

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*



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

	CON Task Force Recommendation	Implementation Progress
<p>Scope of CON Coverage</p>	<p>Increase the capital-expenditure threshold to \$10 million for hospitals regulated by the HSCRC and \$5 million for other facilities</p> <p>Remove the requirement for a public informational hearing for hospital closures in jurisdictions with more than two hospitals</p> <p>Remove the requirement to obtain a CON exemption for hospital closures in jurisdictions with fewer than three hospitals</p> <p>Expand the business office equipment exemption to include information technology</p> <p>Remove home-health agency from the definition of health care facility or, alternatively, eliminate home health from the State Health Plan</p> <p>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</p> <p>Issue a staff report to allow the Commission to act on a CON application for an unopposed project within 90 days of docketing</p>	<p>Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006</p> <p>Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006</p> <p>Statutory changes in Chapter 541 of 2006, implemented through changes to COMAR 10.24.01, effective October 23, 2006</p> <p>Implemented through changes to COMAR 10.24.01., effective April 10, 2006</p> <p>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.</p> <p>Regular review process now completed more rapidly</p> <p>Implemented through changes to COMAR 10.24.01., effective April 10, 2006</p>

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	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	<p>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</p> <p>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</p> <p>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</p>	<p>The Commission updates the State Health Plan on an on-going basis:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>The update of the Ambulatory Surgical Services chapters of the State Health Plan will be initiated by Commission staff in 2009.</p> <p>On September 18, 2008, the Commission adopted as emergency regulations an updated forecast of medical-surgical-gynecological-addictions (MSGGA) and pediatric service for 2016. These bed need forecasts update the 2010 forecast adopted by the Commission in 2004.</p> <p>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</p>

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	<p>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.</p> <p>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</p> <p>Study alternatives to eliminate the inconsistency between the 140 percent rule for determining licensed acute care bed capacity and the Plan occupancy assumptions</p>	<p>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.</p> <p>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.</p> <p>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.</p>
CON Review Process	Restructure the process to require two conferences – an application	Implemented through changes to COMAR 10.24.01.,

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	<p>review conference and a project status conference – as part of the review of any CON application</p> <p>Modify the CON review process to permit certain changes, addressed in a project status conference, without redocketing of the application</p> <p>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</p>	<p>effective April 10, 2006</p> <p>Implemented through changes to COMAR 10.24.01., effective April 10, 2006</p> <p>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.</p>

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
<p>Phase I: Final Report to the Maryland General Assembly</p> <ul style="list-style-type: none"> • Obstetric Services 	<p>Recommendation 1.0 The Commission should continue its regulatory oversight of acute inpatient obstetric services through the Certificate of Need program.</p> <p>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.</p>	<p>The establishment of a new acute inpatient obstetric service continues to be regulated under the CON program in Maryland.</p> <p>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.</p>
<ul style="list-style-type: none"> • Cardiac Surgery and Therapeutic Catheterization Services 	<p>Recommendation 2.0 The Commission should continue its regulatory oversight of open heart surgery services through the Certificate of Need program.</p> <p>Recommendation 2.1 The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care.</p> <p>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.</p>	<p>The establishment of new OHS services continues to be regulated under the CON program in Maryland.</p> <p>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.</p> <p>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</p>

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	<p>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.</p> <p>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.</p>	<p>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.</p> <p>The Commission coordinates its planning and regulatory activities on an on-going basis.</p> <p>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</p>

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		Hospital Center is the only program not meeting minimum volume requirements.
<ul style="list-style-type: none"> • Home Health 	<p>Recommendation 3.0 The Commission should continue its regulatory oversight of home health agencies through the Certificate of Need program.</p> <p>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.</p> <p>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.</p>	<p>The establishment of a new home health agency continues to require CON approval in Maryland.</p> <p>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.</p> <p>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.</p>
<ul style="list-style-type: none"> • Hospice Services 	<p>Recommendation 4.0 The Commission should continue its regulatory oversight of hospice services through the Certificate of Need program.</p>	<p>The establishment of a new hospice program continues to be regulated under the CON program in Maryland.</p>
<ul style="list-style-type: none"> • Nursing Home Services 	<p>Recommendation 5.0 The Commission should continue its regulatory oversight of nursing home services through the Certificate of Need program.</p>	<p>Nursing homes continue to be regulated under the CON program in Maryland. The capital expenditure threshold was modified by Chapter 541 of 2006.</p>

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		Adjusted for inflation, the current capital expenditure applicable to nursing home projects is \$5,250,000.
<p>Phase II: Final Report to the Maryland General Assembly</p> <ul style="list-style-type: none"> Acute Inpatient Services (Medical-Surgical and Pediatric) 	<p>Recommendation 1.0 The Commission should continue its regulatory oversight of acute inpatient medical-surgical and pediatric services through the Certificate of Need program.</p> <p>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.</p>	<p>Acute inpatient hospital services continue to be regulated under the CON program in Maryland.</p> <p>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.</p>
<ul style="list-style-type: none"> Organ Transplant , NICU, Burn Care Services 	<p>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.</p>	<p>Organ transplant, neonatal intensive care unit (NICU), and burn care services continue to be regulated under the CON program in Maryland.</p>
<ul style="list-style-type: none"> Rehabilitation and Chronic Hospital Services 	<p>Recommendation 3.0 The Commission should continue its regulatory oversight of inpatient rehabilitation and chronic hospital services.</p> <p>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.</p>	<p>Special hospital rehabilitation and chronic services continue to be regulated under the CON program in Maryland.</p> <p>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.</p>

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		<p>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.</p>
<ul style="list-style-type: none"> • Ambulatory Surgery Services 	<p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>The establishment of two operating room ambulatory surgical facilities continues to be regulated under the CON program in Maryland.</p> <p>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.</p> <p>The Commission plans to develop a new chapter of the State Health Plan on surgical services that will address issues related to ambulatory surgery.</p> <p>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</p>

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	<p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>are not regulated under CON.</p> <p>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.</p>
<ul style="list-style-type: none"> • Inpatient Psychiatric Services 	<p>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.</p> <p>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.</p>	<p>Inpatient psychiatric services continue to be regulated under the CON program in Maryland.</p> <p>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 Report¹ directed the Commission to develop a plan to guide the future mental health service continuum needed</p>

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.

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	<p>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.</p>	<p>in Maryland. The Plan will include a statewide mental health needs assessment of the demand for:</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>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.</p>
<ul style="list-style-type: none"> • Inpatient Psychiatric Services and Residential Treatment Centers for Children and Adolescents 	<p>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.</p> <p>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</p>	<p>Residential treatment services continue to be regulated under the CON program in Maryland.</p> <p>This recommendation has not been implemented.</p>

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	<p>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.</p> <p>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.</p>	<p>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.</p>
<ul style="list-style-type: none"> • Intermediate Care Facilities for Addictions Treatment 	<p>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.</p>	<p>Intermediate Care Facilities for Addictions Treatment continue to be regulated under the CON program in Maryland.</p>
<ul style="list-style-type: none"> • Intermediate Care Facilities for the Developmentally Disabled 	<p>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</p>	<p>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.</p>

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