***Draft* Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Monday, December 3, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance
Randolph Sergent, Chair
Regina Bodnar (via phone)
Ellen Cooper (via phone)
Lou Grimmel
Ann Horton
Andrea Hyatt
Adam Kane
Ben Lowentritt (via phone)
Brett McCone
Barry Rosen
Andrew Solberg
Renee Webster

MHCC Staff in Attendance
Linda Cole
Julie Deppe
Kevin McDonald
Paul Parker
Ben Steffen
Catherine Victorine
Suellen Wideman

MHCC Consultants in Attendance
Patrick Redmon
Samantha Sender
Thomas Werthman

Others in Attendance
Jack Eller (via phone)
Howard Sollins (via phone)
Donna Jacobs
Tony Kudner
Paul Miller
Robert Jepson
Laura Russell
Spencer Wildanger
Danna Kauffman
Joseph DeMattos
Sherri Thompson-Brusca

Agenda Item 1: Call to Order, Welcome and Introductions

Chairman Randolph Sergent convened the meeting, with Task Force members, MHCC staff and additional attendees identifying themselves. Attendees on the phone identified themselves.

Agenda Item 2: Approval of November 9, 2018 Task Force Meeting Summary

Mr. Sergent asked if there were any comments on the meeting summary of November 9, 2018. No comments were received.

Agenda Item 3: Review of Commissioner Comments at the November 15th Commission Meeting

Mr. Sergent stated that the purpose of the meeting was to review the draft report and receive and discuss final comments from the Task Force and consider changes that should be incorporated into a final draft.

Paul Parker briefly noted the substantive comments received in November from the Commission, after draft recommendations were presented to the Commission. Commissioner Michael O'Grady's stated his view of the importance that Recommendation 9, redefining "ambulatory surgical facility" in Maryland law, for purposes of CON regulation, as a facility with three operating rooms (ORs), and Recommendation 10, providing in Maryland law for eligibility by all persons, including hospitals, to develop outpatient surgical centers with up to two ORs without a requirement of CON approval, not be uncoupled in the legislative process.

Mr. Parker noted that there was a discussion of regulated "medical services" at the November meeting and it was clarified that there was not a draft recommendation to change that definition.

Agenda Items 4 and 5: Overview of the Draft Final Report and Review of Recommendations

Ben Steffen described his conversation with MHCC Chairman Robert Moffit, and the Commission's desire to have full access to all Task Force comments during their review of the recommendations.

Patrick Redmon presented the recommendations as they appeared in the draft report.

The recommendations were presented on individual slides and grouped into three categories: regulatory reforms to be started immediately, reforms requiring statutory changes, and areas for further study from which further regulatory or statutory changes could emerge.

Task Force member commentary as it was provided appears in this summary immediately following each recommendation.

Regulatory Reforms to be Started Immediately

1. **Identify the State Health Plan 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 that do not address these four specific criteria 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 that must be met in order to become an applicant and, as such, will become the single way in which CON regulation addresses quality of care, as a "gatekeeper." 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.**

Andrew Solberg requested that a schedule be developed of proposed regulatory changes. Given the nature of strategic planning, he said, it would be good to have a sense of when regulations were likely to change. Mr. Sergent noted that this was a good point, however, it would not be provided as part of this report, given the prescribed deadlines. The MHCC staff, however, could work on developing such a document. Mr. Solberg noted that, overall, it is important to know which of the changes proposed by the recommendations are doable, and which are not doable.

Brett McCone recommended that the Commission assess the status of all chapters of the State Health Plan (SHP) on an annual basis to set priorities. Mr. Sergent expressed some concern about expenditure of staff resources that could result from pledging annual SHP review or making it a requirement. Mr. McCone clarified that he was not recommending revision of the SHP on an annual basis but only substantive consideration of an annual updating work plan so that none of the plan chapters needing updates were put on hold for too long.

Regarding the request for prioritization and timelines for changes, Ben Steffen believed it would be effective to perform the prioritization publically, allowing Commissioners (and interested parties) to hear what priorities are or would be. Regarding changes to older SHP sections, specifically psychiatric hospital facilities and services, Mr. Steffen explained that staff was working on a white paper.

Mr. Solberg, while understanding the concern with commitment to annual review, still believed a periodic prioritization process is important. Mr. McCone agreed with prioritization, and was mindful of how the annual review could become a burden on the MHCC staff.

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**

Mr. Sergent believed this recommendation represents something the staff can implement itself. It is more of a statement of what MHCC intends to do, as opposed to a legislative change.

Mr. Solberg noted how this recommendation conflicts with the limited completeness review recommendation. Given the extensive work that will be needed to meet the suggested decision deadline, it may not be practical to have competing limitations. Mr. Steffen noted the import of this point as an

aspirational goal and the rarity of submitted applications not requiring any completeness questions. There was some discussion of the difficulty in implementing both of these suggested changes.

Mr. Parker believed this recommendation coordinates with the statutory changes in Recommendation 11 (90 day project approval deadline). If deadlines are imposed (whether by policy, regulation or statute change) it would aid the process, particularly for uncomplicated, unopposed projects. Completeness questions are a different issue. It would be difficult to complete application reviews within the proposed deadlines unless there is a single round of questions and relatively quick response. There may be an increase in denial recommendations related to the unsatisfactory state of applications, but this could be necessary to establish expectations for everyone to improve the quality of application filings and speed up the review process in a satisfactory way over the long run.

Mr. McCone offered potential risks and benefits generated by such an abbreviated process. Mr. Barry Rosen believed this recommendation is an improvement over the current process, which many applicants find frustrating. Mr. Solberg noted the challenge of meeting the deadlines within the context monthly meetings.

Mr. Parker discussed Appendix G from the June Interim Report (a document that listed projects that had received final action or been withdrawn over the last few years). It was developed to give a sense of how long project reviews have been taking in recent time. He noted that a substantial number of these projects would be eliminated from review if the draft recommendations were implemented.

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

Mr. McCone endorsed this recommendation. Mr. Solberg also approved of the recommendation, but he noted that the true test would come in implementation.

d. Establish 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.

Mr. McCone expressed some confusion with the language of Part 2. He does not support allowing changes of "medical services" in a post-CON review process. Mr. Solberg believes staff could perform review of changes in the financing plan with full Commission review.

Suellen Wideman noted that, under existing regulations, determinations by staff can be appealed to the Commission within 20 days. She also believed that allowing certain actions by staff is consistent with regulation and statute.

Commenters expressed a need to define medical services and explicitly state that "change reviews" would be performed by the Commission, not by staff.

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 TCOC model and alternative models for post-acute care.**

Mr. McCone noted the need for better alignment of CON with TCOC and the All Payer Model. He had a concern that this recommendation could give HSCRC ability to usurp MHCC statutory authority. In his view, MHCC should continue to have the ability to 'put the brake" on the process, notwithstanding the HSCRC's approval. There was some discussion by the Task Force of what would occur if the payment model failed, in light of this recommendation.

Mr. Steffen noted the word "ability" was not absolute. Lou Grimmel expressed concern about the recommendation's having no explicit consideration of bed need, and noted the comment letters already submitted on this point.

Regulatory Reforms Requiring Statutory Changes

3. **Eliminate the capital expenditure required for a non-hospital health care facility project as an element requiring CON approval, limiting all definitions of projects requiring CON approval to "categorical" projects involving establishment of facilities or specific types of change to an existing health care facility, no matter what capital expenditure is required.**

Mr. Solberg suggested taking out "as an element requiring CON," and putting in "as a basis for requiring CON." Mr. Sergent asked if this change gets to the same place, procedurally. Mr. Steffen noted it does, and had no objection to the proposed change.

4. **Replace existing capital expenditure threshold with a requirement that hospital obtain CON approval for a project with an estimated expenditure that exceeds a specified proportion of the hospital's annual budgeted revenue, but only if the hospital is requesting an extraordinary adjustment in budgeted revenue, based on an increase in capital costs.**

Mr. McCone agreed that the capital expenditure thresholds need to change, but that there needs to be some limit when addressing major projects. Mr. Rosen asked about the purpose of the term "extraordinary." Mr. Parker differentiated between "extraordinary" and "ordinary" adjustments. It was noted that this adjective is not needed given the reference to "adjustment . . . based on an increase in capital costs."

Mr. McCone cautioned that this recommendation could, with unlimited capital expenditures, adversely affect the TCOC model. He suggested there should be monitoring of service demand and use and a demand assessment after a capital project is built.

5. **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 and**

compliance with the terms and conditions of previous CONs the applicant has received.

Mr. McCone supported the recommendation, but asked that documentation of compliance with previous CON terms and conditions not be made an application requirement. Linda Cole asked whether compliance with prior CON application terms and conditions should be made part of the review. Mr. McCone responded affirmatively. Mr. Steffen addressed the absence of "access" as a consideration, and whether its absence from consideration required statutory change. Mr. Solberg believed it did not. Task Force members discussed the different ways access can be addressed through the CON process.

6. **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.**

Mr. Solberg suggested including an "out" from this recommendation, if need for such services ebbs, and enough beds are available. Renee Webster suggested inserting a restriction on bed growth, e.g., a percentage of existing beds. Mr. Sergent suggested market forces, as opposed to regulation, would appropriately limit bed numbers.

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

Mr. McCone acknowledged a need to add substance abuse and behavioral health capacity. However, before pulling psychiatric bed capacity changes out of CON regulation, a review of an updated psychiatric hospital facilities and services SHP chapter is warranted. Review of the the Intermediate Care Facility SHP chapter is also necessary. Mr. Solberg also agreed that the Commission (as opposed to the hospitals) should perform a comprehensive review of the need for mental health services. He was unsure if the Commission has the expertise to do such a review.

Mr. Steffen noted the difficulty in encouraging hospitals to add psychiatric beds and suggested that further constraints on hospitals should not be added. Mr. Solberg believes a study could reveal ways to incentivize entities to add beds. Ms. Webster agreed that allowing bed expansion without any regulation could expand psychiatric bed capacity in three major state psychiatric hospitals, which could potentially limit access in other parts of the state.

Mr. Sergent questioned the value of CON regulation in this process, specifically.

Mr. Parker reminded the Task Force that this recommendation only applies to hospitals with existing psychiatric programs. Introducing psychiatric hospital services as a new service or establishing psychiatric hospitals would still require CON approval.

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

The Task Force discussed developing a need formula for hospice beds, before eliminating CON requirements. Mr. Parker explained that, under this recommendation, CON regulation would be limited to establishment of new hospices or the expansion of the authorized services areas of existing hospices. This recommended change would simply allow hospices to provide inpatient services under their own license if they desired to do so. He noted that most hospices do not operate inpatient facilities but make this service available to enrolled patients through arrangements with hospitals or other types of facilities. There was a discussion of developing a need standard for inpatient facility capacity in the SHP. Mr. Parker noted that this would not be meaningful if the recommendation is implemented.

9. **Define "ambulatory surgical facility" in the CON as an outpatient surgical center with three or more operating rooms. (Current statute defines "ambulatory surgical facility" as a center with two or more operating rooms).**

Adam Kane mentioned HSCRC discussions about this recommendation, specifically as it pertains to the TCOC and questions about access. Mr. McCone agreed that there is a concern and that monitoring of changes in ASF use in the context of TCOC is necessary. Andrea Hyatt discussed the low Medicaid reimbursement for ASF services, when compared to hospitals providing the same services, as an issue that makes a true level playing field for both hospitals and ASFs unachievable.

Mr. Steffen and Mr. Kane discussed ways to accurately capture volume shifting from hospitals to ASFs or unregulated outpatient surgery centers. The Task Force discussed the issues of access, efficiency, and corresponding public/private payer differences when services shift from hospitals to freestanding outpatient settings. Many commented that this discussion extended beyond CON regulation.

10. **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. Any person would have the ability, under the new definition of "ambulatory surgical facility," to establish one or two operating room outpatient surgical centers without CON approval, but with a determination of coverage after a plan review by MHCC staff.**

Mr. Parker clarified that, under this recommendation, establishment of a three OR ASF would require a CON. Mr. Solberg pointed out that if hospital wants to close ORs and wants to open an ASF, they should be allowed, without a CON. Mr. Parker brought up how raising the OR threshold defining a regulated ASF for all providers will eliminate a fair number of CON or exemption from CON reviews currently required. Some Task Force members were hesitant to deregulate in this way. Mr. Grimmel raised concern that allowing ASFs to possess a post-acute license would essentially create a "mini hospital."

11. **Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days.**

Mr. Sergent noted that this recommendation has already been discussed.

The Task Force discussed considerations regarding charity care, and the need for a more comprehensive discussion.

Mr. Parker noted that, generally, these recommendations sought to reduce requirements in the project review process and certain types of standards typically contained in the SHP. He suggested that charity care should be considered as part of access considerations, which would move the regulatory process away from rigid and uniform requirements for every regulated category of facility.

Ann Horton raised concerns over limiting any charity care requirements, as expressed in recommendation 1.a. Mr. Sergent was concerned about agencies setting requirements they cannot enforce. Kevin McDonald noted that charity care is a low impact concern in considering home health agency projects.

Areas for Further Study from which Further Regulatory and Statutory Changes May Emerge

******* These recommendations were not discussed. They appeared in the presentation as follows:

12. **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. The objectives would be either to: (1) eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or (2) establish MHCC's role in regulating these facility categories solely as a gatekeeper (e.g., any facility of this type that gets a clean bill of health following a rigorous background check and character and competence review and is compatible with limitations for gradual expansion of new providers would be issued a CON, without further review). Establish specific deadlines for recommendations.**

13. **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.**

14. **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.**

Agenda Items 6 and 7: Next Steps and Public Comment

Mr. Steffen indicated that the final draft would be shared with stakeholders, in order to gather comments. Comments would be reviewed, prior to the MHCC meeting on December 20, 2018, where approval of the report would be requested. Mr. Sergent asked for simple comments, given the tight time frame.

Mr. Sergent asked if anyone in the audience wanted to comment. No one indicated that desire.

There was a brief discussion concerning whether statutory changes would be proposed in the 2019 General Assembly session.

Agenda Item 8: Adjournment

Mr. Sergent thanked everyone and adjourned the meeting.