December 14, 2018

Robert Moffit, Ph.D.
Chairman

Randolph Sergent,
Commissioner and Chair, CON Modernization Task Force

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Messrs. Moffit and Sergent:

On behalf of Maryland’s 62 hospital and health system members, we are pleased to submit our comments on the Maryland Health Care Commission’s (MHCC’s) Final Report on Modernization of the Maryland Certificate of Need (CON) Program to the Maryland Senate Finance Committee and House Health and Government Operations Committee (legislative committees). The draft recommendations were presented to the commission on November 15, and the commission will consider the Final Report at the December 20 public meeting.

Final Report Recommendations Published by the Commission

Regulatory Reform
The recommendations, summarized below, would:

1) Identify the State Health Plan (SHP) chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review. Among the changes implemented should be:
   a. Limiting SHP standards to those addressing project need, project viability, project impact, and applicant qualifications. Any other standards...should only be included if absolutely necessary to the particular characteristics of a health care facility. Applicant qualification standards will allow for the establishment of performance or track record thresholds…. For example:
      i. The SHP regulations for home health agencies could be streamlined to facilitate quicker approval of qualified applicants by eliminating extraneous standards or standards with low impact (such as charity care requirements).
      ii. The SHP regulations for general hospices could be revised to create a pathway for facilitating the establishment of alternative choices for hospice care in jurisdictions with only one authorized hospice.
   b. Creating an abbreviated review process for all uncontested projects that do not involve:
      a) establishment of a health care facility; b) relocation of a health care facility; c) the
introduction by a hospital of cardiac surgery or organ transplantation. The features of this review process will include:

i. A goal -- not a hard and fast requirement -- to limit completeness review to one round of questions and responses before docketing an application as complete. (This goal presupposes reforms to significantly reduce and better define SHP standards.)

ii. Issuance of a staff recommendation within 60 days of docketing and final action by the commission within 90 days of docketing.

c. Establish performance requirements for approved projects that include a deadline for obligating the capital expenditure and initiating construction but without project completion deadlines. Failure to timely obligate and initiate construction will void the CON. Timely obligation and initiation of construction will result in a 12-month extension with subsequent requirements to report progress (in essence, an annual progress report) and obtain additional 12-month extensions until project completion. Projects that do not involve construction will continue to have a deadline for completing the project.

d. Establish a process for review of changes in approved projects as a staff review function with approval by the Executive Director. Limit required change reviews to 1) changes in the financing plan that require additional debt financing and/or extraordinary adjustment of a hospital’s budgeted revenue and 2) changes in "medical services" approved to be provided by the facility. Continue current list of impermissible changes.

2) Create the ability for the waiver of CON requirements for a capital project that is endorsed by the HSCRC as a viable approach for reducing the total cost of care consistent with HSCRC’s Total Cost of Care Model and alternative models for post-acute care.

Every chapter of the SHP should be assessed by the commission annually. An assessment means a cursory review and discussion, at a public meeting, all chapters of the SHP in the context of the current health care environment. The objective of the assessment is to determine which, if any, chapters need to be updated that year. If the commission determines that one or more chapters need to be updated that year, the commission should vote to prioritize the order that the chapters should be updated so as not to unreasonably burden staff. It is not feasible for the staff to update every chapter every year. However, if one or two chapters require updates as determined by the commission, hospitals believe this can be accomplished in a given year.

Maryland’s hospitals support updating the SHP and revising CON procedural recommendations, including limiting SHP standards to those identified by staff. We also support a CON review process that aligns with Maryland’s Total Cost of Care Model and is completed in a reasonable time. Details of these recommendations must be addressed in the public process of revising the commission’s regulations. Without proposed revisions to regulations, it not possible to comment on a final version.

The proposed abbreviated review process would create a separate track for CON applications that do not involve establishing or relocating a health care facility, establishing cardiac surgery, or otherwise have interested parties. Health care services could be expanded under this abbreviated application process. We recommended narrowing the focus for all CON applications, limiting the process to the facts needed
to render a decision, and ignoring extraneous information. We agree this should include limiting completeness questions or removing certain criteria. This process ensures all CON applications are given due process and are resolved in a timely manner. We are concerned about unintended consequences of this proposal, including the possible increase in applications with interested parties as stakeholders seek clarity and alignment in the service approval process.

We agree that uncontested applications without service changes or expansions should be approved within 120 days if there is no staff report. The way the recommendation is written allows projects with service expansion, such as adding inpatient beds, to be automatically approved. We do not support this provision as written.

The status of all active CON applications should be a discussion item at every public meeting, rather than just a written report. Commissioners, and the public, should understand the pipeline for CON applications, including identifying and acknowledging reasons for delays in docketing, staff recommended action, or commission action.

Following CON approval, we support recommendations to reduce administrative burdens, including changes to capital obligation requirements. The same is true to allow certain changes once a project has been approved. The proposal would establish a staff review process of proposed changes, with commission approval needed for changes in debt financing and “changes in the location of the project.” We assume “changes in the location of the project” to mean a slight modification in the location after approval. A CON is required to relocate hospitals and health services, and we read this proposal agrees with that requirement.

Hospitals agree that the HSCRC and MHCC should work closely to secure favorable performance under Maryland’s Total Cost of Care Model. However, we do not support the second regulatory proposal because it delegates some statutory authority to the HSCRC. The CON process should align the supply of services with the goals of the Total Cost of Care Model, but the process should stand on its own.

**Statutory Reform**

Nine recommendations to statutes are proposed. These are summarized below, and our comments are grouped accordingly.

1) Eliminate a designated level of capital expenditures by a health care facility, commonly known as the “capital threshold,” for facilities other than a hospital, as an action requiring CON approval.

2) Replace the existing, fixed capital threshold for hospitals with CON approval required for projects that exceed a specified portion of each hospital’s annual revenue. (The portion was not specified)

Maryland’s hospitals support the concept of requiring CON approval for projects above 25 percent of each hospital’s revenue, up to a project cost of $50 million. Any project above $50 million, even if below the 25 percent threshold, should be subject to CON. We appreciate the commission’s intent to remove CON for facility renovation projects.
Under the Total Cost of Care Model, the state of Maryland must comply with certain performance measures, including Medicare spending per beneficiary and total spending per capita. MHCC, and HSCRC, should monitor the growth in utilization of nonhospital services, particularly in areas where nonhospital facilities have been constructed if the capital expenditure threshold is eliminated for nonhospital services.

3) Limit the required considerations in CON project review to: a) Alignment with applicable State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact of the project on cost and charges. This would eliminate the current required consideration of the costs and effectiveness of alternatives to the project compliance with the terms and conditions of previous CONs the applicant has received.

Maryland’s hospitals support this recommendation. We agree that applications must comply with the terms and conditions of previous CONs. While not specified in the recommendation, applicants should not be required to provide MHCC a list of previously approved CONs and evidence of compliance with the conditions of previous CONs. This information is available to MHCC staff. If compliance with conditions of a previous CON is a concern, MHCC staff should address this in the application process.

4) Eliminate the requirement to obtain CON approval of changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility or by a residential treatment center.

5) Eliminate the requirement to obtain CON approval of changes in acute psychiatric bed capacity by a general acute care or special psychiatric hospital.

6) Eliminate the requirement to obtain CON approval of changes in hospice inpatient bed capacity or the establishment of bed capacity by a general hospice.

Hospitals support expanding addiction and behavioral health capacity. However, rather than immediately recommend that CON approval standards be relaxed, hospitals recommended the commission review the psychiatric and intermediate care facilities chapters of the SHP to determine an appropriate course of action. This review should assess psychiatric and behavioral health service capacity across all settings to determine what services are needed.

Hospitals do not have a position on the hospice service recommendation.

7) Define ambulatory surgical facility as an outpatient surgical center with three or more operating rooms instead of the current definition’s threshold of two operating rooms.

8) Limit the requirement for CON approval of changes in operating room capacity by hospitals to the rate-regulated hospital setting, i.e., a general hospital and any other entity would have the ability to establish one or two-operating room outpatient surgical centers without CON approval.
These recommendations are consistent with the changes to the Ambulatory Surgical Facilities (ASF) chapter of the SHP from earlier this year. We agree with recommendation eight that allows hospitals, and other providers, to establish up to a two room ASF, rather than limit this option to “a group of physicians.”

Hospitals recommend that the commission monitor overall Medicare spending for ambulatory surgical facilities. ASFs are generally believed to have a lower price point than acute care hospitals for outpatient surgery. However, ASFs also have no incentives, such as a global budget, to reduce avoidable utilization, and there is no mechanism to hold ASFs financially responsible if related ASF spending increases put pressure on the total cost of care measure.

9) Established deemed approval for uncontested project reviews, eligible for an abbreviated project review if final action by the commission does not occur within 90 days.

Similar to our comments on the proposed regulatory review, hospitals generally agree with this recommendation. However, this should apply to all uncontested projects that do not involve increases in medical services, and there is no need to create an “abbreviated” project review if the criteria are limited and extraneous standards are removed. Recommendation 9 allows for approval at 90 days, while recommendation 1.b.ii allows for approval at 120 days. It is not clear if these dates should be consistent.

Areas for Further Study

MHCC recommended three areas for further study.

1) Engage with the home health, hospice, alcohol and drug treatment, and residential treatment center sectors and the Maryland Department of Health on alternatives to conventional CON regulation for accomplishing the “gatekeeper” function of keeping persons or organizations with poor track records in quality of care and/or integrity from entering Maryland and accomplishing the objective of expanding the number of such facilities gradually.

2) Engage with HSCRC on ways in which hospital CON project review and the Total Cost of Care project can be further integrated. The objective would be to limit hospital projects requiring CON review and to improve MHCC’s use of HSCRC expertise in consideration of project feasibility and project and facility viability.

3) Consider structural changes in how the commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.

Hospitals generally agree with the intention of MHCC to study these issues. We understand that CON is a default “gatekeeper” to discourage unqualified or suspect applicants from initiating facilities or
services. We support analyzing alternatives to the CON process filling this role, including potentially using licensure or other regulatory authority to enforce quality and safety.

We support collaboration between the HSCRC and MHCC to address Total Cost of Care alignment. Hospitals recommended that the authority to review hospital project feasibility should be explicitly delegated to HSCRC, subject to certain time limits. The HSCRC and MHCC should work collaboratively to understand the impact of health services supply on total spending per Medicare beneficiary.

Hospitals recommended an additional commissioner be designated as an alternate review to address CON applications with interested parties. The commission could explore alternative arrangements to process CON applications, but the commission has the ultimate authority to approve or deny applications. This authority should not be changed without substantive debate. The members of the commission reflect a variety of backgrounds designed to represent different viewpoints, including the public, when deliberating commission action.

**Hospital Recommendations Not Included or Unclear in Draft Commission Recommendations**

On September 25, the Maryland Hospital Association (MHA) submitted recommendations to the commission’s CON Task Force for consideration. Our recommendations include revisions to statutes, regulations, and the hospital CON application document.

1) Both the enabling statute and the regulatory language in each chapter of the SHP should be revised to align with Maryland’s Total Cost of Care Model. Review criteria and evaluation standards – and ultimately CON approval – should align with the goals of the Total Cost of Care Model because Maryland is bound to its terms and conditions. This language should explicitly state the need to comply with the All-Payer Spending per Capita and Medicare Spending per Beneficiary limits reflected in the model contract. Spending per capita is a function of price and service use. Health care services supply, controlled by CON, will affect spending per capita. CON and SHP rules must explicitly recognize this link.

2) The HSCRC should implement a new, clear, and transparent capital funding policy. Hospitals need to understand the rules and incentives to fund capital through hospital rates. CON approval should still be required to request capital in rates, unless below the hospital proposed threshold of a hospital’s annual revenue or $50 million.

3) Repeal Limited Services Hospital references since it is not practical that this designation will be used.

4) Hospital specific CON application and approval recommendations, applying to hospitals only:
   a. Financial statement requirements should reflect revenue and cost inflation.
   b. Remove requirements to report charge information, to comply with charity care requirements, and to document quality of care performance. These are all important provisions – and ones that are regulated by the HSCRC for hospitals. There is no need to duplicate efforts.
   c. Align the definition of “primary service area” in determining hospital needs under CON with the primary service area definition used for HSCRC methodologies.
5) Although not specific to CON, MHCC should take a leadership role to align state agency requirements when major service delivery transformation occurs, including conversion from a general acute hospital to a freestanding medical facility, service line closure, etc. This would involve coordinating requirements from Office of Health Care Quality, Maryland Institute for Emergency Medicine Systems and Services (MIEMSS), MHCC, and HSCRC. We appreciate the commission’s time and attention to these important matters. I want to thank Commissioner Sergent for your leadership of the commission’s CON Task Force, all task force representatives for their thoughtful input, and commission staff for their tireless work throughout the process. We look forward to discussing these important recommendations with you at the December 20 public meeting. Should you have any questions, please call me at 410-540-5060.

Sincerely,

[Signature]

Brett McCone,
Vice President

cc: Ben Steffen, Executive Director, MHCC