result, he said, hospitals are subject to standards that are not in the Plan, that are not available to them in advance, and cannot plan their projects and prepare their Certificate of Need applications appropriately.

MHA also recommends that the Commission align acute care bed need projections with the licensure law, making the State Health Plan's bed need methodology identical to the 71.5 percent occupancy rate, instead of its current 80 percent occupancy rate, to reflect the statutory standard for licensed beds of 140 percent of the previous year's average daily census.

The fourth major recommendation by MHA is that the definition of physical capacity in hospitals, applied by staff in Certificate of Need review, needs to take into

account modern architectural and patient care standards and public policy concerns such as the need for adequate surge capacity in the event of some kind of disaster. When a hospital submits a Certificate of Need application for renovation of existing patient care areas, along with the construction of new beds, Mr. Pierson said, there is often confusion and debate about what constitutes legitimate bed space, and a definition is needed that focuses on physical capacity and not just licensed capacity.

Mr. Pierson also summarized MHA's recommendations on the Certificate of Need review process, beginning with the review for completeness of an application. First, MHA wants to restore the original spirit of the completeness review, which, Mr. Pierson said, should only address whether necessary application components are technically complete, and not evaluate the applicant's response to those components of the application.

Second, MHA encourages the Commission to be judicious and time-sensitive in asking relevant additional questions. Mr. Pierson emphasized that MHA did not oppose additional questions following completeness review, but instead asked that such questions be relevant, and posed within 45 days of docketing, as opposed to the current practice, in which additional information questions are asked throughout the process, with little consideration of the relative importance or priority of those questions, or the regulatory timeframe involved.

Third, MHA urges the Commission to streamline standards of review and documentation, by adopting a checklist approach for documenting compliance with standards, in order to focus limited MHCC staff resources on areas where the more complex compliance problems might exist. This change would greatly reduce the time and burden required for CON applications for both applicants and the Commission staff, by making more reasonable and proportionate the amount of analysis necessary to document and demonstrate compliance with a given CON standard.

MHA's fourth major recommendation is that the Commission encourage the efficient use of resources by allowing major capital construction projects to include shell space, under certain circumstances and within certain parameters to support the efficient use of health care dollars. This would give hospitals a more cost effective alternative to starting a needed future expansion from scratch.

Fifth, MHA recommends the creation of a "fast track" review process for certain types of projects, such as those that do not include new beds and/or services. MHA envisions that, in these fast track projects, staff reports should be issued within sixty days, and a Commission decision rendered in ninety days, and if this does not occur, a project would automatically be deemed approved.

MHA's sixth recommendation is the elimination of unnecessary redocketing of applications, if changes to a Certificate of Need application are made in response to requests made by Commission staff or reviewers, changes made to the SHP, or changes to the MHCC's bed need projections.

Mr. Pierson presented two additional recommendations in one final area related to coverage of the CON process. First, MHA proposes that the statutory Certificate of Need review threshold for capital projects be raised to at least $7.5 million, with a provision for annual inflation adjustments, to better reflect the increasing costs of capital improvement projects, as well as the increasing need for physical plant upgrades. MHA believes that raising the capital review threshold to this level would relieve the Commission and its staff of the administrative burden of reviewing minor projects, and allow hospitals and other providers to begin them more quickly.

Finally, MHA recommends that the Commission expand the CON business office equipment exemption to include health information technology, since these clinically-related enhancements to a hospital's information technology improve the efficiency, effectiveness, and quality of care at a hospital, but do not necessarily relate specifically to the development of a new service. MHA recommends that clinically-related information systems and equipment be considered business or office equipment, and legally excluded from the CON process.

In concluding, Mr. Pierson said that MHA commends the MHCC for undertaking this effort to modernize the CON process, and hopes that its recommendations and full report will facilitate and improve that process, which the organization believes will result in a more efficient and effective process.

Chairman Nicolay assured Mr. Pierson that the Task Force will consider everything recommended by MHA. Commissioner Larry Ginsburg asked Mr. Pierson about the Certificate of Need Work Group participants. Mr. Pierson explained that the effort was an internal MHA review with all of its members represented as well as some outside subject-matter experts who have dealt with CON over the years, coordinated by Frank Monius, Associate Vice President of MHA. Mr. Monius noted that the ten-person Work Group also include several health care attorneys with extensive experience in the Certificate of Need program.

4. Mara Benner, Maryland National Capital Homecare Association

Ms. Benner, President of the Maryland National Capital Homecare Association ("MNCHA"), noted that the Association represents more than seventy home care providers and affiliates throughout the state of Maryland and the District of Columbia. She stated that – while her Association's members are equally divided on whether to support or oppose a CON program within the state of Maryland – its members concur in supporting the consistent enforcement of the current CON program, with a strong (Medicare) survey process. MNCHA also wants any additional regulations affecting Medicare-certified home health agency providers to be both fair and equitable.

MNCHA believes that another key aspect is to assure that any new CON regulations are fair and reasonable. Ms. Benner noted that new regulations enacted in October 2003 impacted CON providers who had been grandfathered into the system,

prohibiting newly-acquired home health agencies from serving any jurisdiction in which its predecessor had not provided services during fiscal year 2001, even if the predecessor agency had held a documented authority to serve that jurisdiction. Ms. Benner said that these types of regulatory modifications slowly erode the integrity of the originally authorized CON.

On the issue of enforcement, MNCHA members report that agencies are entering counties where they currently do not have Commission authority to provide services. Ms. Benner stated that it was critically important to enforce the regulatory authority of all home health agencies, whether the agencies obtained that authority through grandfathering, through Certificate of Need approval, or by acquisition of an existing agency.

Finally, Ms. Benner said that MNCHA members strongly believe that agencies should be surveyed on a consistent basis to verify compliance with the CON. This will contribute to "assuring stability of providers within the market," and help patients, physicians, payors, and state officials to know the agencies and know their services. She emphasized the importance of regular licensure and certification surveys in assuring the quality and safety of health care provided in a patient's home. Ms. Benner stated that the MNCHA membership looks forward to working with the Task Force and providing any additional information that is needed.

Commissioner Robert Moffit asked Ms. Benner if her concern for better and more consistent enforcement of Certificate of Need authority implied that the Commission was doing an inadequate job of that at present. Ms. Benner replied that this was MNCHA's main concern. Commissioner Moffit said that this would mean that the Commission or state agencies would have to increase their presence, which would likely cost providers more in licensure and other fees. He asked if MNCHA would favor an increase in the fees to cover increased compliance. Ms. Benner replied that the main concern of the membership is that if there is a CON, it needs to have integrity and be enforced; if Certificate of Need coverage for home health agencies is repealed, she said, those issues go away.

5. Robert Johnson, Jewish Social Service Agency

Mr. Johnson, CFO of the Jewish Social Service Agency ("JSSA"), said that his agency would like to retain CON regulation of hospice services. JSSA serves approximately 12,000 clients in Maryland, in Montgomery County. Its hospice has been in existence since 1984, providing hospice care on a fully non-sectarian basis. JSSA's hospice has become symbolic of the Jewish community and its commitment to care. Non-profit agencies such as JSSA operate on a relatively small, but comprehensive, basis, and work very hard to support families who are facing terminal illness and want to care for their loved ones at home. JSSA believes that if Certificate of Need coverage of hospice services is not maintained, the state will be placing community hospices like that of JSSA -- with long histories of high quality care, and a prompt response with charitable support for poor clients -- in jeopardy. JSSA must do extensive fundraising to raise

money to support care for Medicare- and Medicaid eligible patients, and to provide care to patients that cannot afford to pay. Nonprofit, community-based hospices such as JSSA provide exceptional quality of care. They are rooted in the community, they mobilize volunteers and fundraising dollars, and they are held accountable to their community boards for their quality of care and commitment. At the same time, they are JCAHO-accredited.

Mr. Johnson said that local nonprofit hospices like JSSA cannot commit extraordinary money for marketing campaigns, although they are well-known by all of the local hospitals and referral sources; they must reserve dollars for patient and family care. Local nonprofit hospices are already struggling under shortages of nursing; removal of the Certificate of Need coverage, with the resulting ability for an unlimited number of new providers into this market, would add to that in competition for charitable dollars. Mr. Johnson stated that allowing outside hospices to come into this area would jeopardize the very existence of community-based hospices which have superb reputations. He noted that JSSA has nurses who are available twenty-four hours a day, seven days a week, 365 days a year to give care. JSSA believes that a compelling need for competition in hospice care would only exist if the quality of care is lacking, and JSSA does not believe this problem exists in Montgomery County.

6. Erwin Abrams, Hospice Network of Maryland

Mr. Abrams began by noting that he was speaking both as President of the Hospice Network of Maryland, and also for his agency, Hospice of the Chesapeake. He asked that all representatives present at the Forum representing community-based hospices around the state raise their hands in support of the Certificate of Need process, and said that their presence shows the importance of continuing Certificate of Need coverage to current hospice care providers. Mr. Abrams noted that hospice care has been subject to regulation under the Certificate of Need program for nearly twenty years, and that, under this regulatory structure, hospice care in this state has developed into a thriving, vibrant community. While numerous efforts to deregulate hospice have arisen over the past several years, Mr. Abrams stated that no evidence has been offered to suggest that a change in this regulatory structure would provide any benefits to the terminally ill of the state of Maryland.

Because volunteers are essential elements in home based care, many agencies compete for their time and commitment. Continued regulation of new hospice providers through CON will ensure that the supply of qualified volunteers can meet the demand of the number of certified hospice providers. Mr. Abrams pointed out that the majority of the thirty hospice providers in Maryland are not-for-profit agencies, and therefore rely greatly on the generosity of local donors for fundraising dollars. Increased competition for community donations would increase the considerable pressures of securing economic support for hospice services. According to the Hospice Network's surveys of care provided in 2000, 2001, and 2003, existing hospice care providers are meeting the end of life needs of the citizens of Maryland and is growing as the need grows. Mr. Abrams and his organization believe that retaining the authority to consider additional hospice care

providers only when additional need warrants will help maintain the stability of the mission-driven, mostly not-for-profit community that is heavily dependent on volunteers, and the experience of professional staffs.

Mr. Abrams pointed out that in a study of hospice care, the Commission presented ample evidence that CON has produced high quality end of life care for the citizens of this state. He concluded that the economies of scale available when the number of hospice programs is limited to those needed, the special circumstances that pertain to rural areas with a delicate balance of resources and demand, the need for continuing local control and operation of these community-based agencies, the necessity for hospices to devote every dollar possible to patient care, and the need to retain scarce staff and still compete in the market place all lead the Hospice Network of Maryland to implore the Task Force to retain Certificate of Need for hospice as it is.

Task Force member William L. Chester, M.D. asked Mr. Abrams if he believes that the Certificate of Need process for hospice adequately addresses the issues of end of life pain management. Mr. Abrams replied that the Certificate of Need process addresses this issue, through the requirements of hospice programs described in the applicable State Health Plan review standards, but that the professional community of physicians and palliative care nurses around the state are also addressing this issue, thanks to the Maryland End of Life Project, and its partnerships with hospitals around the state. Task Force member Barry Rosen asked Mr. Abrams how many hospices his organization represents. Mr. Abrams replied that the Hospice Network represents all thirty hospices in the state of Maryland.

Commissioner Moffit asked Mr. Abrams to confirm that he thinks that the current CON program is fine and that their recommendation was for no change in Certificate of Need. Mr. Abrams replied that was correct. Commissioner Moffit asked if there was anything that Mr. Abrams could think of that would improve the Certificate of Need for hospice care. Mr. Abrams said that the Hospice Network of Maryland members are always interested in working with the staff and the Commission to ensure that regulations are strengthened, and that the monitoring of quality of care, whether through Certificate of Need review or by the State's licensure programs, is always desirable.

7. Sue Ellen Stuart, Gentiva Health Services

Ms. Stuart, Maryland Area Director of Gentiva Health Services, noted that Gentiva is the nation's largest, comprehensive provider of home care services. Gentiva serves clients in Maryland through its offices in Pasadena, Maryland. Ms. Stuart stated that Gentiva is supportive of the current CON process if, and only if, the CON is enforced, agencies are consistently surveyed, and all regulations are fair and equitable in their implementation. As a home health agency on a national scale, Gentiva currently provides services in both states with and without CON. One of its main concerns has been the influx of providers in other states without CON. Ms. Stuart cited the example of Florida, which eliminated the Certificate of Need requirement for home health agency services on July 1, 2000. Under the CON requirement, approximately twenty new

providers sought Certificate of Need approval annually. Since the elimination of CON, that number has increased five times, to 120 per year. In real numbers, the State of Florida had 330 Medicare-certified home health agencies in May 2002; three years later, in May 2005, the state now has 658 Medicare-certified home health agencies. Similarly significant increases in the number of certified home health agencies occurred in other states that repealed the Certificate of Need requirement, and Ms. Stuart offered to share Gentiva's information on this issue with the Task Force.

Ms. Stuart said that the increase in providers makes it very difficult to appropriately assure the quality of the services being delivered to the patients needing care, and strains resources available to ensure that the provider is a legitimate provider. Gentiva believes it is critically important to ensure that the CON has integrity, and that providers are caring for patients in their designated CON area. Gentiva also believes that ongoing and consistent survey reviews support the integrity of the regulatory authority conferred through Certificate of Need. Ms. Stuart said that CON should ensure that providers are being surveyed and reviewed in a timely manner and that they meet the CON requirements.

On behalf of Gentiva, Ms. Stuart stated its belief that the Commission has implemented regulatory changes that were not reasonable, citing the October 2003 adoption of a regulation providing that the purchaser of an existing home health agency may only acquire the authority to offer home health agency services in jurisdictions in which the Commission's records show that the facility being acquired either provided that service in fiscal year 2001, or was granted a Certificate of Need after that date, based on the agency's annual reports. While this regulation does not seem to have an immediate impact on a home health agency, it does immediately imply that "their CON is no longer reflective of all of their originally designated counties."

Gentiva strongly urged the Commission to assure a fair and reasonable approach, in making any regulatory changes affecting the Certificate of Need program, and its coverage of home health agencies. The most important factor to Gentiva is assuring quality and stability of home care services to the patients, and for the providers. If the Commission ultimately chooses to eliminate the CON, Gentiva strongly urges Maryland to adopt a fair but strong home care licensure program. This licensure program should assure that those entering into the market meet certain standards and that quality of care is maintained, even after they begin their new home care business.

Ms. Stuart noted that Gentiva is currently represented on the Maryland Department of Health and Mental Hygiene In-Home Health Care Forum, which is reviewing the entire statutory and regulatory framework governing entities that provide some level of health care in people's homes. If DHMH decides to seek changes to the current structure of licensure for home care providers, Gentiva hopes that the Department will seek strong quality control and appropriate oversight for patients, and for providers. Ms. Stuart concluded by stating Gentiva's commitment to work with the Task Force as it considers potential changes to the Certificate of Need process and coverage of health care services.

Lynn Bonde, Task Force member, asked if home health agencies are subject to Office of Health Care Quality (OHCQ) licensure regulation and surveys. Ms. Stuart replied that they are. Ms. Bonde asked if she understood correctly that Gentiva feels these regulations and surveys should be strengthened. Ms. Stuart answered that what appears to be happening is that currently surveys happen only when there is a complaint, rather than on a routine basis.

Dr. Albert Blumberg, Task Force member, asked about Ms. Stuart's relation of the Florida experience, in which the number of Medicare-certified home health agencies doubled in the two years following elimination of the Certificate of Need requirement. He asked if he was correct in assuming that Florida did not impose a strong licensure program, at the same time it eliminated the Certificate of Need requirement. Ms. Stuart did not know whether Florida strengthened its licensure and other market-entry requirements at the same time it deregulated home health agency programs from Certificate of Need.

Chairman Nicolay requested that Gentiva provide the Task Force with the data on other states' experience following deregulation from Certificate of Need that Ms. Stuart mentioned during her testimony. Ms. Stuart said that she would send the additional data to the Commission's staff.

8. Danna Kauffman, Mid-Atlantic LifeSpan

Ms. Kauffman, as Director of Public Policy for Mid-Atlantic LifeSpan, a senior care provider association representing a continuum of settings of care, began by endorsing the recommendation of the Maryland Hospital Association for an expedited review and application process. She said that the state needs to understand that one size does not fit all, and that there are circumstances where an expedited review would benefit both the Commission as well as Maryland in general. Many Maryland nursing homes need renovations, whose cost adds up very quickly. Mid-Atlantic LifeSpan believes that, in the case of renovation process with little or no impact on other providers or the surrounding community, it would be advantageous for the Commission, as well as the state and the providers, to have an expedited review process. Her organization urges the Commission to develop an expedited application process, in consultation with nursing home providers, and said that Mid-Atlantic LifeSpan would provide further comments on this issue in written form.

Task Force member Douglas Wilson, Ph.D. asked if Mid-Atlantic LifeSpan advocates an increase in the Certificate of Need review threshold for capital projects; Ms. Kauffman replied that her organization supports MHA's recommendation to raise the capital threshold.

9. Elizabeth Weglein, Maryland National Capital Home Care Association

Ms. Weglein, Government Affairs Chair for the Maryland National Capital Home Care Association ("MNCHA") noted that the Association represents five sectors of the home care industry, including the Medicare-certified home health agencies currently subject to Certificate of Need review and approval in Maryland. Ms. Weglein also noted that MNCHA represents the residential service agency (RSA) sector, which includes private duty nursing and other home health services, providers of durable medical equipment, as well as nurse referral agencies, hospices, and nurse staffing agencies. The Association is currently considering its position on the question of Certificate of Need regulation of Medicare-certified home health agencies in Maryland. It is now officially neutral on this issue, but believes that it should investigate further what the effects would be on the whole range of home care providers if the Certificate of Need requirement on one sector were to be repealed. The Association intends to share the results of this analysis as its efforts move forward, and asked to be involved in the work of the Task Force, since its recommendations will be critically important to the industry it represents.

10. Howard Sollins, Esq., representing the Health Facilities Association of Maryland

Mr. Sollins, of the law firm Ober, Kaler, Grimes & Shriver, noted that he serves on the Planning and Regulatory Committee for the Health Facilities Association of Maryland ("HFAM"), and was providing testimony on HFAM's behalf, as the representative of more than 150 of Maryland's 260 nursing home providers.

HFAM supports maintaining Certificate of Need coverage of comprehensive care facilities ("CCFs"), the licensure category of Maryland nursing homes. Mr. Sollins noted that in neighboring Pennsylvania, whose Certificate of Need program ended in 1997, the Medicaid program instituted a replacement program that continues to review proposals for new nursing home beds and facilities, because of the relationship between the supply of nursing home beds and the predominant source of reimbursement for those services, the Medical Assistance program.

Mr. Sollins stated that the nursing home industry favors a flexible approach to capital improvements that benefit residents: because of the overall age of much of the industry's physical plant, many facilities need significant upgrades, and these projects very quickly reach the current capital review threshold of $1.65 million. Some facilities need total replacement, and often must identify a site elsewhere in the same community. Each of these actions is now regulated through the CON process. The nursing home industry needs more flexibility to undertake these capital projects, and seeks parity with the hospital industry, in its recommendation to increase the capital review threshold. HFAM also endorses MHA's suggestions to exclude from Certificate of Need review any expenditure for electronic health records or other information technology that improves quality or efficiency of care. The Association similarly concurs with MHA's recommendation that the Commission permit a certain amount of shell space to be included within a Certificate of Need-approved capital project. In nursing homes, the

availability of unprogrammed space can be important in a natural disaster, as happened during last summer's series of hurricanes in Florida, and can also serve as an impetus for the development of community-based services, as an alternative to nursing home admission. Considerable discussion is currently ongoing about the important role of community-based long term care services, and HFAM is an important stakeholder in these discussions, since nursing homes are often a springboard for the development of dialysis, adult day care, assisted living, and other community-based settings of care.

Mr. Sollins noted that HFAM agrees with previous testimony that, in uncontested cases in which no new service is involved, the Commission should establish an expedited review process. He also urged the Task Force to consider extending the ability to undertake a capital project in identified phases within its overall performance requirements – now available only to hospital projects that meet the regulatory definition of "multi-phased construction projects" and over a specified amount of capital cost – to smaller, less costly projects.

HFAM also agrees that the State Health Plan needs to be updated regularly, and kept current. Several issues related to current State Health Plan standards should be addressed in the next update of the Plan. First, the Plan currently subjects applications to expand existing facilities, including those involving capital expenditure over the review threshold – as well as to establish new bed capacity or a new facility – to a standard requiring that every other existing nursing facility in the jurisdiction be at or above 95% occupancy. The Plan permits an applicant to explain reasons why given facilities are below that occupancy level, but HFAM urges that the Commission re-examine the policy itself, since relatively few facilities across the State or the nation are operating at that level. To subject any capital improvement project that expands bed capacity to such a high benchmark operates as an effective barrier, in some cases, to an otherwise beneficial capital project.

Another State Health Plan issue of concern to HFAM is an apparent change of Commission policy with respect to the re-implementation of existing nursing home bed capacity, at another site or another existing facility. This issue was a key element in a recent Commission staff report on a proposal seeking Certificate of Need approval to relocate beds from a hospital-based extended care facility at an existing nursing home in Western Maryland. Subjecting beds already in the system to a showing of continuing need seems to the industry to be a change in policy that should be discussed thoroughly. HFAM agrees with previous comments that the entire issue of licensed versus physical bed capacity needs further discussion, so that the industry knows the Commission's thinking, as it seeks ways to maintain services and use existing physical plants more efficiently.

A third State Health Plan issue that HFAM believes needs re-examination is the requirement that, in order to receive Certificate of Need approval, nursing homes seeking to establish or expand bed capacity or to undertake a capital expenditure over the review threshold must execute a Memorandum of Understanding ("MOU") with the Medicaid program. This MOU is a commitment on the facility's part that it will maintain an annual

average number of Medicaid patient days at least equal to either the jurisdictional or the regional average, whichever is less.

This Plan requirement dates from a time when Medicaid recipients, or those about to spend down to Medicaid, did not have ready access to nursing home care; HFAM believes that this standard is no longer necessary. The MOUs developed in response to this review standard are being actively enforced by the Medical Assistance program, and this is problematic for two reasons: first, being below the agreed-upon level may result in a penalty to providers, in lower Medicaid reimbursement rates, and, second, it may provide a disincentive to encourage Medicaid recipients to seek community-based settings of care, since to do so would reduce a facility's Medicaid occupancy. HFAM believes that the problem of access to care for Medicaid recipients no longer exists, and that the MOU requirement is therefore outdated.

Mr. Sollins noted that the Commissioners have recently discussed, in the context of a matter before them, the statutory requirement that Commission-regulated health care facilities – other than hospitals – must obtain a Certificate of Need to close. In addition, any proposal to re-implement the beds at another location in the jurisdiction, whether at a new or an existing nursing facility also requires Certificate of Need approval. HFAM suggests that this process can be made much more efficient, such as by the assembling of a comprehensive project to come before the Commission for a single Certificate of Need review and approval. The State Health Plan could provide for this approach. HFAM believes that the Commission should also consider the broader question of whether its statute should continue to require a Certificate of Need for the closure of any category of health care facility. This should become a notice requirement only.

Mr. Sollins urged the Commission to re-consider what he described as its new use of a comprehensive published schedule for Certificate of Need reviews for all kinds of nursing home projects, not simply those involving new beds, or a new facility. Within that published review schedule, he said, the Commission has also changed the historic practice of allowing 180 days in which to submit a Certificate of Need application following the filing of a Letter of Intent to apply, instead requiring that an application be filed within 60 days of the Letter of Intent submission, in a scheduled review. The effect of this schedule is that many applications may now arrive simultaneously; this further strains staff resources, and adds to the time it takes to obtain a decision. Although the industry works well with Commission staff, which is collaborative in working with applicants in meeting these deadlines, the Task Force process presents an opportunity to re-evaluate about how the Certificate of Need process works, especially in the context of a set schedule for Certificate of Need reviews.

On behalf of HFAM, Mr. Sollins also observed that – although the Certificate of Need process is characterized by time deadlines – there is no deadline within which the agency needs to get back to the applicant with the results of its review of responses to completeness questions. HFAM also endorses the comments made earlier about the distinction between docketing questions, completeness questions, and additional information questions. Over time, those questions have tended to be blended together,

and HFAM agrees with MHA and other commenters that these distinctions should be revived.

Finally, Mr. Sollins observed that the historic orientation toward evidentiary hearing, inherited from the defunct federal Certificate of Need review process, was changed in 1995, when the former Health Resources Planning Commission proposed and the legislature enacted a measure to streamline the review process. In place of the evidentiary hearing, the statute permitted applicants and interested parties in contested cases to request an opportunity to oral argument before the Commissioner acting as reviewer in the matter. In practice during the ten years since this provision was enacted, Mr. Sollins noted, oral argument is rarely held. Thus, an applicant can be in a contested review, and never have the opportunity for an exchange with the Commissioner who is the Reviewer on your case.

HFAM believes that the Certificate of Need process is an important part of the state's process for considering the future and current health care needs of Marylanders, and favors a health planning process that reflects current data, fosters the ability of providers to compete effectively through new and better programs and services, eliminates barriers to providers seeking to improve the fiscal environment in which quality care is rendered, and enables providers to use the economic value of their beds as part of that process. HFAM therefore urges the Commission, as the Task Force is upgrading and updating the Certificate of Need process, to think about small providers who have property rights, who have need and ability to use that capital to fund community-based services, and not to move toward a CON process that jeopardizes that value. HFAM believes that the Commission can continue to maintain a CON process that provides important benefits to the people who are served by long term care providers, with the right balance between inpatient services and community based services.

Task Force member Carlessia A. Hussein, Dr.PH, asked Mr. Sollins if he is aware of data documenting that Medicaid patients have adequate access to nursing home services, and whether HFAM could provide that data. Mr. Sollins replied that he works with many providers who serve Medicaid patients, and felt that providers seek Medicaid patients in times of declining occupancy, noting that the District of Columbia is currently working to assure that its Medicaid recipients are admitted to DC nursing homes, rather than to Maryland nursing homes.

Task Force member Jack Tranter asked what specific changes HFAM recommends to the current practices of completeness review. Mr. Sollins replied that the initial ten working days allotted in Certificate of Need procedural regulations for completeness review are sufficient, and that there should be a ten to fourteen day timeframe for completeness instead of the present thirty days, which includes the time period necessary to submit a docketing notice for publication in the *Maryland Register,* which initiates the statutory thirty-day public comment period.

Task Force member Barry Rosen asked whether the rationale for requiring Certificate of Need approval for nursing homes is still related to concerns about stress on the Medical Assistance budget, and other forms of reimbursement. Mr. Sollins replied that under Medicaid, private pay dollars are shrinking, Medicare payment is prospective, and that Medicaid payment is based on five cost centers. Medicaid has substantial control that it makes sense to maintain.

Task Force member Joel Suldan asked if the per-bed cost of construction or renovation in current nursing home projects exceeds the allowable portion of capital costs set by Medicaid program, when it assigns a facility's Medicaid rates. Mr. Sollins replied that whether a facility's capital and interest costs exceed the Medicaid formula's cap depends on several factors, including the age of the physical plant. For those facilities whose capital costs exceed the cap, there is intense economic pressure.

Task Force member Hal Cohen asked if Mr. Sollins's discussion of the economic value of nursing home beds referred just to Medicaid reimbursement issues, or to the larger question of any value the beds could hold as a financial asset to a provider, because the overall supply of nursing home beds is controlled by the State health Plan's need projections. Mr. Sollins responded that he was addressing the general concerns. In recent years, the sale of nursing home beds by smaller, older, family-owned facilities allowed for forward-looking people to buy the beds and collect them into more modern facilities. That the owners of existing beds might become subject to new need analysis, and their re-use in a new facility might need to be re-justified would negate the "value of licenses in this marketplace."

11. Donna Jacobs, University of Maryland Medical Systems ("UMMS")

Ms. Jacobs stated that UMMS agrees with many issues and ideas raised by previous testimony, including that of MHA, particularly with respect to making the Commission's State Health Plan need projection methodology for acute care beds assume the same level of overall occupancy as that of the statutory provisions related to the annual recalculation of licensed acute care beds, enacted in 1999. UMMS believes that the so-called "140% rule" – assigning to each hospital a number of licensed beds equivalent to 140% of its average daily census from the previous year – is a better measure of a hospital's actual average daily census and more reflective of the hospital's actual need than a jurisdictional bed need projection, generally based on a higher average occupancy target. UMMS believes that not balancing this inconsistency between the State Health Plan and the licensing statute may have a negative impact on future hospital growth and patient access to acute care services in the state.

UMMS also wished to comment on the Commission's existing regulations that establish different performance requirements, or allowable periods of time applicable to large capital expenditure projects for construction, demolition, or renovation, at COMAR 10.24.01.12. These performance requirements, for "multi-phased construction projects" at hospitals over a specified total cost, require that hospitals obligate 51% of the total capital expenditure for the first phase of construction, and that the first phase be

completed in twenty-four months. For projects over $60 million, Ms. Jacobs stated that this large up-front obligation of capital presents a significant burden, since some of these large-scale projects may take a total of five to seven years to complete. Ms. Jacobs cited the example of three large capital projects, which – had they been Certificate of Need-approved projects, instead of approved via "the pledge" – would have presented this dilemma to UMMS. The first phases of all three projects – the Shock Trauma Center, the Homer Gudelsky Building, and the Weinberg Building – took longer than 24 months, yet all three projects fell within their own construction schedules. UMMS therefore suggests that these implementation standards are too prohibitive for the larger scale projects, and asks that the Task Force reconsider the time line and the portion of capital costs that a hospital must obligate at the start of each approved phase of construction.

UMMS agrees with several previous commenters that the Certificate of Need review threshold for capital projects should be increased, and recommends that the threshold be set at $10 million. Eighteen of the twenty-one CON projects on file and under review by the Commission exceed the current threshold of $1.65 million, but only nine of those projects exceed a $10 million threshold. The state's capital expenditure threshold is below the mid-range among the states with CON across the nation; in our neighboring states, Delaware and Virginia both have a $5 million review threshold, and the District of Columbia's threshold is set at $2.5 million. The highest review threshold for Certificate of Need review of capital projects is that of Massachusetts, at $10.2 million.

On behalf of UMMS, Ms. Jacobs raised the issue of Certificate of Need coverage for inpatient obstetric services: UMMS believes that obstetrics is a basic service that should be provided by any community hospital, without the need to obtain Certificate of Need approval. Any hospital that can demonstrate that it meets quality standards established by a recognized authority – such as the Maryland Perinatal Standards adopted as regulation by the Maryland Institute for Emergency Medical Services Systems (MIEMSS") – should be able to provide the service. UMMS questions the logic behind the Commission's continuing requirement of Certificate of Need approval to establish a new hospital obstetrics service, when a hospital may open a freestanding birthing center in Maryland by obtaining a license from the Office of Health Care Quality. In practice, Ms. Jacobs said, since hospitals without a formal obstetrics services can deliver babies in their emergency rooms or in their operating rooms under certain circumstances, the service is being provided in hospitals without Certificate of Need approval, but in an environment that is far less optimal in terms of patient access and patient care and quality. Being able to add an obstetrics service, without Certificate of Need, would enable all hospitals to provide the best quality care, as well as to support related subspecialties, such as general gynecology, uro-gynecology, and general OB services.

Finally, Ms. Jacobs endorsed on behalf of UMMS the recommendation by MHA that clinical information technology acquired by acute care hospitals should not be subject to Certificate of Need review. Clinical information technology will improve patient safety in hospitals and ambulatory care settings and will enhance the efficient and effective delivery of health care services, so acquiring this capability is clearly in the

public interest. Because advances in this field are occurring so rapidly, the additional time required to obtain Certificate of Need approval can delay implementation of the most up to date and effective systems. The use in hospitals of sophisticated clinical information systems will become the standard of care, and a necessary part of providing health care to patients, managing complex health care providing organizations, supporting research, and training our future clinicians, nurses and other health care professionals

Task Force member Alan Bedrick, M.D. noted that within the state of Maryland, every pregnant woman is within thirty minutes of an acute care hospital with an existing obstetrics service; he asked Ms. Jacobs what efficiencies and or cost containment purpose would be served by permitting a hospital to establish a new obstetrics service in a geographic region in which hospitals already provide these services. Ms. Jacobs replied that UMMS understands that geographic access to obstetrics services currently exists, but that this fact has not stopped an annual average of about 170 women presenting to North Arundel Hospital to deliver their babies. UMMS believes that this situation indicates significant demographic shifts in northern Anne Arundel County, and a greater need for this basic service to be available as close to home as possible, especially when the population is growing.

Task Force member William Chester, M.D. noted that, related to this question of new obstetrics services, another important issue is adequate coverage of medical services directly affected by the presence of an obstetrics program, pediatrics and anesthesiology; the latter service is particularly stressed by the presence of obstetrics, which is time- and labor-intensive for anesthesiologists. Hospitals are forced to subsidize these related services, which – with staffing shortages – is becoming increasingly costly. Dr. Chester asked Ms. Jacobs what she thought that the impact of removing Certificate of Need coverage for obstetrics services would be on this situation. Ms. Jacobs said that she would take that question back to UMMS, and address it in the system's written comments.

Dr. Hussein noted, with regard to Ms. Jacobs' support for deregulating from Certificate of Need the capital expenditures related to the acquisition of clinical information technologies, that these systems can be extremely costly, and wondered what alternative mechanisms could help ensure that hospitals acquire and use high quality, reliable, and cost-effective systems. Ms. Jacobs suggested that, as these information systems evolve, she would expect the hospitals and other health care providers contracting for them to become more sophisticated about the technology, and also to share information about the best vendors and systems.

Task Force member Henry Meilman, M.D. asked if UMMS has considered the possible impact of transferring high-risk mothers and infants to a tertiary care center, as possibly preferable to having an on-site obstetrics program at any hospital. Ms. Jacobs responded that not to have practitioners experienced in obstetrical care on site when women in labor are presenting itself constitutes a risk for hospitals, and this risk is intensified by the presence of high-risk mothers and infants. Ms. Jacobs agreed that there

would always be cases requiring transfer to a tertiary center or to an academic medical center, but most of the cases coming to North Arundel Hospital fall just under that threshold, and most patients are appropriate for care at a community hospital.

Chairman Nicolay observed that the Task Force is concerned about and interested in this issue, and would appreciate any data and other information on this issue that UMMS or other commenters can provide.

12. Sam Moskowitz, Mercy Health Services

Mr. Moskowitz stated Mercy's support for the Certificate of Need process, and his intention to focus on three issues in his presentation to the Forum. Mercy first recommends that the bed need methodology of the State health Plan's acute care chapter be revised, to consider hospitals that serve multiple jurisdictions, those with service areas that extend past the borders of the city or the county in which they are actually located. While the current jurisdiction-level bed need methodology may work in single hospital jurisdictions, it does not make sense in jurisdictions with multiple hospitals, including Baltimore City, where several hospitals have broad service areas based on programs that attract patients from outside of Baltimore City. Mercy's Center for Women's Health and Medicine is one example of such a program, and Mercy has other programs, in vascular surgery and orthopedics, that bring patients into Baltimore City from other parts of the state. The current acute care bed need methodology penalizes hospitals that serve other jurisdictions, by limiting their projected bed need to only the demographic factors in the jurisdiction in which the hospitals are located. Mercy recommends that the Commission revise the way it projects acute care bed need to allow hospitals whose service area is multi-jurisdictional to benefit from population growth occurring within the hospital's entire extended service area. Mercy also believes that the Commission should consider historical growth of hospitals of this type, in projecting future bed need within each of those jurisdictions.

Mercy's second recommendation concerns the "target year" of the Plan's bed need projections, which is now 2010; Mercy believes that the target year should be extended to 2014. Mercy understands that the acute care chapter projection will soon be updated and extended to 2012, based on 2004 data projected eight years into the future. Mercy believes that the Task Force should recommend a ten-year planning horizon for acute care beds, to enable hospitals to better plan their future needs.

Mercy also recommends that the Task Force provide guidance on the circumstances in which the Commission would allow hospital capital projects to include a specified amount of unprogrammed, or "shell" space. As a related change in policy, Mercy recommends that hospitals that are land-locked be allowed to replace existing antiquated inpatient space even though that space will not be demolished, or immediately converted to another patient care-related use. At present, Commission staff focuses on a hospital's total physical capacity in assessing whether new capacity may be constructed, but in the process includes existing space that no longer meets current standards and that the hospital wishes to remove from active use as a result of a new construction project.

Mercy's third recommendation concerns other State Health Plan Certificate of Need review standards that need to be modified or eliminated, in particular the standard at Section .06B(9) in the Acute Care Chapter, which identifies the maximum amount of departmental gross square feet for new construction projects. Hospitals across the state are examining their antiquated physical plants, and need an updated standard for allowable departmental gross square feet that takes into account a patient safety perspective in the context of a move to all private rooms. Maryland is considered a national leader in health care, and the Commission should bring this important Plan standard up to date, using the American Institute of Architects guidelines and other sources.

13. Andrew Solberg, A.L.S. Healthcare Consultant Services

Mr. Solberg, a health care planning consultant for thirty years, began by stating his long-abiding respect for Maryland's health planning efforts, and a desire that it be effective and well respected. He worked for the Commission's predecessor agencies for approximately ten years, first as a planning and CON analyst, then as the Chief of Plan Development, and finally as the Director of the CON program. He also taught a course in comprehensive health planning at the Johns Hopkins School of Public Health for nine years.

For the last twenty years Mr. Solberg has operated his own health planning consulting practice, assisting clients in strategic planning, market studies, development of outreach programs, applications for Certificate of Need, and other related matters. While he participated in the Certificate of Need Work Group on which MHA's comments were based, he emphasized that the comments he presented were his own, and not made on behalf of any client. His written comments, he said, would include recommendations related to the review process itself, including simplifying the format of decisions; returning to the original purpose of completeness review; modifying the Commission's perspective on bed need; adopting all standards used in Certificate of Need review into the State Health Plan; allowing facilities to have "shell space" when it makes sense; fast tracking certain kinds of CON reviews; excluding information technology projects from Certificate of Need review; eliminating CON for home care and hospice; eliminating CON for closure of facilities; changing the scheduled review process; and changing the regulations applicable to the modification of CON applications under review.

Mr. Solberg said that his most important recommendation was that the Commission update the State Health Plan, many of whose individual chapters are quite old, and need to be revisited. The Commission has not undertaken a comprehensive, integrated revision in many years, and, as a consequence, does not appear to have a comprehensive vision of where the health system should be headed. The Commission should take a fresh approach to developing new standards. Every standard should address a documented problem in health care delivery, and demonstrate that it will be effective in resolving the problem, or improving the system.

Mr. Solberg urged the Task Force to recommend that the Commission undertake a complete overhaul of the State Health Plan, which needs to express what the Commission wants to achieve through the CON process. The Certificate of Need process is only an implementation tool for exercising the Commission's vision that it articulates and publishes as regulation, in the State Health Plan. The Plan can have great authority, and it should drive the Certificate of Need process. Through the publishing of its policies and standards as regulations, the Commission tells the regulated industry what it wants to see developed in the health care system. The kind of give and take that occurs during the Plan development process, and the clarity of policy that results, leads to mutual respect between the industry and the regulators. It would benefit the Commission to have more visibility in an active planning process.

Task Force member Terri Twilley, MS, RN, asked why Mr. Solberg proposes elimination of CON for the home care and hospice. Mr. Solberg responded that when he was the director of the CON program in 1982, he testified before the legislature that these community-based, non-facility health care services should be deregulated. Accurately determining the need for new capacity in these areas is difficult, because an agency can expand its patient census simply by adding staff. Members of the legislature may have strong views on maintaining the Certificate of Need regulation of home health agencies and hospice programs, but it is important to recognize that these are not reasons directly related to effective good health planning and regulatory practice.

14. Sean Flanagan, St. Joseph Medical Center

Mr. Flanagan said that most of his hospital counterparts, as well as Mr. Pierson of MHA, had addressed many of the issues that St. Joseph Medical Center wanted to bring to the attention of the Task Force. St. Joseph's advocates and supports the current system of Certificate of Need, and also the array of medical services that are covered by Certificate of Need review. St. Joseph Medical Center is in full support of MHA's recommendations.

Mr. Flanagan noted the general observation or belief that Certificate of Need somehow eliminates all competition. He suggested that Maryland hospitals could, in consultation with the Maryland Hospital Association, develop some type of barometer, a set of indicators that could regularly determine if this effect is really occurring. St. Joseph's own observation is that Central Maryland, in particular, is one of the more highly competitive hospital industry areas in the country, and this fact makes the statement that Certificate of Need precludes a competitive marketplace a fallacy.

15. Nicole Price, SEIU, District 1199 E-DC

Ms. Price, Political Organizer for SEIU, District 1199 E-DC, testified on behalf of the 10,000 health care workers represented by SEIU and of consumers of health care, commending the Task Force for allowing public input in this process. SEIU believes that the citizen involvement inherent in the Certificate of Need process assures that consumers have a voice in the quality of health care provided in our community. Certificate of Need

provides for greater accountability, more fiscal responsibility, and ultimately equity, in assessing and addressing the need for health care services. Access to health care is important to Maryland working families and health care workers in the community, who believe that the Certificate of Need process is extremely valuable in their quest to provide the best health care services in their communities. The rising cost of health care is a huge problem that negatively affects many people in our state on a daily basis. As health care costs continue to skyrocket, the need for consumer protection becomes even more vital. Expansion of health care services must be done in a thoughtful manner that considers the overall health care needs of the community.

Ms. Price stated SEIU's belief that the Certificate of Need process plays an integral role in protecting and promoting access to quality health care for all Marylanders. It creates a rational allocation of health care resources to ensure that the public needs are being met in the most effective manner. The process lowers costs by avoiding duplication of services, and efficiently distributing services across the state. Too often, she said, expansion of services without regard to the need to do so does little to enhance the delivery of health care services to Marylanders in our more affluent communities, but it costs many dollars that could have been used to ensure proper, necessary health care services to people who do not have them in poor communities today. Without Certificate of Need, SEIU believes that we risk losing vital health care services in low income areas.

Ms. Price said that the current Certificate of Need process in Maryland assists in assuring that the playing field is leveled for indigent care, thereby reducing to the same degree cost shifting to the insured population. With the high cost of health care forcing many working Marylanders to lose health care coverage, SEIU believes that we need a state policy that assures effective allocation of health care dollars and services in our state. A strong Certificate of Need process is vital for many basic reasons. We cannot predict our health, and when we may need hospital care. Patients do not have the same information that physicians and hospitals have about where to receive the best quality of service. With greater advances in health care technology, health care costs continue to rise and access to technology is not available to all communities. The Certificate of Need process protects vulnerable populations from a loss of health care services. For all of these reasons, SEIU believes that the Certificate of Need process is needed, as well as other oversight opportunities for the public in legislative review and public hearings to review and evaluate whether the local health systems are meeting the needs of everyone.

Ms. Price reported that states that have eliminated Certificate of Need laws have seen a proliferation of physician-owned specialty hospitals that do not provide uncompensated care, and do not have twenty-four hour ER services. These states have more hospitals offering high-profit services such as heart bypass surgery. This can reduce the quality of bypass surgery and other procedures if the hospital does not perform enough of the procedures to achieve and maintain volume. In Arizona, where the legislature deregulated Certificate of Need in 1980, nursing home capacity doubled in less than five years, while occupancy rates declined to less than 75%. In Utah, where Certificate of Need was deregulated in 1984, psychiatric bed capacity increased so much that major employers retaliated by reducing mental health benefits. Other states, such as

Wisconsin, Georgia, and Virginia, have all concluded that the Certificate of Need process assures quality and the equitable distribution of health care services. In Maryland, as well as across the country, hospitals have merged into large systems, and insurers are merging with each other and converting to for-profit status. These trends suggest to SEIU that Certificate of Need is more important than ever, to preserve public confidence in the quality of health care. SEIU believes that Maryland should retain Certificate of Need regulation to protect access to quality, affordable, secure health care. SEIU 1199 E-DC strongly supports Maryland's Certificate of Need program. As key stakeholders, they are committed to serving the public's interest by promoting access, oversight, and accountability. They welcome the opportunity to work with the Task Force to enhance quality and affordable health care for all Marylanders.

Task Force member Dr. Hussein said she agrees with the statement that the Certificate of Need process is particularly important to maintaining quality of services for vulnerable populations. Dr. Hussein observed that Maryland has some of the best health care facilities in the nation but that minority health care disparities continue here as well as elsewhere; she asked if SEIU could offer specific suggestions as to how the Certificate of Need process can help increase access to quality services. Ms. Price said that her organization would submit written testimony which will include some of those suggestions. Ms. Bonde asked Ms. Price to include the data that she cited about changes to health care access in states that had eliminated Certificate of Need with SEIU's written comments, which she agreed to do.

16. Thomas Firey, Maryland Public Policy Institute

Mr. Firey began by asking the Task Force – whose mandate is to find ways to modify and enhance the Certificate of Need process – to consider instead whether the Certificate of Need program works at all. Mr. Firey said that there has been no empirical analysis in Maryland of that question, of whether Certificate of Need holds down costs, or improves the quality, of the health care services regulated under the program.

Mr. Firey stated that there are two competing theories about Certificate of Need. One theory takes the view that the immense, initial fixed costs of building and equipping health care facilities and establishing new health care services must be paid regardless of how many consumers use them, and that too much supply – too many expensive buildings, duplicated equipment, scarcer staff commanding higher salaries – results in higher costs, since the initial investments must be repaid. The Maryland Health Care Commission, ideally, uses Certificate of Need to examine proposed buildings and programs, to determine if they are necessary, in order to try to reduce fixed costs, and therefore hold down the price of the services to consumers of health care.

The opposing theory is market economics, which holds that market forces operating in a free and unfettered environment lead to the most efficient provision of services and goods, including health care. Under market theory, Certificate of Need is actually a danger to the consumer because any commission, any central planning

authority, brings with it risks for insufficient information, administrative delay, and a tendency to protect certain provider interests.

Mr. Firey noted that considerable academic research has been focused on Certificate of Need in the past quarter-century, much of it conducted during the early 1980s, after the Reagan Administration announced its intention to end the federally-mandated Certificate of Need program, and leave to the states the decision of whether or not they would continue the program. An early evaluation of the effectiveness of the federally-defined Certificate of Need program was that by Frank Sloan of Duke University, writing in the *Review of Economics and Statistics* and in the *Milbank Quarterly*. Sloan examined states that had complied with the federal mandate and states that had not, and he did a statistical analysis showing no statistical relationship between an active Certificate of Need program and lower overall health care costs. Seven other academic studies published in the early to mid-1980s arrived at the same basic conclusion: that Certificate of Need programs did not act to hold down health care costs.

Other studies of approximately the same period found that Certificate of Need was actually statistically linked to higher hospital prices and profits. Several states had dropped their CON laws by the time repeal of the federal program took effect on October 1, 1987, and others subsequently repealed their programs, or changed their scope. Consistent with the studies published at about this time was the conclusion that Certificate of Need laws, over time, resulted in higher hospital profits, by 15 to 25%, and hospital costs approximately 20% higher than in states without a Certificate of Need program.

Mr. Firey stated that similar research has examined the effectiveness of Certificate of Need programs in controlling Medical Assistance budgets, by limiting the supply – and consequently controlling the demand – for nursing home beds. Ohsfeldt, Morrisey, and Grabowski, in the journal *Inquiry,* found that neither CON requirements for nursing homes, nor moratoria on nursing home construction have any statistical effect on Medicaid expenditure. In general, the research has shown that Certificate of Need does not accomplish its often-stated purpose of holding down health care costs and charges.

Mr. Firey suggested that Certificate of Need programs are successful at protecting existing providers, and that anti-competitive risks are inherent in acting to control the supply of health care providers, and thereby restricting the free choice of consumers of care. The Anti-Trust Division of the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") focused on that aspect of Certificate of Need programs in their joint 2004 report, *Improving Health Care: A Dose of Competition*," in which these agencies concluded that ". . . CON programs are generally not successful at containing health care costs. They can pose anti-competitive risks. As noted [in the report], CON programs risk entrenching oligopolists and eroding consumer welfare. Controlling costs is laudable, but there appear to be other, more effective means of achieving this goal that do not pose anti-competitive risks. A similar analysis applies to the use of CON programs for health care quality and access. For these reasons, the agencies [DOJ and FTC] urge states with CON programs to reconsider whether they are best serving their

citizens' health care needs, by allowing these programs to continue." In Maryland, the Maryland Public Policy Institute's recent publication *"Health Care in Maryland: A Diagnosis"* contains a chapter by Michael A. Morrisey that shares this view of the impact of Certificate of Need programs on hospital costs and charges; Mr. Firey provided a copy of this publication to the Task Force.

Task Force member Michelle Mahan asked Mr. Firey how, in his research, he accounted for the nature of Maryland's unique system of hospital regulation, which includes the nation's last all-payer rate-setting program with a waiver from the Medicare prospective payment system, administered by the Health Services Cost Review Commission. Mr. Firey said that he would re-examine the available data and do some Maryland-specific research; he was unclear about how the dynamics between HSCRC and the Certificate of Need program worked.

Task Force member Joel Suldan asked Mr. Firey if he would change his views on the Certificate of Need program if he knew that – through the interaction of the Certificate of Need and the hospital rate-setting system – Maryland's hospital profits and its increases in costs per case for inpatient care over twenty years have both remained lower than those of the nation as a whole? Mr. Firey responded that his view of the program would not change

Mr. Rosen asked about the Maryland Public Policy Institute, specifically with respect to the size of its staff. Mr. Firey replied that MPPI is a very small public policy group, with four staff members—two full time and two part time people—operating out of Germantown.

Closing Comments and Adjournment

Chairman Nicolay asked whether two persons on the sign-up sheet had arrived; they had not. He then asked if anyone else present wished to testify; no one else came forward. Chairman Nicolay congratulated and thanked all who presented comment to the Task Force, and asked for a motion to adjourn. Upon the motion of Commissioner Moffit and a second by Task Force member Jack C. Tranter, the Chairman adjourned the Public Forum at 12:28 p.m.

Revised 7/14/05

Summary of the Meeting of the CON Task Force

June 23, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present

Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Annice Cody
Hal Cohen, Ph.D.
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Anil K. Narang, D.O.
Lawrence Pinkner, M.D.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Douglas H. Wilson, Ph.D.

Task Force Members Absent

Commissioner Robert E. Moffit, Ph.D.
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Henry Meilman, M.D.
Frank Pommett, Jr.
Christine M. Stefanides, RN, CHE
Terri Twilley, MS, RN

Members of the Public Present

Heather Barthel, Johns Hopkins Medicine
Clarence Brewton, MedStar Health

Andrew Cohen, AGC and Associates
Carolyn Core, Civista Health, Inc.
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver
Sean Flanagan, St. Joseph Medical Center
Richard Gasparotti, Adams Management Services
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Donna Jacobs, University of Maryland Medical System
Anne Langley, Johns Hopkins Health System
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Martha Nathanson, LifeBridge Health
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Andrew L. Solberg, A.L.S. Healthcare Consulting & Services
Pegeen Townsend, MHA: Association of Maryland Hospitals & Health Systems
Elizabeth Weglein, MNCHA

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:05 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (May 26, 2005 and June 7, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the May 26, 2005 and the June 7, 2005 meetings and asked for any comments, changes, or corrections. A motion was made and seconded to approve the May 26, 2005 minutes of the Task Force, which was unanimously approved. A motion was made and seconded to approve the June 7, 2005 minutes of the Task Force, which was also unanimously approved.

3. Review and Discussion of the Public Comments Received on the CON Program

Chairman Nicolay announced that the first topic of review and discussion was a summary of the major issues raised in the public testimony and written comments received. He provided an overview of the comments submitted to the Task Force, by health care service. The Task Force received seventeen comments regarding acute care services; as well as comments on hospice services, home health services, nursing homes, ambulatory surgery, and the capital expenditure threshold.

The Chairman said that, together with the staff, he had reviewed all of the comments and had assembled them by category. He added that the Task Force would consider the first group of comments, on coverage. In that group, there were nine comments in favor of retaining Certificate of Need (CON) with no changes; nineteen comments in favor of retaining CON but changing coverage; and fourteen comments recommending deregulation of some or all services or actions. On the subject of a re-focus of completeness review, the Task Force received ten comments.

Additional comments were received regarding changing the capital threshold and simplifying or expediting the review process. In addition, many recommendations received (comments from sixteen people) related to updating the State Health Plan standards. Five comments were received recommending the adoption of a licensure formula for bed need; and three comments were received regarding monitoring and enforcing compliance with CON.

Chairman Nicolay summarized the comments received regarding coverage by CON review and noted that one of the major issues was acute care hospitals. The first item in this area was a recommendation to remove CON coverage for Obstetric Services, as well as comments recommending the substitution of licensure for CON review in some highly specialized services. It was also recommended that the Task Force consider adding CON coverage for Emergency Department services and cardiac catheterization laboratories. Another recommendation was for raising the capital threshold to at least $7.5 million, with individual hospital commenters advocating a $10 million threshold. Various commenters recommended the expansion of the CON business office equipment exemption to include health information technology.

The Chairman then discussed long term care services. On the subject of hospice services, the Task Force received six comments in favor of maintaining a strong CON program, and three comments in favor of deregulation. On the subject of home health agencies, three commenters favor no change to CON; two commenters reached no consensus among their member-agencies on CON coverage but favor stronger enforcement of regulatory authority through more frequent "surveys," and two commenters favor deregulation. Comments received on nursing homes included increasing the capital expenditure threshold, and proposing that the closure of a facility should not require CON review, or should be part of a comprehensive review of a CON project to relocate and re-use nursing home beds.

Chairman Nicolay recommended that the major issues reflected in the comments be considered and discussed by the Task Force with the goal ideally of reaching consensus on recommendations in these areas. Chairman Nicolay reiterated the timetable for recommendations to be made to the Commission in September. Due to the number of topics suggested for consideration, the Chairman urged the Task Force members to keep their comments succinct and on-target.

- **Hospice Services**

The Chairman announced that the Task Force would turn its attention to consideration of hospice services. He noted that consideration of home health services would be deferred to the next meeting (on July 14, 2005) because Task Force member Terri Twilley was unable to attend the June 23rd meeting. Chairman Nicolay urged the Task Force members to participate in making comments and suggestions, debate among themselves, and reach consensus on each item.

Alan Bedrick, M.D. said that his assessment of the testimony was that the current system is working well for hospice services. If the Commission were to deregulate hospice, there would be some deterioration of services. In his opinion, the Commission should maintain the current CON regulation of hospice services.

Hal Cohen, Ph.D. suggested elimination of CON for hospice services because the reasons for CON, largely, do not apply to hospice. In his view, there is very little relationship to capital investment and there is no reason to limit capacity. Terminally ill patients should have the opportunity to use hospice services; therefore, as an agency, the Commission should not care about how many hospices are available. According to Dr. Cohen, the result of current regulation creates a moratorium on new hospice providers. The preference should be in favor of competition, unless there is other evidence showing that it does not work. Dr. Cohen interpreted the hospice providers' arguments in favor of CON regulation as arguments for protection from competition, which, in his opinion, is not an appropriate basis for CON regulation.

Albert L. Blumberg, M.D., F.A.C.R. agreed with Dr. Cohen, adding that CON, in general, eliminates competition, creates monopolies, and does not allow the marketplace to help or encourage a provider to improve services. There is a concern for providers in rural areas that if CON regulation is eliminated, they will lose some type of a protective shield and might have a problem with maintaining solvency. For many hospices, the average length of stay is seven to ten days, often due to patients' difficulty in accepting their medical status and their need for these services, which is not the best utilization of hospice benefits. He added that as a society, we would be better off if patients more fully utilized hospices, though that is not the function of the CON process. As there are outside agencies, separate from state agencies, that evaluate and certify hospice providers, Dr. Blumberg stated that he does not see the value of CON for hospice services.

Lynn Bonde said that all of Maryland's hospice providers support retaining the CON for many reasons. In Baltimore, Montgomery, Prince George's, and Anne Arundel counties, and Baltimore City, there are a number of hospices. Any possible benefits from competition are available in areas where there is sufficient population to support multiple hospices. Of the thirty hospices in the state, twenty-seven or twenty-eight are not-for-profit organizations. Those organizations do not survive without charitable donations. There is competition for both volunteers and for charitable donations.

Ms. Bonde added that in Calvert County, the Calvert Hospice provides free community-wide bereavement services and that this is the case for a number of hospices. The services that hospices provide support community needs beyond simply caring for terminally ill patients. There is a quality baseline incorporated into the CON regulations. Marketplace entry is available through purchase and merger. There are many hospice providers in those states that have eliminated, or never regulated, hospice care, though there is no evidence that more hospices mean better cost control. The classic economic argument—more competition results in lower costs—does not happen. Hospice is basically a fixed cost service, except where issues of patients' needs come into play. The very limited data available shows that hospices in non-CON states do not provide as much patient care, do not provide as many visits, and do not provide as many dollars toward the high cost of pharmaceuticals.

According to Ms. Bonde, CON is one of several ways to ensure that the quality of hospice care is maintained. In addition to the state's licensure laws, most of the hospices in Maryland are JCAHO-accredited; however, unlike hospitals, this is not a requirement. General

hospice providers are also Medicare-certified, which adds assurance of compliance with a set of quality conditions. Thus, there are many spurs to improving and sustaining high quality in hospice processes.

In Ms. Bonde's view, throwing out a system that has supported hospice and its growth in the state on the basis of an economic theory that does not relate to the experience of the organizations that have operated under the CON program, without considering the adverse consequences to hospice providers and their patients, seems to be cavalier. The program has promoted competition where competition is warranted and has encouraged hospices in less densely populated areas to thrive.

Adam Kane, in concurring with Dr. Cohen's opinion, said that if the purpose of CON is to protect the state's capital investment, then CON applications should be evaluated based on the extent of state capital investment. He cited as an example, Erickson Retirement Communities' current issue with the Commission regarding hospice care. In his opinion, innovation is being stifled because of the CON process. There are exceptions that permit Erickson to care for its residents in nursing home beds, home health care, assisted living, and independent living arrangements. The only component of the senior care continuum that Erickson cannot operate is a hospice program. People come to Erickson from independent living, and Erickson provides for their health care needs in assisted living, skilled nursing, and home health care. For hospice services, Erickson must contract with other providers. In his view, there is no consistency or rationale for this rule other than to protect the "monopolist interests" of current hospice providers. Since there is no capital component to hospice, the existing hospices can continue to expand by adding personnel. According to Mr. Kane, the CON program for hospice services stifles innovation and is inconsistent with exceptions to the CON process granted in other areas.

Annice Cody said that the Commission did an extensive review of hospice services and recommended, after evaluating a set of public comments, to maintain CON for hospice services in 2001. She asked what has changed in the marketplace in the way hospice is delivered, or in any other aspect, that would lead the Task Force members to a different conclusion in 2005. Ms. Cody suggested that the Task Force members respect the extensive work that was done in 2001 and if there have been changes, then those changes should be considered.

Dr. Blumberg responded that he read the 2001 study. In his opinion, the difference is that the Commission's staff has driven every prior analysis of CON. In his view, the staff has a different perspective than the stakeholders. He recommended considering how people that are affected by CON view the benefits of CON. Are there economic arguments and state policy arguments that need to be taken into account, regardless of the service?

Jack Tranter said that in reading the comments, he was concerned about the relationship between charitable giving and viability because there was some suggestion that weakening the ability, or lessening the amount of money contributed to hospice, would be problematic in terms of continuity of service. He asked Ms. Bonde to address the relationship between charitable giving and hospice viability, as well as to respond to what she thinks would happen if hospice services were eliminated from the CON program.

Ms. Bonde replied that the relationship between charitable giving and viability is direct for not-for-profit hospices. There is more than a subjective difference in what would happen if CON were eliminated. The capacity of locally accountable, locally based hospice programs to serve the population would shrink. Services like bereavement care (a service that is not provided by the state on free or low-cost cases, but is provided by hospices) would essentially evaporate. Hospice programs would not be able to provide children's grief services, adult support groups, and individual counseling, without charitable dollars to support those programs. Studies show that the percentage of for-profit providers rises in states that eliminate CON coverage as well as in those states that do not have a CON program. She recently read an article that suggested that for-profit hospices, being quite rightly concerned with profits, tend to spend less on care than not-for-profit hospices.

Ms. Bonde added, in response to Mr. Tranter's question regarding the difference in scope of services provided by for-profit and not-for-profit hospice providers, that analysis has shown that the least expensive patients—those with the least costly medication needs and with the least costly staff needs—would be the patients that would go to the for-profit hospice providers due to "cherry picking". Hospice is, by statute, a comprehensive program. It is different from any other health care service provided by hospitals, home health, or ambulatory surgery providers because it involves psychosocial care, medical care, volunteer support, and bereavement follow-up for families, as required by statute and regulations. In addition, hospices are paid on a per diem basis for providing all of those services. Costs can be cut by reducing the cost of medications for patients, reducing the number of staff hours allocated to patients, and reducing the number of direct-cost items provided to patients. Ms. Bonde offered to provide a study to the Task Force as a later submission, which demonstrates that for-profit hospices tend to operate on a lower cost basis. She asserted that the CON program enables the existing structure to survive. Absent CON, national organizations that are not locally accountable, and some others that carry thousands of patients and have operations in many locations across the country would move in and begin to "cherry pick" the patients who are the lowest cost patients, leaving the patients whose medication needs and whose needs for intensive staff time are more expensive to the rest of the providers. In terms of competition, such a situation would weaken the existing structure.

Mr. Kane said that it seems that any time another organization, whether it is for-profit or non-profit, local or out of state, wants to provide hospice services, the hospice community is opposed. In his opinion, the CON structure in place would not ever permit a new provider to emerge. Ms. Bonde replied that there have been new providers since the CON report in 2001 was issued. For example, Seasons Hospice from Chicago moved into the area and Community Hospice moved out of the District of Columbia and into Maryland. Need was projected under the State Health Plan in Prince George's County. In addition, Capital Hospice acquired a hospice in Prince George's County and moved into Maryland from Northern Virginia. It is inaccurate to say that entry is completely barred, and that is not the objective of the current hospice providers. In Ms. Bonde's view, having operated under the existing regulatory structure, these changes have been reasonable and measured. The hospice providers' objective is to be able to sustain the existing hospice population in terms of local control and in terms of the quality of services provided.

Dr. Blumberg reiterated his original position, adding that he had a patient in need of hospice care that has refused that suggestion from his attending physician, the medical oncologist, as well as from him. He agreed with Mr. Tranter that the reason hospices have to depend so much on charitable giving is the length of stay issue. Up front costs are very intensive during the first week of hospice care and if the patient is not in the program long enough, then the program cannot recoup those costs. He added that Ms. Bonde was correct that with less funding, hospice programs would be unable to provide the ancillary services that make hospice such a positive experience for patients and families. As someone who refers patients to hospice on a regular basis, he asked for further information about cherry picking. Ms. Bonde explained that cherry picking is about making clinical choices on the basis of what is going to be the most profitable. Families of patients like the one that Dr. Blumberg described would eventually decide that they want that patient to come into hospice, perhaps two days before the patient was to die. A patient in that status would probably be rejected by a hospice that is looking to save the money that it would cost to provide all of the services for that very short term and very expensive patient; however, for longer-stay patients, they might provide fine care. Dr. Blumberg emphasized that he would never make another referral to a hospice provider that refused to provide care for one of his patients. He thought that many doctors would feel the same way.

Commissioner Larry Ginsburg observed that the discussion was leading to a disturbing and incorrect "all or nothing" approach. There was a great deal of validity in the Commission's 2001 report, which included written testimony from all interested parties. In his view, the 2001 report was not "staff-driven". He suggested that the Task Force use the 2001 report as a baseline and determine what has changed since that time.

Mr. Tranter asked about the benefits of eliminating CON for hospices. If opposition to CON is purely theoretical, in his opinion, then the Commission should not risk deregulation. In response, Dr. Blumberg said that the advantages for eliminating CON for hospice, other than the potential for more providers, included providing some continuity for people already in the system. In addition, there is something positive about having less regulation if the regulations are not providing any benefit. He added that he recognized the point made by Ms. Bonde that a finite donor pool that is spread out over more entities will affect that additional important cash resource. Dr. Blumberg added that if the hospice industry strongly determined that Maryland needs to maintain CON, then he would not remain opposed to the regulatory program.

Barry Rosen asked whether things are different in Garrett County or Calvert County than in Baltimore City. Is there a different down-side for the provider in a metropolitan area versus a rural area if CON went away? Ms. Bonde responded that the issues were population-based morbidity and mortality, and the potential pool of hospice patients. She said that it is an enticing notion to think that more hospices mean that more people would take advantage of hospice services, but that is a false conclusion because the availability of services is not the issue keeping people from coming into hospice. Rather, it is the profound reality of confronting death—a much more difficult and much more painful issue for people. For rural providers, the number of patients who would be appropriate for hospice that they have to draw from is smaller. In Prince George's County or Baltimore City, the population is larger and that population can sustain more providers. The critical, and only, way that the State Health Plan identifies hospice need is through analysis of population morbidity and mortality data. The methodology utilized identifies

probable future utilization based on analysis of trend data on hospice utilization and patient characteristics. If growth were projected, then an additional program would be considered for the jurisdiction. Ms. Bonde said that to criticize the system by saying that hospice is infinitely expandable by adding staff denies the reality of hospice providers in jurisdictions like Montgomery, Prince George's, Anne Arundel, and Baltimore Counties and Baltimore City. Mr. Kane's comment about innovation raised the same kind of issue that Mr. Tranter raised, i.e., the benefit for people in retirement communities who are now being served by their local hospices very well, versus an incalculable result. In Ms. Bonde's view, the issue is not restraining market entry, but looking at the potential impact on the people who are going to be served.

Mr. Kane replied that Erickson's proposal did not clarify what type of hospice product it would offer because, under the current regulations, they are not permitted to provide the services. He said that health systems and other organization have only begun designing elder care and senior care services. These organizations will be making major changes and major investments, and to the extent that regulation stifles creating programs, Maryland will be left behind other states. He cited, as an example, the hospices Erickson contracts with do not have the capacity to work with their residents' electronic medical records. Unless the hospice community comes along, or someone else can provide those services, the best quality of care will not be provided.

Ms. Bonde agreed that innovation is critical. She asked if Erickson would hire and sustain a full-time grief counselor and a full-time volunteer to sit with patients, as well as other ancillary and auxiliary services. Mr. Kane said that Erickson provides many of those services through its current hospice provider. Currently, Erickson must get a contractor instead of moving forward with the potential of establishing a different way—a more targeted hospice program—for its residents. Mr. Kane reiterated that Erickson had not been denied a CON for hospice services because there is no mechanism to apply for an exclusion from CON to serve its internal population in an integrated fashion under the current regulations, as there is in home health and nursing homes services.

Douglas H. Wilson, Ph.D. suggested that the Chairman poll the members, as each Task Force member had not yet expressed his/her opinion on hospice. Carlessia A. Hussein, DrPH, emphasized her dislike for making recommendations, taking positions, and considering issues when other stakeholders who are not necessarily concerned with the profitability of the service were not present. In her opinion, there was not enough information to make a judgment call. Dr. Hussein agreed with Dr. Wilson on the need for taking a straw vote.

Chairman Nicolay asked if the Task Force members wanted more information before making a recommendation. He determined that to facilitate making an informed resolution, the staff would summarize the day's discussion and provide any additional information available for consideration at a subsequent meeting. Dr. Hussein requested that someone provide information about what is broken in the hospice system so that the Task Force members will know what is not working. She asked for information on how need is being met, given the Commission's best ability to determine what the need is.

Commissioner Ginsburg noted that the 2001 study regarding hospice services had been included in the written comments provided to the task force members. He added that the

Commission's entire 2001 study of the CON program was posted on its website and urged the Task Force members to review it. In his view, any question about what has changed since 2001 was important to answer. Dr. Cohen posed additional considerations. To what extent should the decision be driven by what the industry wants, as opposed to what is appropriate public policy? Secondly, what is broken in Maryland and what is broken in states that do not have CON? Dr. Pinkner asked where it was possible to discuss a middle ground. For hospitals, ambulatory surgery, and other services, there are ways of tightening CON, loosening it, or changing some of the parameters. For hospice services, he questioned whether there is only one choice (i.e., to have a regulatory system or not).

Chairman Nicolay said that other states' data would be provided to the members of the Task Force. Following further discussion, he tabled the hospice issue and announced that the next item for discussion was closure of health care facilities.

●Closure of Health Care Facilities

Pamela Barclay briefed the Task Force members on the issue. Ms. Barclay said that some of the comments received related to the coverage by CON for facilities that are closing, particularly nursing homes. With respect to hospitals, depending on where the hospital is located, they are required only to provide notification to the public, or to make an exemption request to the Commission. One of the comments received would be to eliminate CON coverage for closure actions involving other types of health care facilities, in particular, nursing homes.

Dr. Blumberg asked Ms. Barclay to explain, in the acute hospital setting, how the exemption process functions in a closure situation. Ms. Barclay replied that the exemption provisions (that the proposal not be inconsistent with the State Health Plan, be in the public interest, and result in more cost effective care) apply in jurisdictions with fewer than three hospitals. For a hospital in a jurisdiction with three or more hospitals, closures require notification of the public. In a rural jurisdiction that has one hospital, there are more profound implications in terms of access and other issues that are of a public policy concern. There are no interested parties in an exemption proceeding. Ms. Barclay also noted that an exemption is a lower level of review than a full CON review.

Mr. Tranter said that he recognized the public policy concern for not having a hospital go away in a single hospital jurisdiction, but he could not see how the Commission could force that hospital to continue providing services. A number of hospitals, for example, have closed sub-acute care units. Hospitals in jurisdictions with three or more hospitals were required to tell the Commission they were closing and hold a public informational meeting that was sparsely attended. In a jurisdiction with fewer than three hospitals, a hospital was required to go through the closure process described by Ms. Barclay. His perspective was that the CON process cannot force a health care provider to continue to operate. He recommended that the Commission make the statutory changes required to change the process.

Natalie Holland added that the policy should apply to nursing homes as well as hospitals. From a nursing home's perspective, the closure is often coupled with the relocation of beds to

another area or to another provider. Currently, two separate CON filings are required (one for closure and one for bed relocation) , resulting in additional costs.

Dr. Hussein asked whether part of the reason for reviewing closures was to insure that there is notification throughout a community, both for other providers of a similar nature and for the general public that might be using the facility. She suggested that there are other mechanisms, short of the CON process, to insure that that notification takes place. Ms. Barclay responded that notification is part of the issue. In addition, which services are offered by the facility would be an issue. Both facilities, and major services within facilities, would be subject to these kinds of rules. She cited the example of psychiatric services, where there are reimbursement issues in addition to difficulties providing the service.

Joel Suldan said that it seems that one of the ways to improve the entire CON process is to avoid regulatory proceedings whose outcome is essentially assured from the beginning. He asked if the Commission has ever turned down an application for closure. Ms. Barclay replied that she could not recall an application that had been turned down since she has been involved in the process. Closing major community institutions is a very difficult process; however, both for the community and for the hospital. In response to a question from Mr. Kane about duplication of regulatory processes, Ms. Barclay replied that there are provisions in the licensing process, in addition to other resources, for the transition of residents of nursing homes to other facilities. These are consumer protections built into the system for residents of health care facilities. The rules are different for hospitals because patients do not reside there.

Mr. Kane suggested that the Task Force look at duplicative functions among the CON process and the licensing agencies and make recommendations to decide which agency should be the primary agency in order to reduce some of the paper work.

Dr. Blumberg asked for more information regarding the requirements of notification. Ms. Barclay replied that hospitals are required to hold a hearing to inform the community that a closure is taking place and how it plans to proceed. They are also required to place a notice of closure in a local newspaper. Dr. Blumberg said that he did not understand the reason for requiring additional steps when the state is not prepared to deal with the economic issues that led the facility's management team to recommend closure. Dr. Cohen emphasized that it is not a management team, but the facility's board of directors, that makes a closure decision. Boards of Directors care about the community and would not choose to close facilities or services without good reasons. Therefore, only the notification process should be required. He recommended that the Task Force members vote on the issue.

Dr. Pinkner said that he had qualms about the closure of a service. If a hospital decides that psychiatry is not profitable, and the emergency room is not profitable, and obstetrics is not profitable, and so on, and then decides to become a surgical hospital or a specialty hospital, is it the Task Force members' suggestion to eliminate CON and permit the hospital to pick the services that they want to keep? Mr. Kane replied that it would be unlikely or unprecedented for the state to decide something like that. If the state is actually not going to have to decide differently, or to have an active role, then to go through the CON process does not make sense when the goal is simply to notify people that a facility is closing. Dr. Pinkner asked if the

Commission had stopped the closure of any individual services. Commissioner Ginsburg responded that he could not recall the Commission ever denying approval of a closure that was brought before it. He pointed out that the Commission is often notified about a closure long after the fact, and suggested that the Task Force members consider these issues in different sections. For example, it seemed clear that for nursing homes there is no justification for having the closure requirement followed by people having to transfer the beds to another nursing home. However, the CON procedures should be retained for specialty services.

Mr. Tranter said that he thought Dr. Pinkner was correct in a theoretical sense. If there were a service that was necessary to the community, provided by a hospital, then the Commission would have more leverage under the current rules. In a practical sense; however, the likelihood of that circumstance arising is remote because most of Maryland's hospitals are not-for-profit and would not close a service in a community where it is needed.

Chairman Nicolay called for a vote of the Task Force members. A motion was made and seconded to eliminate the public hearing requirements for closures, which was approved by Task Force members Ginsburg, Bedrick, Blumberg, Bonde, Cody, Cohen, Holland, Kane, Mahan, Narang, Pinkner, Rosen, Suldan, Tranter, and Wilson; and opposed by Task Force member Dr. Hussein. It was the consensus of the Task Force to maintain the notice requirement and eliminate the requirement for Commission action (CON /exemption) in the closure of health care facilities.

●Clinical Information Technology

Chairman Nicolay said that the next item to be discussed was capital expenditures for clinical information technology that is directly related to patient care. He asked Ms. Barclay to elaborate on the issue. Ms. Barclay said that this comment came from the Maryland Hospital Association, as well as a number of individual hospitals, and CareFirst, as a payer and provider. She stated that the Commission had recently reviewed two CON proposals involving clinical information technology because the expenditures were over the capital threshold. Clinical information technology was not expressly a regulated service under the CON statute.

Dr. Cohen argued that the Commission should expressly state that it does not regulate clinical information systems. In addition, both the hospital providers and the payers agree that the capital threshold should be much higher. If the threshold were raised as proposed, it would be high enough so that information technology systems would not be eligible for review. Mr. Tranter said that the statute is not clear. It exempts business and office equipment and major medical equipment; however, it was written when clinical information systems were not in the conceptual framework and, therefore, are not clearly exempted.

Following discussion, Dr. Cohen made a motion that if the Commission's attorneys determine that it has the authority to require an application for CON for clinical information systems, then the Task Force recommendation is to change the law so that the Commission no longer has that authority. The motion was seconded by Commissioner Ginsburg, and approved unanimously by the Task Force members.

●Specialized Health Care Services

Chairman Nicolay said that the next item for consideration was specialized acute care services and asked Ms. Barclay to set forth the issues for the Task Force. Ms. Barclay said that the Task Force received comments regarding regulating a specific set of highly specialized services: open heart surgery, organ transplant surgery, neonatal intensive care units (NICUs), and burn care. Some commenters said that as medicine and technology have moved forward since those services were identified as being highly specialized and of a nature that the Commission would plan for, other services have been developed that are equally specialized but are not regulated under the CON program, resulting in, perhaps, inconsistency in terms of the resources, skill, and cost of some services that are generally available and not regulated under the CON program, as opposed to those that are regulated. Another point raised was that the Commission should consider a licensure process that would include attention to quality on an ongoing basis, rather than regulating market entry for these services.

Dr. Blumberg said that he would support elimination of CON for these services and the development of a licensure approach. From a consistency standpoint, one could elect to get rid of CON and not establish licensure as a middle point because there are many medical services currently available, and others that have come and gone, where CON was not required.

Dr. Bedrick asked for information concerning the difference between licensure and the CON application process. What is the difference between licensure and the process that includes a critical analysis for a new service? Ms. Barclay responded that CON is concerned with oversight over establishing new programs and making determinations as to whether or not there should be additional new programs. Licensure would not be concerned with establishing new programs, but would be concerned with how those programs, however many there were, would operate. Would they meet quality standards? Would they have appropriate staff? Under a licensure program, there would not be a restriction in terms of the number of new programs developed.

Ms. Bonde asked for more information regarding for which services a revised licensure procedure could be instituted and who would enforce the quality standards. Ms. Barclay replied that the comments received during the Public Forum were not specific. They were general observations that licensure would be a better way to have oversight over specialized services. The assumption would be that the Office of Health Care Quality and the survey process would administer any type of licensure oversight.

Dr. Bedrick expressed grave concern that eliminating the need for CON for certain specialized services like neonatal intensive care begs the question of CON becoming a "certificate of want." From the perspective of licensure, there are mechanisms through the Maryland Institute for Emergency Medical Services Systems (MIEMSS) and the Department of Health and Mental Hygiene (DHMH) for comprehensive reviews for certain levels of neonatal intensive care. The specific volume requirements that have been established for some services, for example, cardiothoracic services, do not necessarily apply to neonatal intensive care. Both the costs and the processes for establishing that kind of special service are dramatic. It would not

be well-founded or thoughtful policy to allow individuals or hospitals to set up new services because they want to, and then go through the site visit process, after the service has been established.

Dr. Wilson expressed mixed feelings about this question. He had grave concerns about deregulation, having come from California where a family member had open heart surgery at a hospital that performed barely fifty procedures a year, and whose mortality rate was above six percent. Hospitals with low volume eventually stopped providing those services in California, but in the interim, people were injured and died. To not require a CON for those services is neither in the best interest, nor a good policy decision, for the health of Marylanders

Dr. Cohen said that he has mixed feelings on this subject in part, because some services are overregulated and in part, because some of them are regulated so differently from others. There is not a need determination for NICU services as there is for some of the others. Even though the law is the same, they are treated somewhat differently. With regard to burn care, there are not many hospitals providing services. Open heart surgery has a volume/quality relationship that is manageable through licensure. If quality is the issue, then it can be handled through licensure. Any hospital that has a certain, relatively large volume of coronary patients could provide open heart surgery services. For example, there is a requirement that only one new program at a time in a jurisdiction is allowed. If two hospitals can perform 300 to 500 procedures, why should we have the level of restrictions that exist now in order to achieve the appropriate balance between quality and allowing hospitals to serve their patients?

Mr. Tranter said that the philosophical underpinning for cardiac surgery requirements is that there is a volume/quality relationship and that if these procedures can be performed like any other service, there will be too many of these programs performing too few cases. There are other services in the hospital context that are as sophisticated or, in some instances, more sophisticated than cardiac surgery. He favored the status quo because licensure is a review process initiated after the fact. On balance, there are good arguments that, perhaps, cardiac surgery should not be treated in a specialized manner, but the volume/quality relationship makes sense. He proposed to leave the regulations as they are.

Chairman Nicolay asked if Mr. Tranter intended to support keeping the status quo for all four specialized services. Mr. Tranter replied that his proposal applied to cardiac surgery; however, he was uncertain about burn units, NICU services, and organ transplantation services.

Ms. Bonde asked why it was an acceptable principle for CON to sustain quality in these specialized services, when it had been dismissed in the hospice context. Dr. Cohen said that the reason for addressing the issue of open heart surgery and the potential of CON regulation is the volume/quality relationship. It is not clear that there is literature related to hospice showing that there is a quality/volume relationship.

Dr. Bedrick added that it is also worth pointing out that among the four specialty services, there is significant heterogeneity. They are not a homogenous group. There is a reason in the Baltimore region, in the State of Maryland, that there are very few burn centers. There is a reason that many hospitals want provide open heart surgery services. He thought that a critical

analysis of the services continues to be warranted. Not every hospital wants to be a burn unit due to the tremendous outlay of resources for a relatively small number of patients. Dr. Pinkner said that as one who formerly treated burns regularly, he would recommend the elimination of CON regulation for burns, while retaining it for the other three services.

Dr. Blumberg said that Dr. Bedrick's argument was correct, though he would draw the same conclusion. The marketplace has determined that there is no need for many burn units, but is suggesting that more cardiac programs could be supported.

Mr. Tranter said that the volume/quality issue is significant and that licensure would not be able to prevent hospitals that ought not to get into this business from getting into it. Dr. Blumberg added that there are already hospitals in this business that should not be in this business. Because there is not a strong licensure program, there is difficulty in mediating the situation. Mr. Tranter replied that we do have licensure—we have JCAHO and we have hospital licensure—and those mechanisms have not identified that those programs should go away.

Mr. Suldan suggested that it is important to articulate what the principle is and what the principle is not. The principle is not that the next guy will do it worse than I do it now—the market can take care of that. The principle is that if there is a next guy, it will be worse for everybody, and that's the volume/quality relationship. Much of the discussion about hospice related to whether or not the principle applies to hospice, or if it was that the new guys will not do it as well as the existing ones.

Anil K. Narang, D.O. said that the members had discussed comparing quality in CON-related states to quality in non-CON states. He asked if there is a study, especially regarding areas where CON is regulated in acute care services, that a comparison in morbidity or mortality may be drawn with certain states that do not regulate the services? Dr. Cohen observed that with regard to open heart surgery, it is extremely important to note that the nature of the way that CON is applied is very different. For example, Pennsylvania had CON for open heart surgery and then eliminated it. During the time that CON was required, the regulators decided that the number of open heart surgeries required in any market was 350, and then they determined that was the number of services that they would approve. Pennsylvania was listed as a CON-regulated state, but they had a very different process and methodology for determining how many programs there are. Dr. Narang suggested that it might be easier to compare Maryland with the states that do not have CON at all, rather than comparing it with the states that do have CON.

Mr. Rosen said that if there is a CON requirement, then there needs to be a reason for it. He suggested that there are, perhaps, several reasons. One is that if there is a relationship between volume and safety, then it makes sense to restrict the number of providers. That is done through CON and not, in fact, with licensure. For other services, such as hospice, if someone made the case that expanding the number of providers would take certain mission-driven providers out of the system, then that reduces access. CON regulation is not just for safety. It may be for safety reasons, or to protect a mission-driven institution that is meeting a need that the marketplace is not, as well as others. With respect to other situations where there are also safety and volume considerations, then Maryland should consider expanding CON regulation to

those services. There is no a reason to say, therefore, that CON should be eliminated for those services identified as having a volume-safety relationship. Inconsistency is not a reason to eliminate CON.

Ms. Mahan said that there are technology and geographic issues associated with NICU and open heart services that are a part of the CON regulatory process. Technology introductions, such as drug eluting stents, have driven down the open heart population in the last few years. Studies have shown that there are quality/volume outcomes and Maryland has had a process in place incorporating those aspects. It would be making a mistake to think that the Task Force should do something in a short period of time different from what has been supported by public opinion at forums and legislatures for years. Commissioner Ginsburg agreed with Ms. Mahan and reiterated his earlier suggestion for reviewing the 2001 study recommendations, determining what is different, and what should be changed, if anything.

Mr. Tranter set forth a continuum of the four options under consideration. One was to leave everything as it is; the next step over was to leave things as they are for cardiac surgery, organ transplant, and NICU, but not burn units; next was to leave things the way they are but, regulate cardiac surgery differently; and finally, on the other end of the continuum, to eliminate CON for all four services.

Dr. Blumberg proposed that CON be eliminated for all four services and that a licensure program be devised in a manner that would ensure the highest quality of these services for Maryland residents.

Dr. Pinkner recommended that the Task Force take a vote on each of the four services separately.

Commissioner Ginsburg asked for more information regarding the procedures for initiating a burn unit and the capital expenditure involved. Without that information, it would be difficult to determinate that CON should be eliminated, in his opinion. Dr. Wilson asked if CON should be eliminated for burn units because not many organizations want to provide the service anyway. Dr. Pinkner doubted that any new burn units would open, due to their costly nature. Ms. Bonde asked if a hospital wanted to open one, why wouldn't they apply for a CON? Dr. Pinkner replied that a CON application is an additional expense for burn centers that are not profitable. Mr. Tranter asserted that if the marketplace is sufficient to control access for burn units, then Maryland doesn't need to regulate market entry. Dr. Wilson asked for information on how many hospitals have applied to open a burn unit in the past 25 years. If none, then what is the reason for the regulation?

Ms. Cody noted that the CON process can bring forth additional helpful information about how a program would work, such as will it be a high quality program; and does it have outreach services that are appropriate for bringing in patients? There are issues beyond the volume/quality relationship that can be addressed in the CON process that can be valuable and provide reasons for continuing CON regulation.

Dr. Blumberg seconded Dr. Pinkner's motion in favor of the task force voting individually on each of the four services.

Dr. Pinkner made a motion to recommend the elimination of CON approval for burn units. This motion was seconded by Mr. Tranter. Task Force members Blumberg, Cohen, Holland, Kane, Mahan, Narang, Pinkner, Rosen, Suldan, Tranter, and Wilson voted in favor of the motion, and Task Force members Bedrick, Bonde, Cody, Ginsburg, and Hussein voted against it. Chairman Nicolay noted that the motion carried.

Dr. Blumberg made a motion to eliminate CON review for organ transplant services. Chairman Nicolay asked if there was a second to the motion and, there being none, the motion died.

Dr. Pinkner made a motion that the Task Force recommends continuation of CON for organ transplant services, which was seconded by Commissioner Ginsburg as well as other task force members.

Dr. Blumberg asked if an organ transplant surgeon at one of the universities moved to another hospital and that hospital was willing to provide the same kind of quality program that it does for all of its other services, and wanted to make the financial expenditure to support that doctor and develop a transplant team, then what would be wrong, from a societal standpoint, if there was an additional choice in the community? Dr. Bedrick replied that the hospital would be welcome to go through the CON process. Dr. Blumberg suggested that marketplace considerations are an important aspect in an institution's decision-making process about providing these services. He suggested that the Task Force should consider consistency and expand CON to anything that is costly or specialized. In his view, there is an inconsistency in the regulation of the four services for historic reasons and the history does not justify the amount of regulation.

Ms. Mahan observed that as a hospital must make a huge commitment in terms of staff resources and finances to provide organ transplant services, there is no reason that it should not go through the regulatory process. Dr. Hussein added that CON is the forum where marketplace issues are discussed and, in the event that forum was taken away, she was not certain that the marketplace would continue to operate as it does today.

Mr. Kane suggested that if CON is a useful forum to get information and to discuss ideas, maybe there needs to be a review of the criteria for how it is applied, not just in the marketplace, additional factors that a facility might have a proposal for. In his view, there are alternative ways, or different criteria, that could be developed through a licensure program.

Ms. Holland asked if a program can apply for a CON for these specialized services at any time, and must it prove need, or can a program only apply for these services when there is a stated service need? Ms. Barclay responded that the answer depends upon the applicable State Health Plan chapter. There are differences in the way the Plan looks at need, depending on the service. There is not one approach that applies in an equivalent fashion to all of the services. The approach in open heart services is to project future utilization and, if certain criteria are met,

then to consider a new program. For NICU, there is not a need forecast in the Plan. The Commission's regulation of NICU services is inter-linked to MIEMSS and to DHMH. There is a coordinated process with those two agencies to require new NICU providers to meet certain standards as part of the CON review process. For organ transplant services, there are specific requirements, depending on the organ system, and there are minimum utilization thresholds and criteria that need to be met before a CON application would be considered. Data on organ transplant services are not presently suggesting a need for additional programs due to the supply of organs and general utilization patterns. There is no State Health Plan chapter on burn care.

Chairman Nicolay asked if there was second to Dr. Pinkner's motion to continue CON regulation of organ transplant services. The motion was seconded by Commissioner Ginsburg. It was unanimously approved by all members of the Task Force with the exception of Dr. Blumberg, who abstained.

Commissioner Ginsburg made a motion that the Commission retain the CON program for Open Heart Surgery, which was seconded by Dr. Cohen, who noted that the Task Force had not yet considered changes to the CON standards for open heart surgical services. Mr. Tranter asked Dr. Cohen to state his proposed amendment and Dr. Cohen replied that the Task Force should consider making changes to the State Health Plan standards for open heart services.

Chairman Nicolay stated that proposed changes to the State Health Plan standards would be considered at a subsequent meeting and called for a vote on Commissioner Ginsburg's motion, which was approved by all of the task force members present with the exception of Dr. Blumberg.

Dr. Bedrick made a motion that the Commission maintain the CON process for neonatal intensive care units.

In response to Mr. Rosen's request that he clarify his views, Dr. Bedrick expressed reservations about changing the current system. The existing NICUs were established prior to the current, well-defined process set forth in the State Health Plan. There are a certain number of neonatal intensive care units that are existent, operational, have been surveyed by MIEMMS and DHMH, and have been found to be doing a good job. Each has received licensure, for lack of a better term, to continue in its role as a neonatal intensive care unit. In Dr. Bedrick's opinion, Maryland should not have uncontrolled propagation of neonatal intensive care units, therefore, the CON regulation should remain.

Dr. Cohen asked if NICU services need to be subject to CON, as opposed to being required to pass the existing MIEMMS and DHMH standards. Dr. Bedrick explained that one of the problems with neonatal intensive care units is that, until recently, hospitals provided the services and wanted recognition that they had done so. The services were uncontrolled in that regard and that process has come to an end. Currently, a hospital can no longer simply start providing neonatal intensive care services. In the absence of the current regulatory process, one of the concerns would be that if a hospital has an obstetrics service, then it would have the freedom to begin providing neonatal intensive care.

Dr. Blumberg said that though he does not practice obstetrics, he chairs the Claims Committee for Med Mutual, which reviews at least one or two obstetrics cases every month. He argued that as a physician and a citizen, if his wife were pregnant again and she wanted to deliver with her obstetrician at a hospital that he or she recommended, then he would want NICU services available at that hospital. NICU services are a part of the continuum of obstetric services in 2005. He supported removing the CON requirement for NICUs and replacing it with MIEMMS and DHMH licensure.

Ms. Cody remarked that the current CON law, as she understands it, does not prohibit a hospital to state very clearly what it is going to do and to demonstrate, up front, its ability to meet those quality standards. In response to Dr. Pinkner's question regarding when accreditation is given, Dr. Bedrick said that there is a current, stable number of neonatal intensive care units in the state that have gone through a DHMH and MIEMMS combined site visit and accreditation process. There are two NICU units in the state in more rural areas, which have been providing neonatal intensive care, are recognized by the state as having provided the services, and under the new rules, are about to go through the site visit process. Those hospitals will be submitting applications to be certified as perinatal centers. Dr. Bedrick did not know the hospitals' status regarding the HSCRC rate designation for neonatal intensive care or a waiver. They are the only two centers that have been recognized for providing NICU services that will be reviewed for perinatal certification.

Dr. Pinkner asked if any hospital, without a CON, could begin offering NICU services and become accredited afterward. Dr. Bedrick replied that the CON applies to neonatal intensive care units in hospitals that are designated Level III, Level III+, and Level IV. This means that they are taking care of babies of a certain gestational age, requiring a certain amount of technology, at a certain birth weight. There is not a CON process for hospitals that are Level I or Level II providers of special care nursery services. Some hospitals in that category are providing services and are ready to make application to go up to the next level of care. They will be required to go through the CON process, and also the MIEMMS-DHMH certification process, in order to change their designation..

Commissioner Ginsburg asked what the standards are for CON for neonatal intensive care units. Dr. Bedrick replied that every hospital that is providing obstetrics would want to have a neonatal intensive care unit, which is a very expensive infrastructure. In the Baltimore metropolitan region, nearly every hospital that provides obstetrics services has a neonatal intensive care unit.

Due to the lengthy discussion and the time of day, Chairman Nicolay suggested that Dr. Bedrick withdraw his motion and that further discussion of neonatal intensive care units be tabled to the next meeting of the Task Force. Dr. Bedrick declined to withdraw the motion.

Mr. Tranter asked for more information regarding NICU services. He asked if there is a volume/quality relationship in terms of providing Level III or higher NICU services. He also asked what is the difference between a Level II program, which a hospital can have without a CON, and a Level III program, for which a CON is required. Dr. Bedrick responded that there is not the amount of data regarding volume for neonatal intensive care services as there has been

for open heart services. There have been a number of studies done in California that have shown that the smaller programs do a fine job in neonatal intensive care. In the Baltimore region, outcomes for some units that have an average census of 15 patients are as good as those that have a census of 35 or 40. The argument has been made that the much higher volume units may not do as good a job due to limitation of resources for providing the kind of nursing care that these babies need. Generally, for Level I and Level II units, the obstetric and neonatal units take care of larger, more mature babies. For example, assuming that a term baby is 38 weeks gestation, a Level I unit takes care of all full-term, uncomplicated pregnancies and there are few of those in Maryland. There are slightly more Level II units, which take care of babies from term to thirty-three to thirty-four weeks gestation, who are mildly to moderately premature and may need some supplemental care above and beyond normal newborn care like some oxygen or IV therapy. Units that are designated Level III and higher take care of babies of all gestational ages, have the skilled capability to do mechanical ventilation, and have certain subspecialty services available. The American Academy of Pediatrics and the American College of OB/GYN publishes a document called, "Guidelines for Perinatal Care," which outlines the staffing ratios for normal newborns, mildly sick babies, and more critical babies. In response to Mr. Tranter's questions regarding NICU staffing expertise and ratios of nurses to infants, Dr. Bedrick said that there is a big leap between Level II and going to Level III. There is a much different skill set for Level III units, when staff are taking care of babies weighing, perhaps, two pounds who are sick and on ventilators versus Level II units' staffs taking care of babies who may just have a little oxygen hood around their head.

Chairman Nicolay requested that Dr. Bedrick restate his motion regarding NICU services. Dr. Bedrick said made a motion to maintain the current process for CON for NICU in the current structure, which was seconded by Commissioner Ginsburg. Task Force members Bedrick, Bonde, Cody, Holland, Hussein, Mahan, Narang, Pinkner, Suldan, and Wilson voted in favor of the motion; Task Force members Blumberg and Cohen voted in opposition to the motion; and Task Force members Kane, Rosen, and Tranter abstained.

Mr. Rosen said that he had abstained because he did not understand the standards and did not hear an articulation of why CON should be retained when there is no determination of need. In his view, the regulatory process that was described was not a CON process. Dr. Bedrick replied that the neonatal intensive care units were created prior to the creation of the regulatory process regarding the appropriate and necessary leverage, strength, and oversight. Mr. Rosen made a similar comment related to burn units. He said that in spite of his discomfort due to the absence of Ms. Brown from Johns Hopkins Health System, a burn unit provider, he voted in favor of elimination of CON based on the earlier discussion. If further expert information is offered to the Task Force and the issue is reconsidered, he would be happy to have further information

4. Other Business

There was no other business considered by the Task Force. Mr. Tranter requested that his vote regarding the regulation of burn care under the CON program be changed from in favor to an abstention.

5. Adjournment

Chairman Nicolay announced that the next meeting would be held on July 14, 2005 at 1:00 p.m. Mr. Tranter made a motion to adjourn, which was seconded by Ms. Mahan. The Task Force meeting was adjourned at 3:29 p.m.

Summary of the Meeting of the CON Task Force

July 14, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present

Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Robert E. Moffit, Ph.D.
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Terri Twilley, MS, RN
Douglas H. Wilson, Ph.D.

Task Force Members Absent

Commissioner Larry Ginsburg
Hal Cohen, Ph.D.
Anil K. Narang, D.O.
Christine M. Stefanides, RN, CHE

Members of the Public Present

Carla Bailey, Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Clarence Brewton, MedStar Health
Andrew Cohen, AGC and Associates

Miles Cole, Maryland Department of Business and Economic Development
Carolyn Core, Civista Health, Inc.
Richard Coughlan, Cohen, Rutherford + Knight
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver
Sean Flanagan, St. Joseph Medical Center
Richard Gasparotti, Adams Management Services
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Anne Langley, Johns Hopkins Health System
Ann Mitchell, Montgomery Hospice
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Martha Nathanson, LifeBridge Health
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Olivia Stewart, Jack Neil & Associates
Paula S. Widerlite, Adventist HealthCare
Greg Vasas, CareFirst Blue Cross Blue Shield of Maryland

1. Call to Order

Commission Chairman Stephen J. Salamon thanked the members of the Task Force for their service to the Commission and introduced the Commission's new Executive Director, Rex M. Cowdry, M.D.

Chairman Robert E. Nicolay noted his service as chair of the search committee that selected Dr. Cowdry, and welcomed him to the Commission. He then called the meeting to order at 1:10 p.m.

2. Approval of the Previous Minutes (June 23, 2005)

Chairman Nicolay noted that members have received copies of the minutes from the June 23, 2005 Task Force meeting, and that several members have commented on how comprehensively the minutes captured the extensive discussion and deliberation at the last meeting. He drew the attention of the Task Force members to two issues, one a correction, and the other a potential need for further clarification. The first of these is on page 17 of the June 23rd minutes, paragraph 4, which, instead referring to a "vote on Dr. [Lawrence] Pinkner's motion," should read "Commissioner [Larry] Ginsburg's motion." Chairman Nicolay asked staff to make that correction, and then asked Pamela Barclay, Deputy Director for Health Resources, to highlight the other area of the June 23rd minutes that may need clarification.

Ms. Barclay called Task Force members' attention to the discussion in the minutes on the Certificate of Need requirement for closures of non-hospital health care facilities.[4] Staff wanted

[4] Hospitals in jurisdictions with three or more hospitals are only required to notify the Commission and hold a public informational hearing before the closure of a hospital or a hospital medical service, while a hospital in a jurisdiction with one or two hospitals must receive an exemption from Certificate of Need from the Commission before such a closure.

to confirm that the consensus of the Task Force on this question was it favored retaining a notification requirement, but wanted to eliminate the requirement for Certificate of Need exemption, where it applies, and for the public hearing.

Chairman Nicolay asked if anyone had a different recollection of the discussion, or wanted to add anything to this section of the minutes; no one offered further comment on that issue. The Chairman recognized Jack Tranter, who asked for a correction to another item. Following a discussion near the end of the previous meeting, Mr. Tranter had concurred with Barry Rosen's observation that the Task Force should not decide whether to continue Certificate of Need coverage of burn care units in Maryland in the absence of Patricia M. C. Brown of the Johns Hopkins Health System (JHHS). The only burn care unit in Maryland is at the Johns Hopkins Bayview Medical Center, a JHHS member. Mr. Tranter noted that he then asked to change his vote in favor of removing the Certificate of Need requirement from burn care units to an abstention, and he asked that the minutes reflect that change.

Chairman Nicolay asked staff to change the draft minutes accordingly, and then asked for any other additions or corrections to the minutes of the June 23, 2005 Task Force meeting. Hearing none, he called for a motion to approve these minutes as corrected. The motion was seconded and carried.

3. Review and Discussion of the Public Comments Received on the CON Program

- **Recap of June 23, 2005 Meeting**

Chairman Nicolay began his recap of the June 23rd Task Force meeting by recalling the thoughtful and comprehensive debate on the issue of deregulating hospice programs from Certificate of Need review, and noted that he had scheduled the conclusion of that discussion for a future meeting, at member Lynn Bonde's request. He also noted that the Task Force had decided at that meeting that clinically related information technology should not require Certificate of Need review; counsel will determine if Commission statute needs a specific provision to that effect. Chairman Nicolay then observed that, while the Task Force has made good progress, much remains to discuss and decide upon, so he proposed to add two meetings to the schedule. In addition, responding to comments by a number of members who believed that they needed more background on the issues before the Task Force, the Chairman has decided to take a different approach to the remaining issues of Certificate of Need coverage and process that were raised in the Public Forum and subsequent written comments. Prior to consideration of each issue, the members will receive a brief working paper outlining its current statutory and regulatory requirements, and summarizing the views expressed in the public comment provided to the Task Force. As we conclude the discussion of each issue, we will vote in order to have a sense of the Task Force's view, in effect as a straw vote, since the Task Force will consider and vote on a final report with all of its proposed recommendations to the Commission, at the conclusion of its work in September.

- **Principles to Guide the CON Program**

The Chairman then moved to a consideration of the draft "Guiding Principles for the Maryland Certificate of Need Program," asking for members' thoughts and recommendations on this summary of what those who presented comments to the Task Force believe should be the fundamental framework and purpose of CON.

Ms. Brown of the Johns Hopkins Health System began by apologizing for not attending the previous meeting, and asked if the Task Force would apply the guiding principles under discussion today to some of the issues that it discussed and voted on at that meeting. She asked the Chairman if she should state for the record the position of her organization on the Task Force's decision with regard to Certificate of Need coverage for burn care units as part of the discussion on guiding principles. The Chairman asked that the Task Force now consider the Guiding Principles document, but assured Ms. Brown that she could address the burn care issue, and that the full Task Force would revisit its decision as part of the total package of recommendations it will forward to the Commission.

Task Force member Albert Blumberg, M.D. said that he hoped that the Task Force would – once it agreed upon these guiding principles – apply them both to the issues previously discussed, as well as to its future deliberations. With regard to the principle of Certificate of Need as a means of improving the quality of a health care service, he stated his view that Certificate of Need does not function in that way, that it functions as a requirement to meet in order to initiate a service, but cannot guarantee the quality or safety of that service. That is not the purview of this Commission and the CON process, but instead of the licensure process, which we discussed extensively at the last meeting. One could argue, he said, that the CON process allows an opportunity to create quality and safety standards, because without that commitment, a potential provider would probably not receive Certificate of Need approval. However, since the Commission is not the entity with responsibility for seeing that providers keep their commitment to meet quality standards, he wanted to see that particular principle reworded or eliminated.

Mr. Rosen disagreed, maintaining that the CON process is related to safety, particularly in the health care services where a demonstrable correlation exists between volume and the quality and safety, and therefore provides a legitimate reason to restrict the number of providers of that service. Dr. Blumberg responded that, in his view, it was impossible for a proposed new provider to predict its volume would be, and that through the Certificate of Need process, a provider just makes a commitment to meet a minimum volume standard. Mr. Rosen maintained that in some services, giving cardiac surgery and interventional cardiology as an example, scientific studies establish the volume levels associated with safe operation and good outcomes, and that, if projected numbers of cases fall below that number, a new program will not meet that volume standard. Providers below that number of cases should lose their Certificate of Need authority. In services where volume and safety are related, the CON process protects that relationship by restricting the number of providers, and new services should only be considered in areas of rapid population growth, since that growth indicates that a new service will meet those minimum volume thresholds.

Dr. Blumberg asked if Mr. Rosen's view of the volume-quality relationship also applied to the discussion at the previous meeting of the rationale for restricting new providers from entering any market in which the number of potential users of that service is finite – specifically cited in support of continuing Certificate of Need coverage of hospice services. Mr. Rosen affirmed that the volume-quality issue could also apply to hospice, although other considerations might, as well, such as access (the concern that more hospice providers would choose to serve wealthier or more populated areas) and the effect of unrestricted entry of new providers on the margins of existing providers, and thus their ability to serve their patients.

In support of Mr. Rosen's comments, Mr. Tranter reminded Dr. Blumberg of the successive Commission task forces and committees charged with examining the clinical research and evidence on the volume-quality correlation in cardiac surgery, which have determined that this benchmark should be set at 200 cases per year. This is the benchmark in the State Health Plan, which now provides that a proposed new program must demonstrate and document – through surveys of cases that cardiologists will refer, and other means – its ability to meet and stay at that level of surgical volume. The Plan also provides that, if your program drops below that volume-quality threshold, it must relinquish its Certificate of Need authority. This is just one example of where there is a quality element to the regulatory process.

Adam Kane observed that the underlying assumption in this part of the draft Guiding Principles -- that restricting access of new providers to a market improves quality – does not recognize another important relationship – that increasing competition can also promote quality. He suggested that the phrase "improve the quality and safety of these services" is too broad, since, in some services, other mechanisms may improve quality and safety. Mr. Kane suggested narrowing that part of the principles to focus on services with a strong nexus between volume and quality or safety.

Task Force member Annice Cody disagreed that the Certificate of Need process only promotes quality of care in health care services where quantitative research has confirmed a quality-volume connection. As part of the review process, applicants can demonstrate the quality of their services in various ways, and Certificate of Need reviews often compare competing applications according to the ways in which each proposes to address issues of quality and safety.

Henry Meilman, M.D. offered observations, related to several previous comments. First, he questioned whether the award of a Certificate of Need should be permanent, or, instead, whether the authority it confers should be periodically reviewed for adherence to representations of projected volumes and quality of care. The volume-quality relationship, certainly for cardiac services, is real, and those of us involved in that issue in this state are still grappling with how to measure outcomes in cardiovascular procedures. We have had many good ideas, including modeling a quality measurement system after the New England quality improvement project, but we certainly have a way to go to continue to improve outcomes on an ongoing basis. During the last consideration of open heart surgery-related bills in Annapolis, seven different hospitals thought they needed to provide open heart programs; clearly, adding seven new cardiac surgery programs to the denominator, and maintaining a static or decreasing number of cases as the numerator, could decrease average volumes over all programs. This would have profound

implications from a volume-quality perspective, and could affect the access of the indigent population in the cities to the service, seriously disrupting the provision of this service across the state. While Maryland's regulatory framework for this service may not be perfect, Dr. Meilman observed that -- in his experience at both a so-called "have-not" hospital and a hospital with a cardiac surgery program – the Certificate of Need program has predicted the need and designated the right programs, which have all succeeded, and developed into Top-100 programs nationwide.

Dr. Blumberg stated that, after listening to this discussion, the use of the word "improve" still seems inappropriate in the wording of the principle in question. While he considered suggesting the word "insure," that word also implies a role in what he sees as the ongoing function of the state's licensure program. He instead proposed changing the principle to state that Maryland's CON program should *promote* quality and safety of the health care services it covers, since that is what he thinks the CON process is doing.

Lynne Bonde spoke in support of Dr. Meilman's comments, which she believes clearly also apply to the regulation of hospice programs. The Certificate of Need review threshold for consideration of new hospices is a projection of 250 additional hospice clients in a given jurisdiction. That allows growth in provider numbers that maintains the level that existing providers can serve, maintains their survivability and maintains the quality. Whether we use the word improve or the word promote in our principle does not matter as much as maintaining the concept that quality of care is an important consideration.

Patty Brown agreed that the final wording is less important than the continued inclusion of quality of health care services as a fundamental principle in Certificate of Need review. She noted that, twenty years ago when she became involved in health planning issues, the staff of this Commission's predecessor agency believed strongly that it played a critical role in improving the quality of health care in the State of Maryland, and this was a responsibility that they did not simply relinquish to the State licensing agency. She questioned whether the Commission still believes it has a continuing responsibility and an important role to play in improving quality, through the standards it adopts in the State Health Plan. Without its quality improvement component, the purpose of the Plan comes into question, and, if the conclusion is that the Plan functions only to deal with the competitive aspects of the Certificate of Need program, Ms. Brown said, that represents a fundamental shift in the philosophy of the Commission over the years.

Dr. Meilman noted that the National Heart, Lung, and Blood Institute [of the National Institutes for Health] published a report on cardiovascular disease outcomes research, quoting the Institute of Medicine [of the National Academy of Sciences]. This report included a ***Blueprint for Improving Health Care Delivery***, which identified six core goals for the future of American health care: safety, effectiveness, equity, efficiency, timeliness, and patient-centeredness. He observed that these were laudable goals and directly relevant to the Task Force's discussion on guiding principles for the Certificate of Need program.

Mr. Tranter suggested that before the Task Force decides, or even discusses further, these draft guiding principles, it would be useful for us to review what statute says, and what the legislature has clearly outlined as the Commission's responsibilities and proper focus. While

some may disagree on the principles set forth in the enabling statute, we should apply this analytical measuring stick to anything this group eventually agrees upon, and recommends to the Commission.

Ms. Barclay agreed that this would be helpful for the group, and suggested that staff bring back a revised draft of the Guiding Principles document, along with the statute's statement of the Commission's duties and responsibilities, to the next meeting of the Task Force. Alan Bedrick, M.D. asked if the Commission has a mission and a vision statement. Ms. Barclay replied that the Commission has an overall mission and vision statement, and, in each chapter of the State Health Plan, articulates the policies and principles behind the system goals and review standards applicable to each covered health care service. In developing the draft Guiding Principles, Ms. Barclay noted, staff focused entirely on the proposals by the six commenters who wanted the Task Force to consider re-examining the overall principles that should shape the Certificate of Need program.

Ms. Cody noted that one concern she had with the present draft was that it focused on the program's role in preventing negative events in the health care system, and not enough on promoting good things, on promoting positive public policy goals. Dr. Bedrick concurred with this, also wanting to see more emphasis on the positive effects that Certificate of Need can achieve in the provision of health care services.

Dr. Cowdry observed that the Commission's mission statement has breadth, but not specificity, espousing the general concepts of cost containment and quality of care, but silent on the details of how that should be accomplished, and how the Commission's role should relate to that of the health department and its administrations. He noted that a key priority for staff in the next year would be to examine how the Certificate of Need process relates to licensure, in its quality enforcement activities, and how it relates to the work of other key agencies, such as the health Services Cost Review Commission. Dr. Cowdry agreed with the previous comments urging an emphasis on positive outcomes, suggesting that the Task Force's decisions on whether to continue Certificate of Need coverage for a given service should seek a balance between the potential positive and negative effects of increased competition. The focus should be on whether a strong enough justification exists – in the potential impact of increased competition on the cost and quality of care -- to intervene with Certificate of Need. Mr. Tranter recalled the term "managed competition," often used in past discussions on these issues, to describe this ideal of a balance between regulation and competition.

Ms. Bonde said that it was extremely important not to omit access to care from this set of factors, and to consider the potential effects of increased competition will do to access to certain services by underserved otherwise vulnerable populations. Mr. Rosen said that this effort to re-examine and articulate the guiding principles behind the Certificate of Need program, within its statutory context, is arguably the most important work of the Task Force, because these principles will be reflected in future planning activities and regulatory decisions, making them more predictable and clear to the Commission's constituencies.

Chairman Nicolay said that he would work with staff to revise and refine the draft principles, and bring them back to the Task Force for further review. They will be part of the

entire package of recommendations on which the Task Force will vote, before forwarding them to the Commission in September.

- **Coverage by CON Review**
  -Obstetric Services
  -Home Health Agency Services

Chairman Nicolay then opened the Task Force's discussion on the summary table of issues involved in whether to continue Certificate of Need regulation of new inpatient obstetrics programs.

William Chester, M.D. expressed support for continuing to require Certificate of Need to establish new inpatient obstetrics programs, because he believes, based upon his anesthesiology practice at a hospital with a high-volume obstetrics program, that high volumes are critical to maintaining the skill level of obstetrics practitioners and staff. Maintaining program staff of sufficient size and expertise to provide the necessary back up to support a 24 hour-seven-day service is only sustainable in a large volume service. He also noted that, with regard to the challenges presented to obstetricians and their hospitals by rising malpractice insurance premiums, incidence of questionable outcomes are demonstrably lower in high-volume programs.

Dr. Bedrick stated that, on this issue, he represents the position adopted by the Maryland Chapter of the American Academy of Pediatrics, not Franklin Square Hospital Center, where he practices, or MedStar Health, its parent corporation. He urged that members bring their collective expertise to this issue and approach it from the perspective of good public health policy, not individual private interests. He pointed out that the annual number of births is projected to remain stable or decrease, which means that new programs can only reduce volumes at existing ones. In addition, increasing the number of obstetrics programs would only marginally improve access to these services, since more than 98 percent of Maryland women of childbearing age have access to an existing program within a 30-minute drive time. The negative effect of increasing the number of obstetrics programs would offset any marginal increase in access; chief among these would be further strain on already serious staffing shortages. He stated that the Fetus and Newborn Committee of the Maryland Chapter of the American Academy of Pediatrics voted unanimously to support continuation of Certificate of Need coverage for new obstetrics programs.

Douglas Wilson, Ph.D. noted that many categories of health personnel needed to operate an obstetrics program are in seriously short supply, including obstetricians themselves; he believed that the University of Maryland Medical School had no applicants last year for its OB residency program, since the specialty is particularly affected by the crisis in malpractice insurance costs. Dr. Wilson stated that further diluting an already too-small pool of professionals would be detrimental to the state, and so he would support maintaining the Certificate of Need requirement for this service.

Mr. Kane asked if staff could provide information on whether other states with Certificate of Need programs regulate this service. Chairman Nicolay noted that this information is in background materials previously distributed to the Task Force, the latest state surveys by the American Health Planning Association indicate that sixteen of the 37 states (plus the District of Columbia) with Certificate of Need programs require Certificate of Need to establish new OB programs. Mr. Kane then asked about the difference between the services provided by inpatient obstetrics programs versus freestanding birthing centers.

Dr. Bedrick explained these differences, in setting, staffing, equipment, and services offered. He explained that the small number of freestanding birthing centers in Maryland are staffed by nurse-midwives, and intended for mothers with low-risk pregnancies.

Mr. Kane then questioned the rationale for requiring Certificate of Need approval for new inpatient obstetrics programs, but only licensure for freestanding birthing centers. Dr. Bedrick responded that, because unforeseen situations may always arise during labor and delivery, and so proximity to and transfer agreements with acute care hospitals (for emergency Caesarian sections and neonatal specialty care) are crucial. Bad outcomes for infants result from delays in obtaining the higher level of care, which is only provided by an acute general hospital with obstetrics and pediatrics services.

Dr. Blumberg spoke against maintaining the Certificate of Need requirement for new OB services, since he believes that decisions to offer a medical service should be under the authority of a hospital's board of directors. He said that the fact that 170 women in labor reportedly came or were transported to North Arundel Hospital [recently renamed Baltimore-Washington Medical Center] was cause for concern. He noted that staffing shortages exist in all medical specialties, not only obstetrics, and that the major problem in OB is the shortage of obstetricians, because of the still-unresolved malpractice insurance crisis. Dr. Blumberg said that Certificate of Need regulation was unnecessary for this service, that the marketplace will regulate it.

Mr. Tranter began by disclosing his representation of the former North Arundel Hospital in Certificate of Need matters now pending before the Commission, including an application to establish a new obstetrics program. He argued that obstetrics is a basic hospital service, and that it makes no sense that North Arundel has established a birthing center across the street from the hospital by obtaining a license, but must obtain Certificate of Need approval before establishing an inpatient obstetrics service in the hospital. Licensing and JCAHO accreditation is sufficient to regulate obstetrics, pediatrics, and other basic services offered by acute care hospitals.

Dr. Pinkner stated his support for continuing to require Certificate of Need approval for new obstetrics units, since the process provides an opportunity for an applicant to demonstrate that a new service is needed. He asked why freestanding birthing centers may be established under Maryland law without Certificate of Need review. Ms. Barclay responded that Commission statute does not include freestanding birthing centers in its list of definitions of what constitutes a "health care facility" for purposes of Certificate of Need coverage. She explained that State licensing statute includes freestanding birthing centers in its umbrella definition "ambulatory care facilities," and noted that only five of these centers now operate in Maryland. A very small number of births take place in these freestanding centers -- on average,

substantially fewer than one thousand babies of the approximately 75,000 births typical of recent years. Ms. Barclay also noted that, since the North Arundel Hospital application is currently under review before the Commission, it would not be appropriate to comment further on anything specifically related to that matter.

Ms. Cody stated that the changes in the State Health Plan adopted specifically to guide the Commission's consideration of proposed new obstetrics services is beneficial, since it does not preclude approval of a new program in the context of stable or declining births, provided that the applicant can demonstrate a clear public benefit offered by the proposed program. Using the State Health Plan and the Certificate of Need process to achieve a public health benefit is consistent with the principles the Task Force discussed earlier.

Mr. Rosen noted that many comments to the Task Force cited the need to revise and update the State Health Plan, and that the different sections of the State Health Plan take different approaches to defining need and establishing standards used in Certificate of Need reviews for the service in question. He maintained that, as part of its mandate, the Task Force could advocate changes to the Plan, perhaps establishing as its consistent framework the balance among factors of costs and benefits described earlier by Dr. Cowdry.

Mr. Tranter referenced the earlier characterization by Ms. Cody and Ms. Barclay of the current State Health Plan for Obstetric Services, calling the different approach to the demonstration of need a positive step. The obstetrics as well as the cardiac surgery/interventional cardiology sections of the Plan have moved beyond simplistic, mathematical need projections, to a more complex balance between potential costs and potential benefits of approving a proposed new service. However, the issue remains, with regard to obstetrics, that a hospital needs Certificate of Need approval to establish a new service as fundamental to acute care as obstetrics, but may obtain a license and establish a freestanding birthing center across the street.

Dr. Bedrick described birthing centers as an anomaly in the system, suggesting that – despite some imperfections and inconsistencies in the way Maryland statute regulates the different levels of this service – we seek to improve the system, not discard it. He urged the Task Force to consider whether it should recommend adding freestanding birthing centers to those requiring Certificate of Need approval. Dr. Pinkner raised a similar point, asking if part of the Task Force's purview included recommending additional services for Certificate of Need coverage. Chairman Nicolay confirmed that the group could consider such a recommendation.

Carlessia A. Hussein, Dr.P.H. asked if the Commission has access to any outcomes data on births at freestanding birthing centers, as compared to Certificate of Need-regulated inpatient obstetrics settings at acute care hospitals. Her responsibilities at the state health department, related to quality of care and access disparities experienced by minority populations, include finding ways to address the persistent issue of infant mortality. Concern over the contributing causes of infant mortality and poor birth outcomes would seem to argue in favor of more management and oversight of new obstetrics services, not less.

Ms. Barclay responded that the state health department has some birth outcome data collected through the birth certificate registration process, but that she was not sure if that data is publicly available. Staff will obtain whatever data is available on this issue.

Dr. Chester noted that births at freestanding birthing centers are to a pre-screened group of mothers, a low-risk population, but that a significant degree of back-up and emergency transport must nevertheless be available. Obstetrics is not a basic service, and it is often a high-risk service. He stated his strong belief that the staffing availability issues are extremely important, and that there are "immeasurable benefits" to receiving care from teams of professionals in a high-volume hospital. These volumes are maintained by continuing the Certificate of Need coverage for this service.

Chairman Nicolay asked if the Task Force felt prepared to take a straw vote on this subject, which the group would then revisit when it considers its final report and recommendations to the Commission in September.

Mr. Kane asked if we have data from the states that do not regulate the establishment of new obstetrics services through Certificate of Need, with which we could compare the cost, outcomes, and availability of necessary staff, with Maryland's performance in those areas. Ms. Barclay replied that we do not have specific data from other states related to volumes, quality, or cost. Dr. Cowdry stated that staff would look for data and examine the literature to determine how strong a correlation exists, in obstetrics, between volumes and quality of care. He observed that if these benefits were not measurable, they might be questionable.

Dr. Chester replied that if one examined only the relatively absolute outcomes such as death, or lower Apgar scores, the benefits of a more experienced professional team working in a high-volume obstetrics program might not be quantifiable. However, he argued, in clinical situations requiring urgent decisions affecting the outcome of the pregnancy and the health of the newborn, a team with more experience will make better decisions. This is true even if that effect of those decisions is not immediately verifiable or readily measured.

Dr. Blumberg observed that he was unaware of any medical service in which experience did not increase expertise and quality of care, but that there are many areas of medical practice in professionals achieve and safeguard quality in the absence of the requirement of Certificate of Need approval. In addition, he said, he viewed the fact that 172 women in labor came or were brought to the emergency department at Baltimore-Washington Medical Center in FY 2004 as a failure of the Certificate of Need system, although, in this area, the real problem is how to convince a sub-population of women to get early and effective prenatal care.

Ms. Brown noted that encouraging the more effective and accessible provision of prenatal care could be accomplished through the State Health Plan. She expressed concern about what seems to be, in the context of this discussion, a selection among acute care services, of which to regulate and which to deregulate. She reminded the group that the Commission statute provides for Certificate of Need regulation of all acute care services, and said that nothing in the draft Guiding Principles document supports the selective deregulation of certain services within this general category. The only changes proposed to the fundamental statutory framework of

Certificate of Need coverage of acute care services have arisen from an entity's failure to receive Certificate of Need approval for a certain service. Ms. Brown applied the same principle, and had the same concern, about the tentative Task Force decision to single out burn care for deregulation, from among the specialized acute care services covered by Certificate of Need.

Ms. Barclay responded that the Task Force received comment from several persons and organizations on the issue of deregulating obstetrics from Certificate of Need review, which is why it is on the group's agenda for consideration.

Natalie Holland asked if, rather than consider a selective deregulation from Certificate of Need, it might be preferable to revise the State Health Plan to permit different ways to consider proposed new services. Ms. Barclay noted that the Commission's charge to the Task Force did not involve the specific consideration of comprehensive changes to the State Health Plan, but a more focused examination of the Certificate of Need process through which the Plan is implemented. Chairman Nicolay stated that the need to update the State Health Plan has been a recurrent theme among comments to and discussions among the Task Force, and that Commissioners and staff agreed that this is a priority.

Chairman Nicolay asked Dr. Chester if he had any data relevant to the volume-quality relationship in the provision of inpatient obstetrics services. Dr. Chester replied that he had pulled an article from the Journal of the American Society of Anesthesiologists that recommended the closure of low-volume obstetrics programs, but noted that the article did not include such data. He said that he would review literature and positions from the American College of Obstetrics and Gynecology (ACOG) and other organizations for relevant data.

Ms. Bonde noted that only one hospital (of the fourteen hospitals without an obstetrics program) has a Certificate of Need application pending to establish a new obstetrics service, and asked what the benefit would be to removing the Certificate of Need requirement. Joel Suldan stated that the Commission faces very challenging resource issues, and if deregulation of an individual service does not cause harm, Certificate of Need coverage should be discontinued for that service.

Chairman Nicolay ended discussion and called for the preliminary vote. Thirteen members voted to retain Certificate of Need coverage for new obstetric services (Bedrick, Bonde, Brown, Chester, Cody, Holland, Hussein, Mahan, Meilman, Pinkner, Rosen, Twilley, and Wilson) and six (Blumberg, Kane, Moffit, Pommett, Suldan, and Tranter) voted to eliminate this coverage.

The Chairman then moved the group to the consideration of whether to continue the Certificate of Need requirement to establish new home health agencies, and to expand existing agencies.

Terri Twilley began this discussion by noting that she represented an organization whose membership includes home care providers at all levels, including Medicare-certified home health agencies. Her organization is split on the question of retaining Certificate of Need coverage for this level of home health care, but clear in its view that, if Certificate of Need is retained, the

authority to operate an agency in specific jurisdictions should be enforced. Currently, there are many different levels of home care providers, and some, such as residential service agencies, are providing services that are reserved by licensure standards for home health agencies; this should be better enforced.

Dr. Blumberg said that he appreciated the very informative background paper on this service. He stated his position that the marketplace can do, and is doing, an adequate job of regulating the use of this service, through the stringent admission criteria enforced by Medicare, as the predominant payer. Mr. Kane agreed, adding that there is little capital cost to establishing a home health agency, and therefore minimal impact in the areas Certificate of Need has historically focused on.

Dr. Hussein asked Ms. Twilley if removing the Certificate of Need requirement would have a negative impact on quality of care by home health agencies. Ms. Twilley responded that the shortage of nurses and other professionals poses the greatest challenge to maintaining the quality of home health care, and that the Office of Health Care Quality (OHCQ), charged with enforcing licensure standards, is seriously overburdened.

Commissioner Robert Moffit concurred with Dr. Blumberg and Mr. Kane that Medicare regulations provide strict controls on the operation and utilization of home health agencies, whose services should be increasingly needed with the aging of the population. He observed that the federal government has tightened its control over home health agencies considerably in recent years, with more requirements and lower reimbursement. He noted that the imposition of increased duties and a prospective payment system in the Balanced Budget Act if 1997 resulted in the closure of 2,800 home health agencies nationwide. He advocated a greater degree of regulatory freedom for this sector of the health care delivery system.

Ms. Holland asked if an access to care problem exists for home health agency services. Ms. Barclay responded that all Maryland jurisdictions are served by at least one Medicare-certified agency. Ms. Bonde asked Ms. Twilley if the industry has considered the impact of deregulation from Certificate of Need coverage. Ms. Twilley replied that, because her organization represents home care providers in all categories, Certificate of Need-regulated and not regulated, opinions on the impact of deregulation vary accordingly.

Dr. Bedrick asked whether data that the Commission collects annually from existing home health agencies duplicates data collected under the Medicare-mandated OASIS program. Ms. Barclay responded that the Commission's annual survey elicits aggregate data from agencies on the number and the overall characteristics of clients served in each authorized jurisdiction.[5] The OASIS data collection instrument – put into place subsequent to the Commission's annual survey -- is much more detailed and extensive, and permits Medicare to assess the level and extent of care provided to home health agency clients, as well as to monitor quality of care issues. Commissioner Moffit described OASIS as an extensive tool to measure the quality of care provided by home health agencies. Ms. Bonde expressed concern that, in the absence of the

[5] The Office of Health Care Quality has historically considered this annual survey by the Commission the "annual report" required of home health agencies by licensing statute at §19-404(c)(6).

initial review of quality-related capabilities provided by the Certificate of Need process, the entire burden falls on the already-overburdened OHCQ, to enforce both licensure standards and Medicare Conditions of Participation, since OHCQ is Medicare's agent in Maryland. Ms. Twilley noted that OHCQ has responsibility for monitoring compliance with licensure standards by residential service agencies, but cannot adequately oversee that part of the home care sector.

Chairman Nicolay called for a preliminary vote on the question of whether to continue the Certificate of Need requirement for home health agencies. Five members voted to retain Certificate of Need coverage (Bedrick, Bonde, Cody, Pommett, and Wilson), three members abstained (Mahan, Tranter, Twilley), and eleven members voted to deregulate the service from Certificate of Need (Blumberg, Brown, Chester, Holland, Hussein, Kane, Meilman, Moffit, Pinkner, Rosen, and Suldan).

Chairman Nicolay recognized Ms. Brown, who wished to state her position (and that of the Johns Hopkins Health System) of opposition to removing the Certificate of Need requirement for burn care programs, thereby treating this service differently from the other specialized services regulated by Certificate of Need. She indicated her willingness to bring the Johns Hopkins Bayview Medical Center's new burn care director to address the Task Force, and noted that the director confirmed to her that significant issues exist in burn care, with respect to the relationship between volume and maintaining high quality of care. All of these specialized services now regulated through Certificate of Need – burn care, cardiac surgery, NICU, and transplant surgery -- share certain characteristics, most notably their high operating costs, and this correlation between volume of cases and high quality of care. Thankfully, because of the fire safety programs now in place, as a regional burn care center we struggle to maintain the case volumes required by our accreditation agency, the American Burn Association. We do not want to see duplication of these services.

Chairman Nicolay asked if Ms. Brown could supply a written position and further information, to be distributed to the Task Force, so that the Task Force could revisit this issue in a future meeting.

4. <u>Other Business</u>

- Future Meeting Schedule

Chairman Nicolay announced the addition of two meetings, on August 25 and September 8, 2005.

5. <u>Adjournment</u>

Dr. Wilson made a motion to adjourn, which Dr. Meilman seconded. The Task Force meeting adjourned at 3:00 p.m.

Revised August 25, 2005

Summary of the Meeting of the CON Task Force

August 11, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present
Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
Annice Cody
Hal Cohen, Ph.D.
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Lawrence Pinkner, M.D.
Joel Suldan, Esquire
Christine M. Stefanides, RN, CHE
Douglas H. Wilson, Ph.D.
Elizabeth Weglein

Task Force Members Absent
Commissioner Robert E. Moffit, Ph.D.
William L. Chester, M.D.
Michelle Mahan
Henry Meilman, M.D.
Anil K. Narang, D.O.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Jack Tranter, Esquire

Members of the Public Present
Erwin E. Abrams, Hospice Network of Maryland
Robert Ascher, Jewish Family Services
Clarence Brewton, MedStar Health
Regina Bodnar, Hospice of Baltimore
Amy Broderick, Hospice Network of Maryland
Nancy Creighton, St. Agnes HealthCare
Sean Flanagan, St. Joseph Medical Center
Valerie Fox, Stella Maris
Shelley Garfield
Peg Green, HomeCall Hospice
Margaret Hadley, Holy Cross Hospital

Elton Hankins, Coastal Hospital, Inc.
Marie Harkova, Shore Home Care Hospice
Wynee Hawk, Greater Baltimore Medical Center
Katherine Hax, Kaiser Permanente
Kevin Ireland, Coastal Hospice
Deron Johnson, Maryland Ambulatory Surgical Association
Anne Langley, Johns Hopkins Health System
Michael McHale, Community Hospices
Denise Matricciani, MHA: Association of Maryland Hospitals & Health Systems
Ann Mitchell, Montgomery Hospice
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Vanessa Purnell, MedStar Health
Barbara Ray, Hospice Caring
Laura Resh, Carroll Hospital Center
Joyce Sexton, JSSA Hospice
Maryanne Shiply, Capital Hospice
Stephanie Smith, Heartland Hospice
Olivia Stewart, Jack Neil & Associates
Gail Thompson, Kaiser Permanente

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:05 p.m. and welcomed Task Force members and the public. He introduced a new Task Force member, Elizabeth Weglein, who replaced Terri Twilley, MS, RN as a representative of home health agency providers.

2. Approval of the Previous Minutes (June 23, 2005, revised and July 11, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the revised June 23rd and the July 14th minutes and asked for any comments, changes, or corrections. Dr. Albert Blumberg made a motion to approve the revised June 23, 2005 minutes, which was seconded by Dr. Lawrence Pinkner, and unanimously approved. Annice Cody requested that the July 14th minutes be revised to reflect her vote in favor of retaining Certificate of Need for home health agency services, and Dr. Blumberg requested revision of a quote attributed to him in paragraph 6 on page 11. Dr. Blumberg made a motion to approve the minutes, as amended, which was seconded by Dr. Pinkner, and unanimously approved.

3. Review and Discussion of the Public Comments Received on the CON Program

- **Recap of the July 14, 2005 Meeting**

Chairman Nicolay presented a recap of the July 14th meeting. He noted the excellent quality of the comments received regarding what the group believes should constitute the guiding principles of the Certificate of Need program, and recalled similarly thoughtful discussion on issues of Certificate of Need coverage of inpatient obstetric services, home health agency services, and for burn care services. Patricia M.C. Brown, representing The Johns Hopkins Health System, requested that the Task Force reconsider its preliminary recommendation to deregulate burn care services from Certificate of Need. Chairman Nicolay noted that Ms. Brown had promised to submit a position paper on this subject, prior

to a re-consideration of the issue by the Task Force. Ms. Brown again expressed her concern about the nature and effect of votes taken by the Task Force on each of these coverage issues. Chairman Nicolay reiterated that these were only preliminary votes to gauge the sense of the group, and that the Task Force would have the opportunity to revisit these issues when it considers its draft report and recommendations to the full Commission.

- **Coverage by CON Review: Hospice Services**

Chairman Nicolay provided a summary of the Task Force's earlier hospice debate and of the additional information provided to the members, and indicated that he would ask the members to take a vote on this issue. Lynn Bonde noted for the record that the hospice community of Maryland was present in some force, with representatives of hospices from all over the state. Their presence reflected the concern of the hospice community on the work of this Task Force and the outcome of this particular discussion.

Chairman Nicolay thanked the hospice representatives for attending the meeting and listening to the debate. In response to Commissioner Larry Ginsburg's request for clarification on the nature of the Task Force's votes, the Chairman reiterated that all of the votes to date were preliminary in nature. Staff will draft a report and recommendations based on the deliberations of the Task Force, which will come to the group for its consideration. Once this document is final, it will be forwarded to the full Commission for consideration and action.

Ms. Bonde thanked the staff for preparing a comprehensive issue paper for the Task Force, and collecting data about hospice in Maryland and across the country. She emphasized that the current CON regulatory structure for hospice has produced enormous benefits for the people in Maryland, and suggested that those who would argue to eliminate that regulatory structure have not addressed the consequences to the people of this state. She expressed concern about the speculative nature of comments made during the previous Task Force discussion, to the effect that more competition in hospice – an unrestricted growth in the number of new agencies -- will produce either more hospice patients or better outcomes for hospice patients. Ms. Bonde cited anecdotal evidence, provided in a letter to the Task Force from Ann Mitchell of Montgomery Hospice, that hospices in states without CON struggle to provide care, struggle with one another, and have to divert patient care resources to competitive concerns.

Ms. Bonde observed that in Maryland, Certificate of Need does not bar entry into the hospice care market, but does control entry. The chart included in the staff's issue brief indicates that hospices have changed hands, new hospices have come into the market, and new CONs have been issued in accordance with the State Health Plan. While she found nothing particularly compelling in the argument to deregulate, there was something very compelling about the negative consequences to the existing hospices, but also, and most importantly, to patients and their families, if hospice care programs are deregulated from Certificate of Need coverage.

Dr. Blumberg explained that his comments in favor of deregulation during the earlier discussion did not specifically address coverage of hospice programs, as much as they reflected his inherent negative feeling about the way that the CON process is administered in general, and particularly about inconsistencies in the level and nature of regulatory requirements applicable to similar kinds of medical services. Following the group's previous discussion about hospice, and

specifically as a result concerns expressed by Task Force member Adam Kane at that time about ensuring continuity of care for residents at Erickson retirement communities, Dr. Blumberg said that he spoke to a friend who serves as medical director of several area nursing homes, whose viewpoint Dr. Blumberg wanted to share with Task Force members. His physician friend is very much in favor of maintaining the hospice Certificate of Need, for several reasons: he believes that hospice is an important benefit to his patients, that sufficient programs exist to provide a range of choice to nursing home residents, and that he does not want to assume medical direction responsibilities for residents once they enter hospice care. Dr. Blumberg's friend wondered if the interest of some in entering this market aimed at capturing the additional Medicare revenue that would result from admission of a nursing home resident to hospice care, and wondered whether receiving hospice care directly from the nursing home provider could mean that a resident would receive fewer services than those provided by an outside contractor.

Mr. Kane responded that he was aware of the "revenue stream" argument, and explained further his organization's interest in providing hospice services directly to the residents of Erickson-managed continuing care retirement communities. The average length of stay for a resident of Erickson communities—from independent living through assisted living through skilled nursing care -- is between seven and eight years. During that time, a resident has his or her entire range of health care needs managed and provided by a consistent set of professionals; people come to Erickson communities specifically to receive that integrated system of services, and the system works well. Erickson's data demonstrate that residents receiving this set of integrated services are much less likely to need nursing home- or hospital-level care. In addition, Erickson has also recently received approval to establish its own Medicare Advantage program, so not only does it provide housing, meals, and health care, but it now also bears the full risk, as a payer, on the health care outcomes of its residents. The only service in the continuum of care -- from independent living through home health, assisted living, and skilled nursing care – that Erickson cannot directly provide to its residents is hospice care. According to Mr. Kane, it is counterintuitive that state policy recognizes exceptions to the CON process for home health care and for skilled care for continuing care retirement communities, because there is a value to continuity of care to have the same caretakers for residents, but then, at the end of life, residents have to have a different provider of hospice care. Mr. Kane maintained that this does not serve the best interests of CCRC residents, and that Erickson was not seeking to provide a lesser level of services to its residents than an outside hospice does.

Mr. Kane added that Erickson has been working with the University of Maryland School of Nursing to develop an online hospice training program, which will train 100 students to provide hospice and palliative care. If the State Health Plan is not changed to allow CCRCs to seek Certificate of Need approval to provide hospice care to their own residents, many of these nurses employed by Erickson will have to seek employment elsewhere, in order to use this training. In general, he said, Maryland's use rate of hospice care is lower than the national average, and people are dying in hospitals and assisted living facilities without the benefits available from a hospice program. The fact that the State Health Plan standards for hospice services does not include the same kind of "specialty" designation that permits CCRCs to seek approval to provide home health agency services to their residents means that the Erickson-managed communities cannot provide this more integrated range of health care, with a continuity of caregivers.

In terms of CON in general for hospice, Mr. Kane said, he is unsure of the ultimate effect, except that Certificate of Need coverage seems to have kept for-profit hospices out of the state. If the

most frequently-cited rationales for Certificate of Need regulation include the protection of state budget funds, especially Medicaid expenditures, avoid unnecessary capital costs, and promote higher volumes to ensure higher quality of care, Certificate of Need for hospice would not seem to achieve any of those goals. Hospice is overwhelmingly a Medicare-reimbursed health care service, and its home-based programs incur virtually no capital cost. The high volume-quality correlation is unclear in hospice care: as Ms. Bonde mentioned at an earlier meeting, hospice volumes in Maryland range from an annual census of 20 to one of 200 patients, but few would suggest that the program caring for ten patients is doing a poor job, while the one with 200 is giving better care. In his view, quality of care in a hospice program is likely to have a higher correlation to the experience and dedication of the caregivers.

In response to Dr. Blumberg's question about whether Erickson has ever applied for a CON for hospice, Mr. Kane replied that within the current regulatory structure there is no legal mechanism to allow Erickson to seek Certificate of Need approval to establish a hospice program that provides care only to CCRC subscribers, as there is for skilled nursing beds and home health agency services. Pamela Barclay, Deputy Director of Health Resources, confirmed this, adding that the Commission has under consideration a petition by Erickson communities to change the hospice chapter of the SHP that would permit CCRCs to seek Certificate of Need approval to establish such a "specialty" hospice program.

Mr. Kane said that Erickson-managed communities in Maryland have about 6,000 residents, of which forty receive hospice care at any given time. He stressed that for Erickson, it is not a financial issue, but part of its ethical and moral obligation to provide coordinated care to its residents. Dr. Blumberg asked if Erickson is barred legally from applying for a CON to establish a general hospice program. Ms. Barclay replied that Erickson could apply if there was need identified for a new hospice agency in the jurisdictions where its communities are located. The need projections, which the Commission is in the process of updating, do not currently identify need for additional hospice programs. In response to a question from Dr. Blumberg, Ms. Barclay said that the Commission has not analyzed whether the State's nursing home residents represent an underserved population where hospice services area concerned.

Dr. Blumberg asked if there is anything in the law to preclude Erickson communities from buying an existing hospice, and adding it to the services that they provide. Ms. Barclay responded that acquisitions are not subject to CON review. Hal Cohen noted that Erickson does not want to do general hospice—only hospice for its own patients. Ms. Brown asked if a proposed "specialty" hospice program, to serve only a specific CCRC, would be subject to the Plan's projection of need. Ms. Barclay explained that, similar to the specialty home health agency available to a CCRC applicant, a prospective CCRC specialty hospice would be required to support its proposed program by showing sufficient volume, staff, and financial resources, but would not be precluded from applying if no need were projected for new programs in the State Health Plan. In contrast, Commission statute and regulations provide that CCRCs may establish – outside of the Certificate of Need process – a skilled nursing facility for its subscribers, with a number of beds based on a percentage of the communities' independent living units. Task Force member Douglas H. Wilson, Ph.D. asked if there has been interest on the part of other Maryland nursing homes to establish hospice programs; Ms. Barclay replied that, to her knowledge, no individual nursing homes have raised this issue.

In response to Ms. Bonde's question about how Erickson is currently providing hospice care to its forty patients, and the quality of that care, Mr. Kane said that Erickson contracts with a variety of existing hospice providers, who are doing a good job. He emphasized that Erickson's elderly residents desperately need integrated health care, and that hospice services are the only service that its communities cannot provide directly.

Ms. Bonde asked if Erickson's residents have requested that Erickson provide hospice care. Mr. Kane responded that he did not know, but that residents' councils at one or two of Erickson's communities had written in support of its request to change the State Health Plan. Mr. Kane added that, even if it were to become a hospice provider to its subscribers, they would still be free to choose other providers, and might do so based on religious affiliation, or on the preference of their physician. He said that Erickson simply wanted to give its residents the ability to maintain the integrity and continuity of their health care services in the event of a terminal diagnosis, to keep their same nurses (that Erickson is already training to give hospice and palliative care), the same pastoral staff and the same physicians, supported by their on-site electronic medical records.

Ms. Bonde suggested that Erickson's decision to establish a hospice agency represented a corporate decision, rather than one based on a stated desire of its residents to maintain their continuity of care. Mr. Kane replied that he viewed the matter differently, and that Erickson is trying to improve the quality of care and experience for its residents. He maintained that the negative reaction by the existing hospice community to Erickson's proposal to change the State Health Plan by creating the "specialty CCRC" category in hospice care has itself concerned the bottom line and corporate issues, and not focused on the impact of such a change on the quality and the continuity of care for CCRC residents.

Chairman Nicolay pointed out that the proposal for Plan change by Erickson was different from the question before the Task Force of whether to continue or end the coverage by Certificate of Need review of hospice programs, and noted that the Commission was in the process of addressing the Erickson State Health Plan proposal.

Alan Bedrick, M.D. expressed concern that the Task Force was moving along in similar fashion as the consideration of CON for obstetric services, where there was a tendency to focus on a particular institution or a particular stakeholder without necessarily looking at broad state interests. He cited the experience of South Carolina, cited by the Hospice Network, in which deregulation from Certificate of Need was followed by anecdotal reports of a deterioration in the kind and quality of hospice care. He asked if there was additional data from other states. Ms. Bonde replied that the national data from hospices is fairly scanty, although, based on the limited data that is available, hospices in CON states have higher numbers of visits by hospice staff to patients, and also higher overall spending on patient care per admission, than hospices in non-CON states.

Ms. Bonde stressed that hospices provide a fixed-price service, and that their only flexibility is in how much money the program chooses to spend on patient care. The single largest after-staff cost item in hospice care is for pharmaceuticals – largely pain medications -- for patients. Hospice providers who spend less of the fixed Medicare reimbursement for their patients do not serve their patients well: the programs are not as innovative, and do not spend as much money on pharmaceuticals and on alternate therapies. The concern is that if a hospice provider must compete for a limited pool of

patients, the costs of increased competition, such as advertising, will consume the resources otherwise available for direct patient care.

Task Force member Carlessia A. Hussein, DrPH asked what the mechanism is for measuring quality in the hospice marketplace; Ms. Barclay replied that hospices in Maryland are licensed as either a limited or a general program, and receive State licensure as well as Medicare certification from the Office of Health Care Quality, in the Department of Health and Mental Hygiene.

Ms. Bonde noted that OHCQ staff is more overburdened than the Commission's staff, and that the benefit of Certificate of Need coverage of new hospice programs is that it only permits new providers into the market when and where increased need exists. She agreed with Mr. Kane that hospice use is low in nursing homes nationwide, and said that several factors may be responsible – including the differences in the hospice benefit for a nursing home resident and the facility's costs and charges. However, Maryland data shows a higher use of hospice care by minorities than in other states, and Maryland also has several hospices that provide pediatric care. She emphasized that the hospice providers meet the needs of the people of this state.

Dr. Hussein expressed concern about the potential for "punting the responsibility for quality to the licensure program, absent some factual information on its ability to accept it and carry it out." She recalled that this suggestion has been proposed on several different occasions, and noted that she has scheduled a meeting with members of OHCQ staff to hear their views on the subject, since they have not been present to respond to the suggestion that OHCQ bear all of the responsibility for quality promotion and oversight. Dr. Hussein emphasized that it would only be acceptable to shift this entire responsibility from one agency to another if OHCQ can effectively handle their additional responsibility. Chairman Nicolay agreed that Dr. Hussein's comments must be a part of the Task Force's consideration. Elizabeth Weglein added, with respect to the current level of licensure and oversight for home health agencies currently regulated by OHCQ, that OHCQ can only review their performance, by survey, once every two years; OHCQ is not currently conducting on-site surveys of the other levels of home care providers it licenses, even though statute requires it to do so. She concluded that OHCQ does not have enough resources or staff to effectively meet its current oversight responsibilities.

Dr. Blumberg reiterated his previously-stated view that Certificate of Need cannot "ensure," but can "promote" quality of care. Quality oversight and enforcement is within the statutory authority of the State's licensure agency, once a project receives Certificate of Need approval and begins operation. If the licensure agency cannot perform these duties adequately, it might be appropriate for the Commission to bring that to the attention of other state officials, but it is not within the Commission's mandate to ensure quality in an ongoing fashion. He maintained that the job of the Commission in the Certificate of Need process is to establish a bar that one has to meet in order to allow a service or facility to be initiated, inaugurated, and moved forward. He suggested that the Task Force focus on one of its primary charges, defining the role of the Certificate of Need process. Dr. Hussein replied that in the sections of Commission statute related to the Certificate of Need program, promoting quality is one of its responsibilities, not simply cost and availability of services.

Ms. Cody expressed concern about not only the effect of complete deregulation of hospice services, but also the current need methodology, which has not allowed for growth in the number of hospice providers. She suggested that some middle ground should be identified between those two

extremes. Other chapters of the SHP take the approach of permitting only one new program at a time, for example, or permit a proposed new program that may not be needed according to a formulaic need methodology to demonstrate the benefits to its community if its Certificate of Need application is nevertheless approved. She suggested, as an example, that the Plan could include a requirement for greater outreach to potential patients, with a goal of increasing the number of patients enrolled in hospice. Alternatively, Ms. Cody suggested including requirements related to demonstrating increases in quality of care, and requirements for more supportive services, in order to raise the overall benefit of hospice.

Dr. Cohen observed that he had commented at some length when the Task Force last discussed hospice, and he continues to believe that the rationale for (and benefits of) CON are largely related to capital investment, and therefore do not apply to hospice programs. He reiterated that if need is defined by the number of patients that hospices can serve, then there is, in theory at least, no limit to the capacity of an individual hospice program. An approved hospice can continue to grow depending upon how many people it hires. Dr. Cohen expressed concern about the hospice industry's assumption that more competition leads to lower quality, and suggested that one way to lower costs is for patients to be attracted earlier and more patients to be attracted into the industry. On balance, it was not clear to him that there is any reason to preclude a greater choice of providers from this market.

Chairman Nicolay noted that the purpose of the Task Force was to hear and consider both sides of these issues. Joel Suldan observed that providers spend a lot of money trying to enrich the patient experience in today's competitive environment, because their competitors are doing so. Consequently, he expressed surprise at Ms. Bonde's comment that experience following deregulation from Certificate of Need in other states suggests that where there is more competition, there is less spending on patient care, which would be a compelling argument to retain Certificate of Need coverage if it were true. Mr. Suldan also disagreed with the argument that CON has ensured a stable market, citing the fact that over the past several years, this market has seen nineteen acquisitions, two mergers, and three closures, by his count, and that the acquisition or merger of a provider usually means that it is not doing well.

Chairman Nicolay asked if other members of the Task Force had something to add to the discussion. Ms. Brown again expressed concerns about the direction of the discussion, suggesting that she was not certain that the Task Force had received an adequate briefing and analysis on the underlying policy issues on this question, and on why new hospice programs, or expansions into new jurisdictions by existing hospices, require Certificate of Need approval. She said that the assumption seems to be that Maryland regulates hospice services through Certificate of Need in order to minimize the negative effects of competition on current providers.

Ms. Brown maintained that other policy reasons support maintaining Certificate of Need coverage of hospice, as well as of other health care services. She cited the possibility of "cherry-picking" by new, potentially for-profit entities, discussed in the Task Force's earlier discussion on the hospice issue, as one such reason. An unrestricted market could introduce new providers who are not interested in seeing Medicaid patients, for example; the State Health Plan currently addresses this access issue, with a Certificate of Need review standard requiring potential new providers to accept Medicaid as well as Medicare, and to agree to provide charity care. Those are the types of standards, as well as other quality-related requirements, that the Plan and this Commission adds to the competition argument, Ms. Brown said. She suggested that the Task Force to date seems to be

considering solely arguments for or against increased competition in the health care market, and the rationale for the Certificate of Need program goes beyond that issue.

Natalie Holland said that there was a requirement that new hospice programs serve some level of Medicaid patients, and asked if Medicaid does in fact reimburse hospice care. Ms. Bonde responded that the Medical Assistance program does pay for hospice care, but that its share of total reimbursements was quite small. Ms. Barclay added that, in addition to its requirement that a new hospice be certified to receive reimbursement from both Medicare and Medicaid, there is a requirement in the Plan that programs provide charity care. Ms. Bonde explained that charity care is provided to patients who have neither Medicare, Medicaid, nor any private insurance, and that hospice providers care for those patients as well. The Maryland Medicaid program provides essentially the same hospice benefit for the single-eligible that Medicare covers for its recipients. The largest portion of Medicaid dollars for hospice is spent for those dually eligible for Medicare and Medicaid, in the form of room and board costs at nursing homes, for residents who are also in hospice care.

Ms. Brown observed that this fact illustrated that more reasons exist to continue Certificate of Need coverage of hospice programs than the group discussed earlier. Dr. Bedrick asked if there have been many applications for hospice. Ms. Barclay replied that there have not, adding that the Commission last conducted a comparative review for hospice a number of years ago, but had scheduled no recent reviews because the currently-effective State health Plan does not project need for new agencies in any jurisdiction. She noted that the Commission implemented a new system for collecting data two years ago, and is now updating its need projections based on that new data; this analysis will come to the Commission later this year. Dr. Bedrick asked if anything has precluded an applicant from applying for a CON. Ms. Barclay said that when the SHP projects need, that is basically an invitation to submit proposals to establish additional hospice capacity. When the Plan does not project need, the Commission does not solicit or accept new applications.

Dr. Blumberg suggested that Ms. Brown's questions and Ms. Bonde's comments merited the Task Force's reconsideration of the hospice issue. Dr. Blumberg added that his reading of the hospice section of the Commission's report on its 2000-2001 legislatively-mandated examination of the CON program suggested that Certificate of Need coverage of hospice programs went into effect sometime in the 1980's. He asked why Maryland imposed the requirement at that time, on a service not previously covered by Certificate of Need. Susan Panek of Commission staff clarified this history, explaining that the Certificate of Need requirement actually dates back to the 1970s, but generally applied to inpatient facilities modeled after those advocated by Dr. Elizabeth Kubler-Ross and the early hospice movement. The Joseph Richey House in Baltimore received Con approval during this period. The change in hospice regulation in the 1980s was a clarification and expansion of State licensure statute, which explicitly required hospice programs to obtain a license, whether they provided care at an inpatient facility or in the home or another kind of residence.

Ms. Brown observed that, as a matter of policy, the Task Force should assume that the concerns expressed by the existing hospice providers – about cherry-picking and the impact of a potential increase in the number of providers to intensify staffing problems caused by the current shortage of nurses and other direct care staff – are also challenges facing home health agencies, with implications for continuing Certificate of Need coverage of that service. Ms. Brown stated that the State Health Plan CON review standards address the availability of nurses and other key staff, for purposes of reviewing an application to establish a new hospice or home health agency, and asked if any other

review process, by OHCQ or any other agency, would address that issue, if Certificate of Need coverage were eliminated. Ms. Barclay responded that licensing's perspective on staffing issues is different; OHCQ looks at staffing with respect to care provided to individual patients, quite a different issue from the availability of sufficient staff in the community to support existing programs, or additional ones.

Ms. Bonde said that in addition to issues related to the overall supply of nurses, hospice faces an additional, unique challenge, in that not every nurse who comes out of the community college nursing program inclined or even able to choose hospice nursing as a career path. Hospice nursing is not generally perceived, among new nursing graduates, as a preferred career path, since -- in addition to being a home care provider -- a hospice nurse is dealing with dying patients every day, and that is not something that is very easy for a lot of people.

Dr. Cohen observed that, although current providers argue that more competition would create more competition for a limited pool of nurses, he was not aware of any needed project ever being denied on the grounds that the service was needed but the proposed provider would not be able to hire anyone to provide it. Applicants provide a plan for how they will recruit and hire staff, and if the Commission finds that the service to be needed, it approves the application. A bigger concern about hospice services, he said, is that they are underused. He did not believe that any staffing shortage provides in itself a rationale for Certificate of Need coverage of a health care service.

Chairman Nicolay observed that the debate was beginning to recycle key points, and suggested that Task Force members had enough information to make a decision. He called for a vote. Three members voted in favor of deregulating the hospice program from the CON regulations (Cohen, Kane, and Suldan). Nine members voted in favor of retaining the current regulation (Bedrick, Bonde, Cody, Holland, Hussein, Pinkner, Stefanides, Weglein, and Wilson), with three members abstaining (Blumberg, Brown, and Ginsburg). Chairman Nicolay thanked the Task Force members, as well as the members of the hospice community who had attended the meeting, and Ms. Bonde for her information and guidance in the discussion.

- **Coverage by CON Review: Ambulatory Surgery Services**

Chairman Nicolay moved to the next agenda item, the regulation of ambulatory surgical services by Certificate of Need. He noted that Dr. Larry Pinkner represents the Maryland Ambulatory Surgical Association on the Task Force.

Dr. Blumberg said that the staff briefing paper on this issue demonstrated to him that no easy or obvious answer exists to the question of Certificate of Need coverage for ambulatory surgical capacity, and also that the same inconsistency of regulatory oversight that he has cited in other services also affects ambulatory surgery. Data in the briefing paper show that Maryland has the highest number of Medicare-certified ambulatory surgery centers in the country. These freestanding outlets are not subject to the rate-setting authority of the Health Services Cost Review Commission, as are Maryland hospitals, and therefore are more attractive to payers in search of lower costs and discount arrangements. An incentive exists for practicing physicians, receiving less per unit of service from payers, to maintain or increase their revenue by establishing office-based surgical capacity, thereby capturing the "facility fee" for procedures once performed in hospital outpatient settings. Dr. Blumberg emphasized that he did not know how to fix the system, but believes that there should be more uniformity in how we regulate the same service across its different settings of care. If the Task

Force supports deregulating ambulatory surgery from Certificate of Need review, then rates for hospital outpatient procedures should also be removed from the authority of HSCRC, so that the settings of care are treated equally in that regard.

Dr. Cohen observed that HSCRC went to the General Assembly several years ago to propose deregulating rates for ambulatory surgery services at hospitals; Maryland hospitals opposed that change, and prevailed, thus continuing the inequality between hospital and freestanding ambulatory surgery settings in pricing and the ability to negotiate discounts with payers. Mr. Suldan described another inequality in the rate regulation of hospital-based ambulatory surgery, the so-called "awning test." This refers to a finding by HSCRC, historically requested by some hospitals, that their ambulatory surgical capacity is not "at the hospital" for rate setting purposes. This determination required that hospitals take measures to differentiate the outpatient surgical setting from the rest of the hospital buildings on the campus, such as different entrances (with separate awnings), different signage, and separate parking areas. Another irrational provision of the current regulatory structure results from the implicit distinction made in Commission statute (related to capital expenditures) between hospital outpatient and inpatient surgical capacity. He suggested that as the Task Force considers what should be regulated in a freestanding setting, the members must remember that the same rules that govern regulation of ambulatory surgery in the freestanding setting carry over into the hospitals.

Dr. Pinkner noted that he had provided to the members a written statement by MASA expanding upon its reasons for maintaining Certificate of Need coverage and the regulatory structure as they are. He agreed that the system is potentially confusing, since its underlying regulations and definitions have changed over the last nineteen years, including the last major change in 1995, when matters of medical specialty and group membership were removed from the law, and the number of operating rooms alone became the determining factor in Certificate of Need coverage. This had led to some providers establishing one operating room, and also multiple procedure rooms, which are not required to obtain CON approval, and using those "procedure rooms" as ORs. Dr. Pinkner said that once a surgi-center is approved and built, it is rarely inspected after its initial survey, because licensing staff is greatly overburdened. Dr. Pinkner did not know how many centers are using so-called procedure rooms as operating rooms, but repeated MASA's position that an important piece of addressing this issue is to develop clearer definitions of, and distinctions between, operating and procedure rooms.

Dr. Pinkner said that three-fourths of the 26 states with Certificate of Need coverage of ambulatory surgical facilities also cover birthing centers and procedure rooms, and make no distinction between ORs and procedure rooms. Medicare reimbursement policies also cause problems in this area, by dictating that certain procedures must either be done in a physician office, because they are "too small" for a freestanding surgery center – or else at a hospital. Ambulatory surgical centers are contesting this policy at the national level. He acknowledged that Medicare does pay more for procedures it permits physicians to perform in an ASC than if the same procedure were done in a physician office setting.

Dr. Pinkner emphasized that he and his organization strongly support maintaining the one OR exemption from CON. In Maryland, most of the office-based single OR providers are plastic surgeons, podiatrists, and endoscopy centers. Only about 12 or 13 large, multi-specialty surgery centers exist in the whole state; many are wholly or partially owned by hospitals. He also noted that no one has ever

applied for determination provided for under Commission statute that a center may add a second OR without Certificate of Need review, if necessary for "efficiency, safety, and quality" of the services offered. Ms. Barclay noted that the Commission has not promulgated regulations to implement that provision. She also said that the Commission has begun to receive an increasing number of Certificate of Need applications from one OR entities seeking to add a second operating room. This makes the center a health care facility, for Certificate of Need purposes, and subject to any regulation applicable to health care facilities under Commission statute.

Dr. Blumberg added anecdotal evidence regarding "perverse incentives" in Medicare reimbursement policy, which affect how and where surgical procedures are performed, but observed that these inconsistencies in the system – though they should be addressed -- are beyond the purview of the Task Force.

Chairman Nicolay asked Dr. Pinkner what he thought ought to be done, regarding the identified regulatory inconsistencies and definitional issues affecting this medical service. Dr. Pinkner responded with his personal view that doctors should be able to establish one operating room without Certificate of Need review, because reimbursement policies require them to perform many procedures in office settings, in order to receive payment. However, he believes that more than one room, in any specialty and of any configuration, should require Certificate of Need approval.

Task Force members discussed some of the definitional issues related to operating rooms versus procedure rooms. Ms. Barclay noted that, in its administration of determinations of non-coverage by Certificate of Need since the 1995 statutory change, the Commission has counted as an operating room any treatment space within a restricted sterile corridor. In recent years, staff has added questions about the size and specific physical features (ventilation, room surfaces, etc.) of rooms in existing centers, to understand more completely the nature and use of the outpatient surgical capacity in place around the state. No explicit definitions of the categories of surgical and treatment capacity exist currently in regulation.

Ms. Brown asked how many of the licensed ASCs in the Commission's inventory have more than one operating room, and if those centers were among those established under previous statute (in effect between 1986 and 1995) that permitted a physician or group practicing certain specified medical specialties and treating their own patients to establish up to four ORs. Ms. Barclay replied that most of the centers do not have more than one OR, and that most have one OR plus a number of procedure rooms. In addition, the inventory also includes endoscopy centers with non-sterile procedure rooms and no operating rooms. Ms. Panek explained that, although these centers may seek and receive Medicare certification as an ambulatory surgery center for purposes of obtaining a facility fee, most are licensed as "freestanding endoscopy centers," a separate category of State license codified under the umbrella term "ambulatory care facilities" in licensure law.

Chairman Nicolay asked Dr. Pinkner if, as part of recommending that single OR entities remain not subject to Certificate of Need and that regulatory enforcement become more clear-cut, he also supported the elimination of the current administrative distinctions between a procedure room and the scope of procedures performed there, and the space and scope of what is considered an operating room. Dr. Pinkner replied that if even if current Certificate of Need coverage remains unchanged, the industry still needs better, clearer definitions of and distinctions between ORs and procedure rooms.

The Task Force continued to discuss the reimbursement incentives and policies that have contributed to the inconsistencies and irrationalities of the present regulatory framework. Ms. Brown observed that the State Health Plan does not have a need projection for ambulatory surgical services, and that may also have led physicians to find ways to evolve their practices by adding surgical capacity. Ms. Cody asked if there is a need methodology in the Plan; Ms. Barclay responded that one of the changes made to the Plan, after the changes to the definition of "ambulatory surgical facility" that permitted establishment of single ORs without Certificate of Need, was the removal of its need methodology. The Commission analyzes proposals to convert single OR entities into health care facilities by adding a second OR using the volume standards for optimal utilization still in the Plan.

Dr. Pinkner noted that it is difficult to identify need for ambulatory surgery, because every year more procedures move out of hospitals and into the freestanding setting because of both advances in surgical techniques and equipment and payer policies. In response to a question from Chairman Nicolay, Dr. Pinkner emphasized that single OR entities should be regulated, for reasons of patient safety and quality of care, but should continue to not require a Certificate of Need. Dr. Blumberg suggested -- because of the complexities of this issue, the need for more information, and the fact that so many factors affecting it result from reimbursement policies beyond its control -- that the Task Force not take a position, but instead refer the question of Certificate of Need coverage for ambulatory surgical services to the full Commission.

Dr. Pinkner asked that the Task Force confirm, if it decided to refer the issue to the full Commission, that it did not recommend deregulating ambulatory surgery from Certificate of Need coverage. Chairman Nicolay replied that he preferred to consider the issue in its entirety. Mr. Suldan stated that he was hesitant to defer to the full Commission on all aspects of the issue, suggesting a recommendation to the Commission that it regulate through Certificate of Need review only the establishment of new facilities, which, once established, could operate any number of operating rooms they wished.

Dr. Blumberg observed that if only 49 of 276 facilities had to undergo Certificate of Need review, then Certificate of Need in this area was not acting to constrain capital or payer costs or to link supply to need for new service capacity. He would support deregulation from Certificate of Need because of the incomplete and inconsistent nature of the current regulatory structure. He added that he could also support Dr. Pinkner's proposed tightening of regulatory control, which, if it exists, should be meaningful and consistently applied. He agreed with Chairman Nicolay's suggestion that the Task Force reconsider this issue in the context of additional information from Commission staff.

Commission Executive Director Rex W. Cowdry, M.D. expressed concern about the direction of the group's deliberations, given the short time frame in which the Task Force is to complete its work and forward recommendations to the Commission. It would be very difficult, in an issue area with the long and complex history as ambulatory surgery, for staff to present the Task Force with recommendations for action based on an appropriate level of analysis. The same holds true for the other coverage issues the Task Force has considered and on which it has taken preliminary actions. An analysis of specific coverage issues should include a careful analysis of the philosophical and economic bases for the CON. To reach a decision on whether to continue Certificate of Need coverage of hospice programs, for example, without examining the impact of Certificate of Need regulation on the number of hospice providers in the state over the last fifteen years, or the number of Marylanders served by hospice in relation to national averages over that period of time, is problematic.

What is needed, Dr. Cowdry emphasized, are ways to streamline the process of handling of CON applications. The Commission needs recommendations from the Task Force, as the users of this process, for ways that the staff can do its job better, smarter, and more efficiently within its existing resources, while protecting both the money that Marylanders pay out of pocket in insurance premiums and the quality of care that they receive in these facilities.

Dr. Wilson concurred with Dr. Cowdry, stating that he has been uncomfortable with the discussions and decisions on service-specific issues, and wanted to proceed to process issues. Mr. Kane agreed, adding that much of the public comment to the Task Force involved process issues, which are less controversial and on which Task Force members had a great deal of expertise. He expected that many of the proposals for streamlining the review process could be enacted without statutory change.

- **CON Review Process Issues: Interested Parties**

Chairman Nicolay began the discussion of potential changes to the Certificate of Need review process with the issue of interested party status, and presented a chart conveying key issues related to the discussion.

Ms. Barclay explained that this is the first of several CON review process issues identified in public comment presented to the Task Force, which included the definition of interested parties to CON review, completeness review of Certificate of Need applications and redocketing after significant changes to applications under review, and the capital review threshold for Certificate of Need coverage.

With regard to interested party status, CareFirst has proposed that Certificate of Need regulations be changed to provide that CareFirst is an automatically-designated interested party in all hospital projects involving capital expenditures of $25 million or more. One hospital system submitted comments suggesting that the definition against which interested party status is determined should be narrowed. Ms. Barclay noted that staff's briefing paper examines the changes over time in the definition of who qualifies to receive legal standing in CON review as an interested party.

Dr. Cowdry asked whether Task Force members understood the impact that a contested case with one or more designated interested parties has on the work of the Commission staff, on the Commission members, and on the review process itself. An understanding of that impact is crucial in this consideration, he explained, because this is a defining issue in the review process. A formally designated interested party – as opposed to the participation in a review by any member of the public, who can submit written comments for the Commission's consideration that will become part of the record in a case – represents a threshold issue, in terms of increasing demands on already-constrained staff resources.

Ms. Barclay explained that in cases with a designated interested party, the Commission is required to appoint a Commissioner as reviewer, who is responsible for developing a recommended decision, issued in advance of the meeting at which the Commission will consider action on the CON application. An interested party may file a written exception to that decision, to which the applicant responds in writing, and both parties then argue those exceptions before the Commission prior to its final decision. In uncontested cases, Commission staff develops a report and recommendation that

goes directly to the Commission for action. Interested parties may take a judicial appeal of the Commission's decision.

Dr. Blumberg asked if the Commission receives comments submitted by those without legal status as an interested party status for its review and consideration. Ms. Barclay replied that all comments and information received in the course of a review are reflected in the project analysis, but Commission members do not typically receive copies of the full text of those comments. Chairman Nicolay added that, in a contested matter, the Commissioner acting as reviewer does receive the entire written record of the case. Dr. Blumberg then asked if a group without formal interested party status that opposed the Commission's decision to approve a project that would affect its community would be prevented from appealing that decision in court.

Commission Assistant Attorney General Jason Sapsin replied that Commission statute provides interested parties with an explicit statutory right to appeal a Commission decision. Beyond that status and its attendant right, other legal mechanisms exist, such as due process considerations, which would also give a right of appeal. Mr. Sapsin said that, as counsel to a neighborhood or community group without interested party status that wanted to appeal a Commission decision, he would assert before the court a right of appeal, based on other considerations related to administrative law and constitutional due process.

Dr. Blumberg stated that, if any person or group has an ultimate right to appeal a Commission decision, he supported the elimination of interested party status altogether, as unnecessary to protect due process rights to appeal. Dr. Cohen strongly disagreed, noting that the burden of winning an appeal in court is much different from the burden of persuading the Commission to allow participation in the review process as an interested party. He asked the Task Force members to remember that the goal is to help get the best decision—not whether a party can get a court to say that the Commission acted in an arbitrary and capricious way, and that nothing in the record supports its decision.

Chairman Nicolay suggested that, in the decision whether to confer interested party status in a Certificate of Need review, the Commission needs to seek a balance between fairness and efficiency -- fairness, in getting everything in the record to consider in the CON case, and efficiency, in accomplishing the review in an appropriate time frame without unnecessary administrative requirements. Dr. Cohen continued to argue for the importance of the participation of interested parties in large and complex Certificate of Need reviews, and, specifically, for the importance of participation by CareFirst in projects involving the kinds of significant capital expenditures under review by the Commission, now and for the past several years.

Ms. Bonde observed that it is more difficult for someone with interest in an administrative proceeding, who is not a legally-qualified interested party, to successfully argue before a court to overturn an agency's decision.

Dr. Cohen argued that CareFirst should become an automatic interested party to reviews of large hospital capital projects, since – as the State's dominant third-party payer – it is directly affected by any decision that results in higher costs and potentially higher hospital charges. The current regulations require CareFirst or any other third-party payer to claim that a project will have a negative impact on the system, in order to gain status as an interested party. In practice, this means that when

(as has happened) CareFirst wants to support a project, it may not become an interested party, with legal rights to re-enter a proceeding if the Commission approves changes to a project that CareFirst does not support.

Task Force member Christine Stefanides opposed expansion of the designated interested party definition, in the interest of keeping the process efficient. She has participated in a contested CON matter, and experienced the high resource requirement of a contested case, on both her hospital and the Commission and its staff. When the real "interest" of an interested party is to delay a project, or leverage a concession of some kind, that constitutes an abuse of this process. However, she concurred that legitimate interested parties need to have the right to participate, and suggested that some of the ideas proposed in the briefing paper for the tightening up of who is considered an interested party would help to avoid the kind of misuse of the system that adds unnecessary burdens and costs to the regulatory process.

Ms. Holland asked how many people submit written comments when they do not have interested party status. Ms. Barclay replied that in large CON cases, the Commission generally receives three types of comments: first, since local health departments receive copies of CON proposals, the Commission sometimes receives comments from those sources; second, the Commission receives comments from people in the community served or affected by the facility proposing a project; and, third, detailed written filings from persons or organizations seeking formal interested party status. Ms. Holland asked if many people file for interested party status. Ms. Barclay responded that most written comments do not include requests for interested party status. Mr. Suldan asked what percentage of CONs filed and approved are contested. In response, Ms. Barclay asked whether Mr. Suldan meant the percentage of cases that are contested and then approved subsequently or, the percentage of cases that are contested. She observed that because of the nature of some of the projects that the Commission is dealing with, including proposals for hospital projects, ambulatory surgery projects, and nursing homes, it has more contested cases than in the past.

Dr. Cohen pointed out that his comments specifically apply to hospitals, where CareFirst spends millions of dollars per year; and that the issue has nothing to do with hospices or home health agencies, from the standpoint of what CareFirst is saying. He reiterated that CareFirst should be part of the process. Mr. Kane asked how often CareFirst has been denied interested party status on projects for more than $25 million. Ms. Barclay deferred to Dr. Cohen, who said, once CareFirst learned that to get interested party status as a third party payer it had to challenge or oppose some aspect of a proposed project, it has qualified as an interested party. Ms. Barclay replied that the Commission follows the procedures set forth in statute and regulations, which require a Commissioner appointed as reviewer to make decisions on matters involving qualifications and challenges for interested party status. The determination is not made by the staff. Ms. Barclay suggested that one of the things that might be helpful for the Task Force to look at is whether that is the correct test.

Dr. Cohen thought that Ms. Barclay's point was an important one since, he said, a competing institution in the same market is entitled to interested party status, virtually automatically, because it may lose one customer and argue adverse effect. It does not have to be impacted significantly—it just has to provide the same service in the same community. In his opinion, a definition of "interested party" that ignores millions of dollars' worth of impact on CareFirst unless it can demonstrate that the project will have a negative impact on the entire system does not make sense.

Dr. Bedrick suggested that the Task Force was dealing with two separate issues. Regarding the first, he urged the group to consider removing the regulatory requirement that interested parties must oppose a given project, and permit those making positive comments to have legal standing in a review. The second issue was CareFirst's insistence, as the major payer in the State, that it receive automatic interested party status in large hospital capital projects. Dr. Bedrick argued that to single out CareFirst among all other payers was inappropriate. Dr. Cohen replied that all third party payers have the right to be identified as designated interested parties for HSCRC reviews, though they do not participate.

Chairman Nicolay noted that CareFirst has requested automatic designation so that it does not have to make a filing in each proposed application. Dr. Cohen added that CareFirst is also seeking the recognition that a regulatory system works best when various sides are presented—not just the perspective of providers. Ms. Brown observed that the interest of payers in cost containment is not always consistent with the mission of the Commission to promote health care quality and access. Ms. Brown maintained that it would be inappropriate for the state to deem one payer as the designated interested party.

Commissioner Ginsburg called the question, citing two important considerations. He believes that the Commission should be a public process, and wants as many people involved in a decision as possible. As a Commissioner who participated in one of the most contentious of these interested party cases, his view was that the Commission wants to streamline the process. He cautioned that excluding people from the process is not the right way to accomplish this. He agreed with the position that entities submitting positive comments should also qualify for interested party status. The Commission, perhaps, should focus on how to include more people, rather than exclude them.

Chairman Nicolay replied that in the projects for which he has served as reviewer, the Commission received considerable informal written comment, which the recommended decision considered and incorporated. Ms. Brown added that any change in the definition of interested party process would require a regulatory change. Consequently, it would not be reasonable to change interested party status without looking at how a change in the definitional criteria would affect who can qualify as an interested party to a review. Potentially, a change might mean that more reviewers will be required, and the Commission is in need of more reviewers under current rules. Chairman Nicolay suggested, having listened to the Task Force members' opinions, that the Commission staff do further work on the definitional issue, and bring this back to the Task Force.

- **Completeness Review**

Chairman Nicolay said, on the issue of completeness review, that he had developed for the Task Force's consideration a proposal for substituting conferences for the current completeness review process. He recommended conferences composed of all of the parties at the completeness review level, for the purposes of meeting and discussing the issues, rather than corresponding back and forth by mail. He asked the Task Force members to review the proposed recommendation and defer further consideration of the issue to the next meeting of the Task Force. Ms. Barclay added that she had an earlier conversation with Douglas Wilson, Ph.D., whom, she noted, was unable to stay for the remainder of the meeting. Dr. Wilson questioned what time frames for the application review conference and project status conference would be. She indicated to him that the recommendation was a conceptual idea, though it would be possible to include time frames as a result of input from the Task Force members.

- **Capital Expenditure Review Threshold**

Ms. Barclay presented the briefing paper to the members present. Chairman Nicolay proposed that the Task Force consider the issue prior to adjournment for the day. Dr. Bedrick proposed that the threshold be modified to $7.5 million. Dr. Blumberg suggested that the modification should be $7.5 million with an index to inflation. Other Task Force members suggested that the threshold be set at $10 million. Chairman Nicolay noted that the threshold was currently $1.65 million, adjusted by the CPI. Years ago, the threshold was set for $1.25 million and has been adjusted up. He referred the Task Force members to the briefing paper and asked Ms. Barclay to discuss the issue.

Ms. Barclay said that staff had put together some data looking historically at the capital review threshold projects. For hospitals, a very small number of projects would be impacted at the levels under consideration because most hospitals, for the smaller capital projects, are taking the pledge and not going through the CON process. The data suggests that increasing the threshold would not really materially affect the number of projects that would be coming to the Commission because only a few projects have such a low capital threshold. With regard to nursing homes and some of the other projects, the status is a little less clear. Some of the nursing home projects that the Commission now reviews would not come to the Commission if the capital threshold were raised to $10 million. These would be, principally, renovation projects and not projects that would trigger other reasons for CON.

In response to a question from Chairman Nicolay about the effect on hospice services, Ms. Barclay replied that a new hospice requires a CON regardless of the capital threshold. Ms. Bonde said that to her knowledge, none of freestanding hospice buildings have been subject to CON separately from the hospice operational CON regulations. Ms. Panek clarified that Hospice of Baltimore, a GBMC affiliate that operates Gilchrist House, an inpatient hospice facility, did obtain a CON as part of its application to establish a general hospice program serving Baltimore County and contiguous Central Maryland jurisdictions. Joseph Richey House in Baltimore obtained a CON to establish its inpatient hospice facility in the 1970s, because Certificate of Need statute at the time included hospice coverage but did not distinguish between facilities and home-based hospice. In 1987, the General Assembly enacted statutory provisions that separated hospice licensure standards from those of home health agencies, and clarified that all hospice programs required a Maryland license. General hospice programs that wish to construct a residential site need a determination of Certificate of Need coverage for the related capital expenditure, not for the residential setting itself, since statute does not provide for separate licensure of residential or inpatient hospice beds or facilities.

Dr. Pinkner asked if a proposed surgi-center with one OR cost more than the threshold amount, would an applicant then have to get a CON? Ms. Barclay replied that for a one OR facility, a CON would not be required because it would not be a health care facility subject to CON review. A one OR facility is exempt from CON review, regardless of the capital expenditure level. Dr. Pinkner asked if the capital expenditure threshold only affects hospitals and nursing homes. Ms. Barclay responded that it would affect anything that is defined as a health care facility under the Commission's statute, including home health, hospice, acute care hospitals, nursing homes, residential treatment centers, and some kinds of non-hospital, non-acute care projects. The threshold also could apply to an ambulatory surgery facility that is a CON project, meaning that it has two or more ORs. The two related issues are, (1) should the Commission continue to index the threshold, as raised by Dr. Blumberg and in the comments received; and (2) should there be a separate threshold for nursing homes versus hospitals? Chairman Nicolay added, and (3) how much should it be?

Dr. Cohen proposed that the hospital threshold be $10 million, indexed by the Consumer Price Index (CPI). He declined to make a recommendation for nursing homes. Ms. Holland recommended $10 million for nursing homes, pointing out that this would enable a very aging group of facilities to renovate more quickly and easily. Mr. Suldan said that when hospitals are taking the pledge, which is what the vast majority of these transactions were about, the outcome is largely known from the beginning. In his view, the only question is how much back and forth will there be with Commission staff, and how much time it will take for people who are preparing the letters, and people who are reviewing the letters. In his opinion, it makes sense to reduce the number of letters that have to go in, which would be accomplished by raising the threshold. He also suggested creating a standardized format for seeking approval of non-coverage when hospitals take the pledge. Ms. Barclay took issue with the statement that the outcome of projects proposed under the pledge is always known and always positive, but agreed with Mr. Suldan's suggestion for a standardized format, adding that the staff would prefer to get a more standardized filing because we struggle in understanding and analyzing the information that different hospitals file because that information varies greatly.

Dr. Blumberg supported Ms. Holland's suggestion for including the nursing homes in the $10 million proposed threshold. In consideration of the Task Force's earlier deliberations regarding nursing homes, he suggested that if the Commission can allow them to function and they want to stay in business, the regulations should be encouraging them to stay in business and upgrade their facilities. Mr. Kane agreed with Dr. Blumberg, as did Dr. Cohen, who suggested changing the inflation index to the Engineering News Record. Chairman Nicolay asked the inflation index in the Engineering News Record varies that much from the CPI. Dr. Cohen replied that it is considerably higher than the CPI because the CPI is Medicare's index for measuring what is happening to capital costs over time, taking into account the fact that capital costs at any one time are a blend of historical capital costs; whereas, the Engineering News Record calculates what is happening to the cost of construction moving forward.

Commissioner Ginsburg asked how much the proposed change would affect the Commission's work because, in his view, the Commission should separate the hospitals from the nursing homes. Chairman Nicolay suggested $7.5 million for the nursing homes and $10 million for the hospitals. Ms. Holland reiterated her proposal for a threshold of $10 million for the nursing homes. Commissioner Ginsburg suggested $5 million for nursing homes because there are many projects that will go under the Commission's radar. Ms. Holland clarified that nursing homes would not be able to change sites or capacity under her proposal. The capital expenditure threshold would only apply to on-site projects for renovation. If a nursing home wanted to change capacity, or add a service, or move, it would continue to be required to apply for a CON. Ms. Barclay confirmed that Ms. Holland was correct in her assessment.

Dr. Cohen noted that Medicaid has its own capital formula, so the proposed change is not likely to generate additional payments to nursing homes. In his opinion, if nursing home operators want to spend their money, that should be fine, and the $10 million threshold made sense. He made a motion that the capital threshold for all services be $10 million, for 2005 dollars, indexed by the Engineering News Record methodology currently in use by the CON staff. This motion was seconded by Dr. Blumberg. Task force members Bedrick, Blumberg, Bonde, Cody, Cohen, Ginsburg, Holland, Hussein, Kane, Pinkner, Stefanides, Suldan, and Weglein voted in favor of the motion, and Ms. Brown abstained from voting.

4. Other Business

There was no other business considered by the Task Force.

5. Adjournment

Chairman Nicolay announced that the next meeting would be held on Thursday, August 25, 2005 at 1:00 p.m. Commissioner Larry Ginsburg made a motion to adjourn, which was seconded by Ms. Bonde. The Task Force meeting was adjourned at 3:57 p.m.

Revised September 9, 2005

Summary of the Meeting of the CON Task Force

August 25, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present
Commissioner Robert E. Nicolay, CPA, Chairman
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
Annice Cody
William L. Chester, M.D.
Hal Cohen, Ph.D.
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Christine M. Stefanides, RN, CHE
Jack Tranter, Esquire
Douglas H. Wilson, Ph.D.
Elizabeth Weglein

Task Force Members Absent
Commissioner Larry Ginsburg
Alan Bedrick, M.D.
Natalie Holland
Commissioner Robert E. Moffit, Ph.D.
Michelle Mahan
Anil K. Narang, D.O.

Members of the Public Present
Clarence Brewton, MedStar Health
Jack Eller, Ober, Kaler
Denise Matricciani, MHA: Association of Maryland Hospitals & Health Systems
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Olivia Stewart, Jack Neil & Associates
Gail Thompson, Kaiser Permanente

Pegeen Townsend, MHA: Association of Maryland Hospitals & Health Systems
Greg Vasas, CareFirst BlueCross BlueShield

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:12 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (August 11, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the August 11th meeting and asked for any comments, changes, or corrections. Patricia M.C. Brown, Esquire, requested a revision to reflect that it was her opinion that some of the proposed changes would require a regulatory change, rather than a change to the Commission's statute. Task Force member Albert L. Blumberg, M.D., F.A.C.R., made a motion to approve the minutes, as revised, which was seconded and approved by the members present with the exception of Hal Cohen, Ph.D. and Jack Tranter, Esq., who abstained.

3. Review and Discussion of the Public Comments Received on the CON Program

- **Recap of August 11, 2005 Meeting**

1. Task Force Review and Discussion of CON Issues

- Recap and Follow-up: August 25, 2005 Meeting
  - Follow-up Items
- Review of Draft CON Task Force Report (9/8/05)
- CON Review Process
  - Streamlined ("Fast Track") CON Review Process
  - CON Application Form and Filing (Electronic Filings/Website Access)
  - Require Site Visits and Local Hearings on All Major CON Projects
  - Eliminate Scheduled CON Reviews
  - Other
- State Health Plan
  - Emergency Department/Outpatient Services
  - Freestanding Birthing Centers

2. Other Business
   - Burn Care Services

3. Adjournment

Chairman Nicolay presented a recap of the August 11th meeting. He noted that the Task Force received many comments regarding the Commission's need to revise the State Health Plan for

Facilities and Services (State Health Plan, or SHP); however, time would not permit the Task Force to consider all of the State Health Plan issues.

- **State Health Plan Issues: State Health Plan Update**

Chairman Nicolay suggested that the Task Force members consider several options, with a goal of reaching consensus, on the best way to address the subject.

Pamela Barclay, Deputy Director of Health Resources, presented the following options for updating the State Health Plan:

- Defer review of all new CON applications until the State Health Plan is fully revised and updated;

- Continue the review of CON applications and focus on updating only those portions of State Health Plan chapters needed to review the types of CON applications that are likely to be filed over the next 12 to 24 months; or

- Target 1-2 State Health Plan chapters for a full revision annually so that in a five-year cycle, the Commission will have addressed all of the chapters.

Dr. Cohen noted that his written comments to the Task Force included a suggestion for adding a chapter to the SHP on emergency department services—one of the most rapidly growing hospital services for which Certificate of Need (CON) applications are filed, in his opinion. He emphasized that no standards address these services in the SHP. Chairman Nicolay assured the Task Force members that emergency department services, in addition to several other proposed changes, would be considered at a future meeting.

Dr. Blumberg noted that, as he had previously proposed, reducing the requirements for CON would make revision of the SHP less acute. His interpretation of the cause of delays in the update of the SHP was that "finite staff resources" had been diverted from monitoring the SHP to analyzing CON applications. In his view, the second and third options presented, in light of the Commission's budgetary and staffing constraints, were not achievable. Ms. Barclay suggested that Task Force members should assume that that the Commission would not be given major additional resources to devote to its work regarding CON and the SHP.

Dr. Blumberg asked if the staff believes that it has sufficient staff to achieve option two or option three. Ms. Barclay replied that option two described the current process. Targeted updates of the SHP, driven predominantly by the CON work, such as the recent updates of the acute care bed need projection and the Obstetrics Chapter, have been promulgated by the Commission. She noted that staff shares the concerns expressed in the comments.

Jack Tranter, Esquire, opined that the declaration of a moratorium described in option one would be an unlawful act. Option two would be the best and most appropriate approach, in his opinion. He expressed disappointment at the suggested deferral of consideration of some of the issues in the acute inpatient services chapter of the SHP because it is presently used most often. Mr. Tranter noted that the Maryland Hospital Association (MHA) identified many standards in the acute inpatient

services chapter that were "not useful," such as requirements in CON applications for utilization data, the travel time standard, information regarding charges, and charity care policies, among others. He suggested that the Task Force deliberate those targeted comments as it considers SHP issues. Dr. Cohen agreed with Mr. Tranter's suggestion, and observed that the record of many of the CON applications, in his view, contains numerous irrelevancies. In response to a request for clarification from Carlessia A. Hussein, DrPH, Mr. Tranter stated that the Commission could adopt and change the CON review criteria.

Dr. Hussein suggested that the staff assess the extent to which the review criteria are necessary in analyzing applications and making recommendations to the Commission. Ms. Barclay noted that staff agreed that some of the SHP standards should be revisited for appropriateness in the applications being currently reviewed; however, other comments received by the Task Force related to how the SHP is structured and higher order issues, since the SHP is the guiding blueprint for the Commission's work in these areas. The staff could do a "targeted" adjustment, as it has been doing, or it could revisit some of the larger policy issues in a full re-write of the SHP.

Mr. Tranter suggested that the Task Force consider and recommend adoption of the twenty-four specific "housekeeping" recommendations made by the MHA work group to the Commission.
Joel Suldan, Esquire, proposed that the Commission adopt a different review process that includes a requirement for CON applicants' certifying that they meet the standards on the "housekeeping" list. Ms. Barclay pointed out that the Commission is required to make a finding for all review criteria set forth in the CON regulations.

Adam Kane, Esquire, proposed that subcommittees be created for deliberation and recommendations on these State Health Plan issues. William L. Chester, M.D. opposed Mr. Kane's suggestion, observing that the entire Task Force's breadth of expertise, as shared during deliberations, was a valuable component in forming recommendations; however, he would favor disposition of the housekeeping issues by a subgroup. Christine M. Stefanides, RN, CHE agreed that the housekeeping issues must be addressed. In her view, the Commission is burdened with monitoring regulations that do not pertain to CON applications. The expertise of staff needs to be focused on the CON issues and not addressing "other regulatory monitoring that seems to be cluttering up the application." Barry F. Rosen, Esquire, surmised that one of the problems presented by the proposed options was the assumption that they were "black and white options." He proposed that the Commission undertake a "quick and dirty clean-up" of the SHP chapters followed by a thorough review. In his view, the proposed options had merit. He stressed that his proposed solution would occur contemporaneously. The Commission should commit to a full revision of the SHP and achieve that goal within four or five years. Mr. Rosen also proposed that the Commission and staff create an implementation plan for his proposed solution.

Dr. Cowdry expressed deep concern about several constraints. The Commission's proposed budget, recently submitted for FY 07, is nearly $10 million. The statutory cap will be reached by next year (in the FY 08 budget cycle). Staffing PINs continue to be frozen by the Department of Health and Mental Hygiene and management positions continue to be frozen by the legislature. He emphasized that the Commission's finite resources will continue and that this was one of the reasons staff sought to find ways to prioritize and streamline the planning and CON process.

Dr. Cowdry suggested that there are several ways to manage the workload and one of them is to determine what facilities and services no longer need to be subject to CON; a second way is to determine if there are standards that are no longer necessary and are not determined to be top or middle tier priority issues. Dr. Cowdry proposed that, as there is agreement between payer and provider representatives, staff should work with a small group of representatives on revisions to the State Health Plan acute care standards used in CON review. Following additional discussion, Chairman Nicolay asked staff to draft a recommendation for updating the State Health Plan for Task Force consideration. Frank Pommett, Jr. volunteered to be a member of the proposed subgroup. Chairman Nicolay thanked Mr. Pommett and asked other Task Force members to volunteer. Mr. Kane suggested that subgroups be organized on a SHP chapter basis.

Chairman Nicolay announced the next topic for consideration.

- **State Health Plan Issues: Licensure of Total Acute Care Hospital Beds and Projecting MSGA Bed Need**

Commission staff member Paul Parker presented a description of the methodology used for arriving at an acute care hospital's annual number of licensed beds and for the projection of bed need. The briefing memo to the Task Force described the licensure process and the bed need projection methodology in detail. Mr. Parker explained that staff calculates the total acute care hospital capacity based on hospitals' patient census, as required by the 140% rule in the Commission's statute, which was implemented beginning in calendar year 2001. The calculation is based upon hospitals' data on total physical bed capacity, which is reported to the Commission. Commission staff sends notification of the hospital's licensed capacity each year. Hospitals are required to designate the number of beds for each acute care service. The resulting licensed bed capacity serves as the single, official source of acute care hospital bed inventory for the state.

Mr. Parker noted that the licensure figure is dynamic—changing from year to year pursuant to the hospital's patient census. He used Greater Baltimore Medical Center as an example of licensure calculations based upon DHMH records and the hospital's self-reported data in order to illustrate his explanation.

Mr. Parker explained that as a result of implementing the 140% rule's new methodology in 2001, there was a drop from 12,300 to 9,500 licensed acute care hospital beds, as reflected in the table below. The number of licensed acute inpatient beds has increased from 10,321 last year to 10,323 for the upcoming year (fiscal year 2006). Licensed beds have not changed materially statewide because the average daily census has not changed significantly.

LICENSING ACUTE CARE HOSPITAL BEDS IN MARYLAND

Maryland

	WM	MC	SM	CM	ES	MD
2000:	1,011	1,512	1,625	7,314	866	**12,328**
2001:	784	1,294	1,077	5,714	693	**9,562**
2002:	761	1,302	1,082	5,919	727	**9,791**
2003:	766	1,299	1,143	6,052	734	**9,994**

2004:	756	1,305	1,153	6,129	723	**10,066**
2005:	782	1,338	1,190	6,258	753	**10,321**
2006:	779	1,298	1,155	6,328	763	**10,323**

He described the calculations that the 2010 forecast is based upon, which utilizes an average daily census (ADC) range and an assumption of 80% of average annual occupancy, in order to identify net bed need (as set forth in the table below.) The Commission adopted the bed need methodology in calendar year 2004 for MSGA beds.

PROJECTING THE NEED FOR MSGA BEDS IN MARYLAND

MHCC Occupancy Rate Scale for MSGA Beds

ADC	Avg. Ann. Occupancy Rate
0-49	70% (143% rule)
50-99	75% (133% rule)
100-299	80% (125% rule)
300+	83% (120% rule)

Mr. Parker emphasized that the calculation does not apply to all licensed beds, for instance, there is no bed need methodology for obstetric beds. He also noted that, for psychiatric beds, the dramatic decrease in average length of stay (ALOS) would be included in the methodology proposed in the revised SHP chapter.

Mr. Parker said that elimination of the 140% rule would require a statutory change. Currently, a hospital whose physical capacity is lower than its licensed capacity may expand its licensed capacity without meeting the bed need standard; however, other CON regulatory requirements remain in effect, such as the capital threshold.

In response to Task Force members concerns regarding actual physical capacity, surge capacity, and "expansion capacity" when larger, single hospital rooms are configured, Mr. Parker noted that many hospitals have been constructing a larger number of private rooms that are not large enough to permit a later conversion to semi-private rooms. Mr. Rosen suggested that a hospital's physical capacity is irrelevant. Ms. Cody asked why the Commission would be concerned with a hospital's actual capacity when it has demonstrated financial viability for proposed expansion projects. Ms. Barclay replied that a potential danger would be that hospitals would build capacity in excess of what will be used. Mr. Rosen asked why the Commission does not capture trends in a geographic area, such as the baby-boom generation resulting in a growing population of aging patients; dynamic tertiary care, and the decline of managed care factors. Ms. Barclay replied that staff conducts such analysis in updating bed need projections and that results of analysis have revealed trends similar to Mr. Rosen's description; therefore, there is no debate regarding Maryland's need for greater acute care capacity. She also clarified, in response to Dr. Blumberg's concern regarding hospital's actual capacity, that the Commission's calculations are based upon each hospital's self-reported data on physical capacity.

Mr. Tranter observed that the issue of proposed hospital projects based on a 2010 projection of need ties into the issue of "shell space." In his view, hospitals should build shell space now for

projected utilization beyond calendar year 2010 and that the pledge not to increase rates is an important factor in planning. He added that if a hospital builds "shell space," then it does not logically follow that utilization would be equal to its physical capacity. Dr. Cohen expressed concern about hospitals' maximum need, asserted that the Commission must use a correct definition of "efficiency," and emphasized that CareFirst has supported hospital project applications for conversion to private rooms because, while there is greater expense per bed, "there are cost savings in other areas related to improved quality, such as lower hospital infection rates, which drive lower lengths of stay, which drive lower utilization rates, and there is the ability to have higher occupancy rates…that is all part of the system that drives a reasonable expenditure for capital." Mr. Suldan suggested that changing the Commission's "shell space" policy would provide an immediate benefit to many hospitals and, in the long run, would save money for the system. He suggested that the shell space policy is not set forth in either the Commission's statute, or regulations, and should be eliminated.

Chairman Nicolay presented the following options for consideration:

- Eliminate 140% Rule for Licensing Beds
- Adopt the 71.4% Average Annual Occupancy Rate Assumption Implied by the 140% Rule as the Occupancy Rate Standard Used in Bed Need Projection
- Eliminate CON Regulation of Expansion of Hospital Bed Capacity
- Adopt the Occupancy Rate Scale Used in the State Health Plan as the Implied Average Annual Occupancy Rate in Hospital

Chairman Nicolay suggested that one of the Task Force members make a proposal regarding the options. Dr. Cohen offered a general observation that the Commission should determine appropriate occupancy rates for hospitals and apply them through the SHP, rather than codification of those rates by legislative action. He recommended that the Task Force consider a proposal to recommend that the legislature eliminate the 140% rule and set licensed beds as determined by SHP methodologies. Dr. Cowdry observed that the 140% rule was not the pivotal question. The crucial question was whether the 140% rule gives a hospital, by right, the ability to expand bed capacity without a need determination. In his view, none of the proposed options captured the crux of Dr. Cohen's concerns, i.e., equity among different providers and fidelity to the concept of need based regulation.

Dr. Cohen agreed with Dr. Cowdry's assessment. Ms. Barclay clarified that the term "licensed capacity" means the number of beds a hospital is authorized to operate. Mr. Tranter pointed out that it is implicit in the current licensure law. Dr. Cohen reiterated his recommendation to eliminate the 140% rule, and added a recommendation that the ability to have the number of beds for which a hospital is licensed, unless that number is based on a determination of need, also be eliminated. Ms. Brown argued that no hospital builds, or plans to build, to 140% of occupancy. In her opinion, no hospital believes that it is achieving maximum efficiency at 71% of occupancy. The 140% rule provides the flexibility that hospitals need to expand capacity, as necessary, in response to growing demand. Bed capacity and bed need projections, with new standards projecting need as of 2004, have been established in statute and regulation.

Mr. Parker pointed out that pursuant to the 140% rule, a hospital's license changes each year. For all forty-seven acute care general hospitals, the licensure rule is roughly congruent with the bed need projection. Following discussion among the Task Force members, Mr. Pommett pointed out that as a result of the 140% rule, demonstrating consistent, sustained growth permits flexibility for acute care hospitals.

Dr. Wilson noted that he would be reluctant to recommend limits to flexibility, citing, for example, that Peninsula Regional Medical Center's (PRMC's) licensed bed capacity was increased by twenty-three beds last year (due to the 140% rule) and in light of the recent unprecedented regional growth , PRMC has reached maximum capacity. Dr. Wilson was concerned that if flexibility were eliminated, then PRMC would exceed capacity prior to completion of its proposed expansion project.

Mr. Rosen said that the licensing rules should drive the Commission's methodology. In response to Chairman Nicolay's request, Mr. Rosen proposed that the Commission use a need projection that is consistent with the 140% rule, as mandated by the legislature. Dr. Cohen argued that the 140% rule was adopted in order to eliminate paper beds. In his opinion, using the rule as a standard in the SHP would be result in a policy that would be inconsistent with the legislative intent when the rule was adopted. He proposed that the Task Force adopt the fourth option under consideration. Mr. Tranter and Mr. Rosen disagreed with Dr. Cohen's analysis.

Mr. Rosen again reiterated that the Commission should be establishing policies that are consistent with the statutes enacted by the legislature. He proposed that the option recommended by the Task Force should be that the Commission's rule remain the same as the licensure rule. He also suggested that if the Task Force wanted to recommend a change to the licensing rule, then the issue should be delegated back to the Commission for consideration. In the interim, he indicated that the policy must be that the Commission conforms until there is change to that which it conforming to. Mr. Tranter agreed with Mr. Rosen.

Mr. Rosen made a motion that the Commission adopt a need projection that is consistent with the current licensing criteria for all medical services, for all licensed beds. He clarified, in response to questions from Mr. Tranter and from Ms. Barclay, that he was not addressing the allocation of beds. Mr. Rosen restated his motion: "For projected bed need, the Commission should be using the licensing formula for beds in the State of Maryland, whatever it is at a current period of time." Following discussion, the motion died, as there was no second.

Dr. Cohen made a motion that the Task Force recommend option number four to adopt the occupancy rate scale used in the SHP as the implied average annual occupancy rate for hospital licensure, which would require legislative change. Chairman Nicolay observed that Dr. Cohen's motion died, as there was no second.

Dr. Blumberg made a motion that the Task Force adopt option two, which was seconded by Dr. Hussein. Ms. Stefanides said that the motions proposed thus far had not addressed the issue of the policy application for allocation of licensed acute care hospital beds, as Ms. Barclay had discussed. Following further discussion, Chairman Nicolay called for a vote on the motion. Voting in favor were: Blumberg, Chester, Hussein, Pinkner, Pommett, Rosen, Suldan, Stefanides, Tranter, and Wilson. Dr. Cohen voted against the motion, and the following Task Force members abstained: Bonde, Brown, Cody, Kane, Meilman, and Weglein.

Dr. Cohen made a motion that the Task Force recommend the elimination of the 140% rule, which was seconded by Dr. Blumberg. Voting in favor were: Blumberg, Cohen, and Kane. Opposed were: Brown, Pinkner, Pommett, Stefanides, Suldan, Tranter, and Wilson. The following Task Force members abstained: Bonde, Chester, Cody, Hussein, Meilman, Rosen, and Weglein.

Mr. Suldan made a motion that the existing policy of not permitting hospitals to construct shell space be eliminated and that hospitals be permitted to build shell space, so long as they do not seek to include the cost of the vacant space in their rates while it is vacant. Dr. Wilson seconded Mr. Suldan's motion. Dr. Meilman pointed out that there is a probable inability of our current hospital system to absorb any type of catastrophic event with survivors, such as an anthrax attack or another event similar to September 11th in the Washington area. When he was in medical school, approximately half of the hospitals' patients could have been asked to go home at any time because they were receiving elective care. Presently, most hospital patients are too sick to move. The Task Force and Commission should consider hospital capacity to deal with this issue. Susan Panek, the Commission's Chief of Certificate of Need, noted that Maryland Institute for Emergency Medical Services Systems (MIEMSS) has a work group considering the issue.

Mr. Kane inquired whether Mr. Suldan's motion included shell space in nursing homes, which also had surge capacity issues. At Chairman Nicolay's request, Mr. Suldan clarified that his motion applied to only to hospitals. Chairman Nicolay called the question. The motion was unanimously approved.

Mr. Kane moved that nursing homes be able to build shell space. The motion was seconded by Dr. Cohen. Task Force members Cohen, Kane, and Wilson voted in favor of the motion. Abstaining were: Blumberg, Bonde, Chester, Cody, Pommett, Rosen, Stefanides, and Tranter.

- **Follow-up Items: Guiding Principles**

Chairman Nicolay announced that a Working Paper, *Guiding Principles for the Maryland Certificate of Need Program,* had been revised and provided to the members present for purposes of discussion. He thanked the Task Force members for sharing their views on the subject, which were reflected in the first half of the document. Dr. Cowdry commented that the second half of the document articulated principles that had been triggered by the stimulus provided in comments received about the role of competition and the interesting tension between the Commission's work and market forces in the health care market. He emphasized that the draft Working Paper was not meant to be a statement of policy. Instead, it was a "thought piece" analogous to some of the written comments received by the Commission. In Dr. Cowdry's view, it was quite possible that the majority of Task Force members' written responses to the draft would endorse the short list of general principles; however, it would be of great interest to understand the Task Force members' perspectives on his comments as the Commission goes through a strategic planning process for the next five to ten years, e.g., what the performance reporting system should be like and to what extent that system should interact with health care technology capabilities in ten year's time; and what should the Certificate of Need program be like in an environment where there is better information and, at least in some areas, better opportunities "for the market to actually operate like a market."

Chairman Nicolay added that the draft Working Paper represents the mission statement for the deliberations and considerations of the CON program by the Task Force and the Commission. Due to the absence of some of the members, he directed that the staff email the document following the meeting.

- **Follow-up Items: Completeness Review and Re-Docketing**

Chairman Nicolay introduced proposed restructuring of the review process:

- Require two conferences in the review of any CON application.
  - Application Review Conference
  - Project Status Conference
- Allow for changes in a project that bring it in closer conformance with the staff's or Reviewer's analysis, without penalizing such changes by adding more process or time to the review.

Dr. Wilson thought that the restructuring would result in faster docketing of applications; however, he asked if staff would continue to pose questions to applicants after an application has been deemed complete. Mr. Parker stated that the proposed application review conference would provide an opportunity for better communication and efficient responses for the applicant, Commission staff, and any appointed reviewer. Mr. Tranter suggested that the Commission retain the current completeness review rules and return to the "old process" that limited the number of times an application was reviewed for completeness. Ms. Wideman stated that the purpose of completeness questions was for staff to get sufficient information to review an application. Ms. Brown noted that, in Johns Hopkins recent major application, completeness review was not a problem because Hopkins knew the information staff needed and supplied it. Mr. Rosen suggested that the critical question relates to the timeframe within the context of when an application is deemed complete. Chairman Nicolay replied that the proposal did not include a change to the timeframe regulations. Dr. Blumberg made a motion that the Task Force recommend restructuring of the review process as delineated in the briefing paper, which was seconded by Dr. Chester. Task Force members Bonde, Blumberg, Brown, Chester, Cohen, Kane, Meilman, Pinkner, Pommett, Rosen, Suldan, Tranter, and Weglein voted in favor of the motion; Stefanides and Wilson abstained from voting.

- **Follow-up Items: Interested Parties**

  - Designation of Third Party Payers
  - Definition of Adversely Affected

Chairman Nicolay emphasized the importance of taking a balanced approach in the designation of interested parties. In response to a question from Dr. Blumberg regarding rights to make comments in support of a proposed application, in consideration of the public process described by Commissioner Ginsburg at an earlier meeting, Ms. Wideman described the current standards for designation of interested parties, as provided in regulation. Following discussion, Mr. Tranter made a motion that the Task Force recommend that the Commission leave the existing rules for interested parties, third party payers, and the definition of adversely affected exactly as they are. His motion was seconded by Ms. Stefanides. Task Force members Bonde, Brown, Chester, Kane, Meilman, Pinkner, Pommett, Rosen,

Suldan, Tranter, Weglein, and Wilson voted in favor of the motion; Blumberg and Cohen voted against the motion, and there were no abstentions.

- **Follow-up Items: Ambulatory Surgery Services**

Chairman Nicolay announced that comment received from Dr. Pinkner and Deron A. Johnson on behalf of the Maryland Ambulatory Surgical Association was distributed to the members of the Task Force for later consideration.

4. Other Business

- **Updated Meeting Schedule**

Chairman Nicolay pointed out the addition of a Task Force meeting to be held on Thursday, September 22, 2005 at 1:00 p.m.

5. Adjournment

Chairman Nicolay announced that the next meeting would be held on Thursday, September 8, 2005 at 1:00 p.m., and upon a motion by Dr. Blumberg, and seconded by Ms. Brown, adjourned the meeting at 4:28 p.m

Revised September 23, 2005

Summary of the Meeting of the CON Task Force
September 8, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present
Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Larry Ginsburg
Commissioner Robert E. Moffit, Ph.D.
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Annice Cody
Hal Cohen, Ph.D.
Natalie Holland
Carlessia A. Hussein, DrPH
Michelle Mahan
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Christine M. Stefanides, RN, CHE
Jack Tranter, Esquire
Elizabeth Weglein

Task Force Members Absent
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Adam Kane, Esquire
Anil K. Narang, D.O.
Douglas H. Wilson, Ph.D.

Members of the Public Present
Clarence Brewton, MedStar Health
Richard Coughlan
Jack Eller, Ober, Kaler
Sean Flanagan, St. Joseph Medical Center
Chris Hall, Adventist HealthCare
Katherine Hax, Kaiser Permanente
Anne Langley, Johns Hopkins Health System
Denise Matricciani, MHA: Association of Maryland Hospitals & Health Systems

Chantel Ornstein, Alexander & Cleaver
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Michelle Rice, MNCHCA and Potomac Home Health Care
Linda Stahr, Maryland Legislative Information Services

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:12 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (August 25, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the August 25th meeting and asked for any comments, changes, or corrections. Albert L. Blumberg, M.D., F.A.C.R., requested a revision to reflect that he had abstained from voting on Mr. Kane's motion regarding shell space for nursing homes, and made a motion to approve the minutes, as revised, which was seconded by Jack Tranter, Esquire, and approved by the members present.

3. Review and Discussion of CON Program Issues

- **Recap of August 25, 2005 Meeting**

Chairman Nicolay presented a recap of the August 25th meeting.

- **Review of Draft CON Task Force Report (9/8/05)**

Guiding Principles

Chairman Nicolay announced that the Task Force would consider the Draft CON Task Force Report. The first issue discussed was the Task Force Recommendation regarding the Principles to Guide the CON Program. Following discussion, Commissioner Robert E. Moffit, Ph.D. made a motion to strike the word "unrestricted" in the second principle of the draft Guiding Principles, which was seconded by Hal Cohen, Ph.D. Additional discussion ensued, resulting in Commissioner Moffit's restated motion that the second guiding principle state that "Certificate of Need should be applied only in situations where competition through normal market forces is likely to result in significantly higher or unnecessary costs to the system, decreased access to care by vulnerable populations or less populous regions of the state, or a diminution of the quality or safety of patient care." Task Force members voting in favor of the motion were: Bedrick; Blumberg; Cody; Cohen; Holland; Mahan; Moffit; Pinkner; Pommett; Rosen; Stefanides; Suldan; Tranter; and Weglein. Task Force members Ginsburg, Hussein, and Mahan abstained from voting. None of the Task Force members voted in opposition to the motion. Following further discussion, Chairman Nicolay emphasized that all comments would be addressed and that the Commission's guiding principles would promote and improve access by

"addressing the needs of the underserved population as well as the racial disparity, which presently exists."

- **State Health Plan**

Chairman Nicolay announced the next agenda item would be consideration of the Task Force recommendations on slides 4, 5, and 6 of the presentation. Frank Pommett proposed that the Task Force add a fourth bullet on page four under State Health Plan that, "Review of each chapter shall be consistent with the guiding principles of the CON program." Following discussion, it was unanimously agreed that Mr. Pommett's suggestion would be adopted. Additional discussion ensued regarding whether the Long Term Care chapter would be reviewed in a similar manner as the acute care chapter, and whether operating room and procedure room should be defined in the Commission's State Health Plan chapter regarding ambulatory surgical facilities. In response to Task Force members' questions regarding whether the Final Report of the Task Force would describe its deliberations prior to recommendations that would be made to the Commission, Commissioner Moffit observed that minutes of earlier Task Force meetings included that information. Chairman Nicolay pointed out that concerns regarding specific Task Force recommendations would be discussed at the next meeting.

- **Review of Draft CON Task Force Report (9/8/05)**
- **CON Review Process**

Task Force member Christine Stefanides said that there were inconsistencies in the Task Force recommendations for eliminating CON review for home health and burn services, while retaining CON for other services. Chairman Nicolay reiterated that deliberations regarding those decisions were reflected in the minutes of earlier meetings. Mr. Pommett observed that he might have changed earlier votes if the guiding principles had been more fully considered prior to deliberations regarding specific services. In response to Mr. Tranter's question regarding the status of the Task Force recommendation on burn care services, Chairman Nicolay replied that the Task Force had not yet received recommendations from Task Force member Patricia M.C. Brown, Esquire. Task Force member Joel Suldan suggested that the review standards regarding expansion of hospitals' operating room capacity and distinctions between inpatient and outpatient capacity created unnecessary complexity. Following discussion among the members of the Task Force and staff, it was agreed that, if a Technical Advisory Committee is created to deal with ambulatory surgery, it should consider this issue.

- **Streamlined ("Fast Track") CON Review Process**

In reply to a question from Ms. Bonde regarding how projects eligible for "Fast Track" would be identified, Ms. Barclay replied that the types of projects would be set forth and specifically addressed in the State Health Plan. Task Force members Cohen, Blumberg, and Tranter expressed concerns about the potential effects upon hospitals, staff resources of the MHCC, as well as the HSCRC, caused by any new regulations that would include a "deemed approved" clause. Mr. Tranter made a motion that the Task Force adopt the language proposed for a Streamlined ("Fast Track") CON Review Process that for a renovation or new construction project with no new services/beds, the Staff Report must be completed within 60 days and the Commission issue its decision in 90 days or project

is deemed approved. The motion was seconded by Mr. Pommett. Dr. Cohen proposed additional language, which was accepted by Mr. Tranter. Following discussion, Mr. Tranter restated his motion that the Task Force recommendation would be:

- Streamlined ("Fast Track") CON Review Process for Renovation Projects/New Construction Projects with No New Services/Beds
- Staff Report in 60 Days/Commission Decision in 90 Days or Project Deemed Approved, unless a hospital applicant applies for a partial rate review.

Mr. Pommett seconded the amended motion. Mr. Tranter specified that the motion applied only to hospital projects and not to long term care facilities. The following Task Force members voted in favor of the motion: Bedrick; Blumberg; Bonde; Holland; Mahan; Moffit; Pinkner; Pommett; Stefanides; Suldan; Tranter; and Weglein. Opposing the motion were Task Force members Cody, Cohen, Ginsburg, and Hussein. Dr. Meilman and Mr. Rosen abstained.

Mr. Suldan made a motion that requests for determination of non-coverage from CON, under the capital review threshold standard, would be deemed approved unless adverse action is taken by the Commission or the Commission staff within sixty (60) days. Dr. Cohen seconded Mr. Suldan's motion. The following Task Force members voted in favor of the motion: Bedrick; Cody; Cohen; Holland; Mahan; Meilman, Moffit, Pinkner, Pommett, Rosen, Stefanides, Suldan, Tranter, and Weglein; opposing the motion were Task Force members Blumberg, Ginsburg, and Hussein. Ms. Bonde abstained.

- **CON Application Form and Filing (Electronic Filings/Website Access)**

Mr. Suldan made a motion, which was seconded by Ms. Bonde, and unanimously approved by the Task Force members present, that requests for Determinations of Non-Coverage from CON become an online process.

- **Require Site Visits and Local Hearings on All Major CON Projects**

In response to questions from Task Force members, Ms. Barclay clarified that the proposal was intended to make site visits a more formal part of the CON review process, as suggested in comments received by the Task Force. Following discussion, Dr. Blumberg proposed that the Task Force partition its recommendation and vote separately.

  - **Require Decision-Makers to Visit Location of Proposed Projects**

Dr. Blumberg made a motion, which was seconded by Dr. Meilman, and unanimously approved, not to require that a decision maker visit the site of a proposed project.

- **Require Commission to conduct Local Hearings on All Contested Projects**

Task Force members voting not to require the Commission to conduct local hearings on all contested projects were Cody, Cohen, Holland, Mahan, Meilman, Moffit, Pinkner, Pommett, Rosen, Stefanides, Suldan, Tranter, and Weglein; voting in favor were: Bedrick, Blumberg, Bonde, and Hussein. There were no abstentions.

- **Eliminate Scheduled CON Reviews**

Dr. Cohen proposed that the Task Force recommend that scheduled CON Reviews be retained, which was seconded by Commissioner Ginsburg. Voting in favor of the motion were Task Force members Bedrick, Blumberg, Bonde, Cody, Cohen, Holland, Hussein, Mahan, Moffit, Pinkner, Pommett, Stefanides, Suldan, and Tranter; no Task Force member opposed the motion. Task Force members Meilman, Rosen, and Weglein abstained.

- **State Health Plan**

  - Emergency Department/Outpatient Services
  - Freestanding Birthing Centers

Dr. Cohen recommended adding a new State Health Plan chapter for Emergency Department services. Following discussion, Dr. Blumberg made a motion that Emergency Department/Outpatient Services and Birthing Center services not be added to the State Health Plan, which was seconded by Mr. Pommett. Following discussion, Dr. Pinkner proposed that the Chairman partition the question.

Dr. Blumberg restated his motion that a new Emergency Department/Outpatient Services chapter not be added to the State Health Plan, which was approved by the following Task Force members: Blumberg; Cody; Holland; Meilman; Moffit; Pinkner; Pommett; Rosen; Stefanides; and Suldan. Task Force members voting in opposition to the motion were Bedrick, Cohen, Ginsburg, and Tranter. Task Force member Weglein abstained.

Dr. Blumberg then moved that free-standing birthing centers not be regulated under the same rules as hospitals. The motion was seconded. Task Force members Blumberg, Cody, Cohen, Meilman, Moffit, Rosen, Stefanides, Suldan, Tranter, and Weglein voted in favor of the motion. Task Force members Bedrick, Ginsburg, Pinkner, and Pommett opposed the motion. Ms. Holland abstained.

Dr. Meilman made a motion that the Task Force recommend the consideration of a rational transport system to the Commission, which was seconded by Mr. Tranter. Following discussion, it was the consensus of the Task Force that timely transfer and transport of patients was within the purview of the Maryland Institute for Emergency Medical Services Systems (MIEMSS).

4. Other Business

- Burn Care Services

Chairman Nicolay observed that Burn Care Services would be considered by the Task Force after receipt of comment from Ms. Brown on behalf of Johns Hopkins Health System.

5. Adjournment

Chairman Nicolay announced that the next meeting would be held on Thursday, September 22, 2005 at 1:00 p.m., and upon a motion by Dr. Pinkner and seconded by Mr. Tranter, adjourned the meeting at 4:12 p.m.

Summary of the Meeting of the CON Task Force
September 22, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present
Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Robert E. Moffit, Ph.D.
Alan Bedrick, M.D.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Hal Cohen, Ph.D.
Natalie Holland
Carlessia A. Hussein, DrPH
Michelle Mahan
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Elizabeth Weglein

Task Force Members Absent
Commissioner Larry Ginsburg
Albert L. Blumberg, M.D., F.A.C.R.
Adam Kane, Esquire
Anil K. Narang, D.O.
Frank Pommett, Jr.
Christine M. Stefanides, RN, CHE
Douglas H. Wilson, Ph.D.

Members of the Public Present
Tyler Brannon, Johns Hopkins Health System
Clarence Brewton, MedStar Health
Sean Flanagan, St. Joseph Medical Center
Katherine Hax, Kaiser Permanente
Donna Jacobs, University of Maryland Medical System
Anne Langley, Johns Hopkins Health System
Chantel Ornstein, Alexander & Cleaver
Vanessa Purnell, MedStar Health

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:10 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (September 8, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the September 8th meeting and asked for any comments, changes, or corrections. Hal Cohen, Ph.D., requested revisions to reflect (1) that he had seconded a motion by Mr. Suldan regarding deemed approved actions; (2) that the Task Force members presented had voted unanimously not to require that a decision maker visit the site of a proposed project; and (3) that the majority of the Task Force members present had voted not to support requiring the Commission to conduct local hearings on all contested Certificate of Need projects. Task Force member William L. Chester, M.D. seconded Dr. Cohen's motion, and the minutes were unanimously approved by the members present, as revised.

3. Review of Draft Final Report of the CON Task Force

- **Guiding Principles for the Maryland CON Program**

Chairman Nicolay announced that the Task Force would consider and either affirm or amend the recommendations in the draft Final Report. The first issue considered was the Principles to Guide the CON Program. Chairman Nicolay noted that there had been considerable interest and input from Task Force members on these principles and that they had been modified following the last Task Force meeting. At the request of the Task Force members, Pamela Barclay, Deputy Director of Health Resources, provided input from the Commission's staff. Following discussion regarding the second guiding principle, Chairman Nicolay suggested that staff would provide a revision to the Task Force members prior the next meeting. Further discussion ensued and Jack Tranter, Esq., made a motion that Commission staff would revise the second principle regarding the access, cost, and quality of health care services, which was seconded by Carlessia A. Hussein, DrPH, and unanimously approved by the members present.

Following additional discussion, Lynn Bonde made a motion to adopt Mr. Tranter's suggestion to phrase the second principle in a neutral manner, which was seconded by Dr. Hussein. Task Force members Bedrick, Bonde, Brown, Chester, Cody, Holland, Hussein, Mahan, Meilman, and Tranter voted in favor of the motion; Task Force members Cohen, Moffitt, Rosen, and Suldan opposed the motion, and there were no abstentions. In addition, it was the consensus of the Task Force members that the commentary should be removed from the draft report.

- **Scope of Coverage**
  -Burn Care Services

Ms. Brown requested that Task Force members reconsider the elimination of burn care services from the CON program. Mr. Tranter made a motion that the Task Force rescind its earlier straw vote, replacing it with a recommendation that the Commission continue to include Burn Care Services in the CON program, which was seconded by Dr. Meilman. Task Force members Bedrick, Bonde, Brown, Chester, Cody, Holland, Hussein, Mahan, Meilman, Pinkner, Rosen, Suldan, Tranter, and Weglein voted in favor of the motion; Task Force members Cohen and Moffitt opposed the motion; and there were no abstentions.

- **CON Review Process**

  - **Capital Expenditure Review Threshold**

Ms. Barclay presented the staff's proposed capital expenditure review threshold of $10 million, indexed for inflation, for acute care hospitals and $2.5 million, indexed for inflation, for all other services. Lawrence Pinkner, M.D. made a motion that the Task Force recommend increasing the capital expenditure review threshold from $1.2 million to $10 million, indexed for inflation, for acute care hospitals, and increasing the capital expenditure review threshold from $1.2 million to $2.5 million for all other services, which was seconded by Mr. Tranter. Following discussion, Dr. Hussein voted in favor of the motion, Task Force members Bedrick, Bonde, Brown, Chester, Cody, Cohen, Holland, Mahan, Meilman, Moffit, Pinkner, Rosen, Suldan, Tranter, and Weglein opposed the motion; and there were no abstentions. Task Force member Natalie Holland made a motion that the Task Force recommend increasing the capital expenditure review threshold from $1.2 million to $10 million, indexed for inflation, for acute care hospitals, and increasing the capital expenditure review threshold from $1.2 million to $5.0 million for all other services, which was amended by Barry Rosen, Esq., that the Task Force recommend increasing the capital expenditure review threshold from $1.2 million to $10 million, indexed for inflation, for those facilities whose rates are set by the Health Services Cost Review Commission, and increasing the capital expenditure review threshold from $1.2 million to $5.0 million for all other services. Following discussion, Task Force members Bedrick, Bonde, Brown, Chester, Cody, Cohen, Holland, Mahan, Meilman, Moffit, Rosen, Suldan, Tranter, and Weglein voted in favor of the motion; Task Force members Hussein and Pinkner abstained from voting, and there were no Task Force members voting in opposition.

  - **Staff Report in 60 Days/Commission Decision in 90 Days or Project Deemed Approved, unless a hospital applicant applies for a partial rate review.**

Ms. Barclay discussed staff's concerns about "deeming approval" on a timeline, especially with regard to the proposals for a "Fast Tracked" process. She asked the Task Force members to consider why a project should be considered reviewable if it was eligible to be deemed approved. Ms. Barclay emphasized that while staff supports and encourages

streamlining incentives, and is keenly aware of workload issues, it would be unusual to have a regulatory clause granted automatic "deemed approved" status. Following discussion, Dr. Cohen made a motion that the Task Force affirm the recommendation to Revise Determination of Non-Coverage requirements for hospitals taking the "pledge" not to increase rates to deem the request approved if not acted upon by the Commission within 60 days, which was seconded by Task Force member Joel Suldan. Task Force members Bedrick, Bonde, Brown, Cody, Cohen, Mahan, Moffit, Pinkner, Rosen, Suldan, Tranter, and Weglein voted in favor of the motion, Dr. Hussein voted against the motion, and Task Force members Chester, Holland, and Meilman abstained.

- **State Health Plan**

  - **Add policies to the Acute Inpatient Services chapter of the State Health Plan permitting shell space.**

The next agenda item was consideration of the Task Force recommendation to add policies to the Acute Inpatient Services chapter of the State Health Plan permitting shell space. Mr. Suldan made a motion that the Task Force's recommendation be revised to permit hospitals to construct shell space so long as they do not apply for a rate increase as long as the space remains vacant, which was seconded by Ms. Brown. Following discussion, Task Force members Bedrick, Bonde, Brown, Chester, Cody, Holland, Mahan, Meilman, Moffit, Pinkner, Rosen, Suldan, Tranter, and Weglein voted in favor of the motion; Dr. Hussein voted against the motion, and Dr. Cohen abstained.

  - **Use the 71.4% occupancy rate assumption implied by the Office of Health Care Quality's statutory 140% licensing rule as the occupancy rate standard in acute care bed need projections for all services.**

Ms. Barclay stated that staff opposed adoption of the Task Force's recommendation for several reasons. She said that the recommended policy will overstate bed need for larger hospitals, facilitating costly construction of excess bed capacity at these facilities. It will understate bed need for smaller hospitals and certain categories of service (such as obstetrics and pediatrics), resulting in inadequate need projections for these facilities and services. There is no support in the literature or practice of health planning for application of a single occupancy rate standard to all hospitals, whatever the size of the hospital's average daily patient census. In Maryland, acute care hospital average daily patient census in CY2004 ranged from 5.5 patients to 676.5 patients. Because Maryland hospitals are rapidly converting their bed capacity to all private room accommodations, Barclay noted that this trend would increase achievable average bed occupancy. Finally, Ms. Barclay indicated that the recommendation employs a standard which was established in law to achieve the objective of reducing licensed bed capacity, when average annual occupancy of most hospital's physical capacity was in the 50% to 60% range. In complete contradiction to this legislative purpose, adapting this standard to bed need projection will encourage growth in bed capacity beyond that necessary for reasonable average bed occupancy.

Following discussion of the occupancy rate methodology, the effects of the 140% licensing rule on hospitals' future need projections, the length of the planning horizon, and consideration of alternative solutions, the Commission's Executive Director, Rex Cowdry, M.D., observed that staff would prefer the status quo to the Task Force's proposed recommendation. Ms. Bonde made a motion that the Task Force rescind the recommendation, which was seconded by Mr. Cohen. Following discussion, Ms. Bonde withdrew her motion. Chairman Nicolay suggested that Task Force members continue discussion of this issue and send proposed recommendations and comments to Ms. Barclay for inclusion in the draft Final Report.

4. Other Business

- **Home Health Care Services**

Chairman Nicolay observed that the Task Force had considered the issues raised by the Commission's staff. He thanked the members of the Task Force for their input and asked if there was other business for consideration. Ms. Brown requested reconsideration of the Task Force's recommendation to remove home health Services from the CON program, for reasons set forth in a letter from Johns Hopkins Health Care Group and consistent with the application of the general principles governing the CON program. Chairman Nicolay requested the members of the Task Force to send comments on the issues that had been deliberated to staff following receipt of the revised draft Final Report.

5. Adjournment

Chairman Nicolay announced that the date of the next meeting had not yet been determined, and upon a motion by Mr. Tranter, and seconded by Mr. Rosen, adjourned the meeting at 4:09 p.m.

Summary of the Meeting of the CON Task Force
October 27, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present
Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Robert E. Moffit, Ph.D.
Commissioner Larry Ginsburg
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Hal Cohen, Ph.D.
Adam Kane, Esquire
Michelle Mahan
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Elizabeth Weglein

Task Force Members Absent
Natalie Holland
Carlessia A. Hussein, DrPH
Anil K. Narang, D.O.
Frank Pommett, Jr.
Christine M. Stefanides, RN, CHE
Douglas H. Wilson, Ph.D.

Members of the Public Present
Tyler Brannon, Johns Hopkins Health System
Ing-Jye Cheng, MHA
Sean Flanagan, St. Joseph Medical Center
Anne Langley, Johns Hopkins Health System
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center

1. Call to Order

Chairman Robert E. Nicolay called the meeting to order at 1:12 p.m. and welcomed Task Force members and the public.

2. Approval of the Previous Minutes (September 8, 2005)

Chairman Nicolay noted that the Task Force members had received copies of the minutes of the September 22, 2005 meeting and asked for any comments, changes, or corrections. Task Force member Lawrence Pinkner made a motion to approve the minutes, which was seconded by Albert L. Blumberg, M.D., F.A.C.R, and unanimously approved by the members present.

3. Review of the Revised Draft of the Report of the CON Task Force

- **State Health Plan**

Chairman Nicolay announced that the Task Force would consider and either affirm or amend the recommendations in the revised draft report. Following consideration and approval of the Task Force members, the report would be presented to the Commission for consideration at its November 22, 2005 meeting.

The first issue considered by the Task Force was the proposed review and update of the State Health Plan for Facilities and Services. Following discussion of the recommendation regarding ambulatory surgery, Task Force member Barry Rosen proposed that the Task Force's recommendation be revised to state as follows:

> The revision of the Ambulatory Surgical Services chapter should consider ~~the implications of~~ better defining the exemption from CON regulation for establishment of single operating room ambulatory surgical facilities ~~as an exemption~~ for a single room for the provision of invasive procedures within a practitioner's office~~. whether the room is a sterile operating room or a non-sterile "procedure room."~~ This will require consideration of definitions of the terms "operating room" and "procedure room"~~. and revised and expanded definitions of "full" and "optimal capacity" for different categories of surgical room.~~

Following further discussion, it was the consensus of the Task Force to adopt the revised language as proposed by Mr. Rosen.

Dr. Pinkner made a motion that the Task Force recommend to the Commission be that a study of the CON laws should be extended to include other outpatient services (e.g., birthing centers), which was seconded by Task Force member William L. Chester, M.D. Task Force members Bedrick, Bonde Chester, Pinkner, and Ginsburg voted in favor of the motion; Task Force members Blumberg, Brown, Cody, Cohen, Kane, Meilman, Moffit, Rosen, Tranter, Suldan, and Weglein voted in opposition to the motion; and Task Force member Mahan abstained. The motion failed.

Following discussion, Mr. Rosen made a motion that the Task Force recommendation regarding revision of the acute care chapter of the State Health Plan be revised as follows: The revision of the Acute Inpatient Services chapter of the State Health Plan should eliminate or substantially modify the following standards to the extent that they are obsolete and redundant, including: .06A(2) Utilization Review Control Programs; .06A(3) Travel Time; .06A(4) Information Regarding Charges; .06A(5) Charity Care Policy; .06A(6) Compliance with Quality Standards; .06A(7) Transfer and Referral Agreements; .06A(8) Outpatient Services; .06A(9) Interpreters; .06A(10) In-Service Education; .06A(11) Overnight Accommodations; .06A(12)Required Social Services; .06A(19) Minimum Size for Pediatric Unit; .06A(20) Admission to Non-Pediatric Beds; .06A(21) Required Services When Providing Critical Care; .06A(22)Average Length of Stay for Critical Care Units; .06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients; .06B(1) Compliance with System Standards; .06B(2)(a) Duplication of Services and Adverse Impact; .06B(4) Burden of Proof Regarding Need; .06B(5)Discussion with Other Providers; .06B(9) Maximum Square Footage; .06C(2) Compliance with System Standards; .06C(3) Conditions for Approval; and, .06C(5) Maximum Square Footage-Renovations. Ms. Brown made a motion that the Task Force recommend that Staff move expeditiously to draft proposed regulations eliminating those standards that it agrees are obsolete or duplicative (as stated in Mr. Rosen's earlier motion) and that the remaining issues regarding revision of the SHP to be considered by a technical advisory group. This motion was seconded by Mr. Tranter, and unanimously approved by the Task Force.

Following discussion, Dr. Blumberg made a motion that the Task Force recommend that the Commission conduct a comprehensive review and update of the State Health Plan for Facilities and Services, including the final modifications approved, which was seconded by Dr. Pinkner, and unanimously approved.

Following discussion regarding the issue of shell space, Rex W. Cowdry, M.D., the Commission's Executive Director, suggested that the Task Force recommendation regarding shell space be revised as "Add policies to the Acute Inpatient Services chapter of the State Health Plan addressing shell space." Mr. Tranter made a motion that the Task Force adopt Dr. Cowdry's suggestion, which was seconded by Ms. Brown, and unanimously approved by the Task Force members present.

- **CON Review Process**

Ms. Cody noted concerns about recommending removal of standards from the State Health Plan review criteria, particularly standards for charity care, quality compliance, and the size of pediatric units, that had not been discussed by the Task Force members. Following discussion of the review criteria and development of a streamlined ("Fast Track") CON review process, Task Force member Patricia M.C. Brown, Esquire made a motion to approve the language in the final draft report, with the exception of the recommendation regarding home health services, which was seconded by Task Force member Jack Tranter, Esquire, and unanimously approved.

Dr. Blumberg made a motion that the Task Force recommendations to the Commission regarding the Certificate of Need Review Process be adopted, including the final modifications approved, which was seconded by Task Force member Lynn Bonde, and unanimously approved by the Task Force members present.

- **Scope of Coverage**
  -Home Health Services

Chairman Nicolay said that the next agenda item for consideration would be the Task Force's recommendation regarding home health services. Following discussion, Mr. Suldan made a motion that the Task Force recommends that the Commission, effectively, issue a CON for home health applicants that agree to meet the Medicaid and the charity care requirements, but eliminate the capacity constraints by eliminating the need projection methodology for home health agencies in the State Health Plan, which was seconded by Mr. Kane. Following further discussion, Mr. Suldan withdrew his motion. Mr. Tranter made a motion that the Task Force recommend removal of home health agencies from the definition of "health care facility", which was seconded by Commissioner Robert Moffit. Task Force members Blumberg, Cohen, Kane, Moffit, Pinkner, Suldan, Tranter, and Chairman Nicolay voted in favor of the motion; Task Force members Bedrick, Bonde, Brown, Cody, Ginsburg, Mahan, and Meilman opposed the motion; and Task Force members Chester, Rosen, and Weglein abstained.

Additional discussion ensued and Mr. Rosen made a motion that if the Commission chooses not to move forward with deregulation of home health services, then Certificate of Need should be granted when the applicant agrees to meet the Medicaid, charity care requirements and all other standards. Mr. Rosen's motion was seconded by Dr. Chester. Task Force members Bedrick, Blumberg, Bonde, Brown, Chester, Cody, Cohen, Kane, Mahan, Moffit, Pinkner, Suldan, and Tranter voted in favor of the motion and Task Force members Ginsburg, Meilman, and Weglein abstained. There were no votes cast in opposition to the motion.

Commissioner Moffit made a motion that the Task Force recommend the deregulation of obstetrics services, which was seconded by Mr. Tranter. Following discussion, Task Force members Blumberg, Cohen, Kane, and Tranter voted in favor of the motion; Task Force members Bedrick, Bonde, Brown, Chester, Cody, Ginsburg, Mahan, Meilman, Pinkner, Rosen, and Suldan opposed the motion, and Task Force member Weglein abstained. The motion failed.

- **Scope of CON Coverage**

Chairman Nicolay announced that the next item for consideration would be the remaining recommendations regarding the scope of CON coverage. Discussion ensued and Mr. Rosen made a motion that the Task Force's recommendation be partitioned regarding the review process. One recommendation would be for the development of a streamlined review process. A separate recommendation would be that the Commission issue a Staff Report within sixty days and a Commission decision within ninety days or a project is deemed approved. Mr. Rosen's motion was seconded by Mr. Tranter. Task Force members Bedrick, Bonde, Blumberg, Brown, Chester, Cody, Ginsburg, Kane, Mahan, Meilman, Pinkner, Rosen, Suldan, Tranter, and

Weglein voted in favor of the motion; Task Force members Cohen and Moffit opposed the motion, and there were no abstentions. The motion carried.

- **Principles to Guide the CON Program**

Chairman Nicolay announced that the next item for consideration would be the guiding principles. Dr. Blumberg made a motion to approve the guiding principles, which was seconded by Mr. Rosen. Ms. Bonde amended the motion to include the modifications proposed by Task Force member Carlessia A. Hussein, DrPH, which was acceptable to Dr. Blumberg. The motion was unanimously approved by the Task Force.

- **Next Steps**

Chairman Nicolay said that the final draft report would be sent to the Task Force members for their approval in early November, followed by presentation to the Commission at its next meeting on November 22, 2005, and a public comment period. The Commission will consider the report for final action at its December 15, 2005 meeting and develop an implementation plan thereafter.

4. Other Business

Chairman Nicolay thanked the members of the Task Force for their input and asked if there was other business for consideration. Dr. Cohen stated that the Commission members should note the composition of the Task Force membership as it considers the recommendations in the final report.

Chairman Nicolay emphasized that it had been a pleasure to have worked with the distinguished members of the Task Force, thanked the Commission staff for its outstanding work, and invited the Task Force members and members of the public to the next meeting of the Commission on November 22, 2005.

5. Adjournment

There being no further business, the meeting was adjourned upon a motion by Mr. Tranter, and seconded by Mr. Rosen, at 3:34 p.m.