***Draft* Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, June 29, 2018 (0:00.00-2:05.45)
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance
Randolph Sergent, Chair
Regina Bodnar (by phone)
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Ann Horton
Andrea Hyatt
Adam Kane
Ben Lowentritt
Jennifer Witten (proxy for Brett McCone)
Michael O'Grady (by phone)
Richard Przywara
Barry Rosen
Andrew Solberg
Renee Webster

MHCC Staff in Attendance
Ben Steffen
Paul Parker
Suellen Wideman
Kevin McDonald
Megan Renfrew
Linda Cole

Others in Attendance
Erin Dorrien
Anne Langley
Patricia Cameron
Paige Cameron
Paul Miller
Martha Nathanson
Noson Weisbord
Keith Hobbs
Dawn Seek
Laura Russell
Dana Kauffman
Caitlin Cooksey
Eric Lindemann

Per Mr. Steffen, meeting observers need not identify themselves.

Agenda Item 1: Call to Order, Welcome and Introduction

Chairman Randolph Sergent welcomed everyone to the first meeting of Phase 2. Commissioner Sergent noted that this round would focus on sifting through recommendations, getting everything on the table (pro/con), and seek integration for the Maryland Health Care Commission (MHCC or "the Commission") on what the thoughts are, on either side.

Mr. Ben Steffen noted at the start of the program that step 1/stage 1 has been completed, and the Task Force has added three new members for Phase 2:

- Renee Webster, OHCQ
- Richard Przywara, Ashley Addiction
- Bonnie Katz, Sheppard Pratt

Mr. Steffen stated that Ms. Jennifer Witten would be serving in place of Brett McCone.

Agenda Item 2: Approval of the May 11, 2018 Task Force Meeting Summary

Commissioner. Sergent inquired if there were any comments on the May 11 Task Force meeting summary. No comments or corrections were made.

Agenda Item 3: Review of Modernization of the Maryland Certificate of Need Program, Volume I: Interim Report, June 1, 2018 and Comment Received

Commissioner. Sergent stated the next item was to review the Certificate of Need (CON) program report, which was adopted by the Commission as a final version. Commissioner Sergent introduced Mr. Paul Parker to provide additional information.

Mr. Parker reviewed the slides used at the MHCC meeting and offered clarifying comments on the process thus far. These comments included: 1) a summary of the charge to the MHCC from the General Assembly Committee co-chairs and accompanying letter requesting study of CON process; 2) the process utilized earlier this year that culminated in the issuance of the interim report, which focused on problems with CON and the attempt to set the Phase 2 agenda; and 3) the common themes in the interim report, as far as issues with CON regulation. These common themes touched on a number of areas:

- Most facilities see a need for CON regulation.
    - A few comments said eliminate it altogether.
    - Lots of comments on various ways program needs to be reformed.
- Substantive Task Force discussion during interim study phase of need for current scope of CON/appropriateness of current regulatory process be considered.
- Literature review, and corresponding overview does not provide strong support for CON regulation as an effective cost-control tool or a tool for improving quality. CON regulation does shape the healthcare system (in Maryland, for example, it is seen in areas of ASC, home health, and hospice). Generally, Maryland has lower per-capita numbers of regulated facilities and levels of capacity when compared with other states.

- Supporters of CON regulation see benefits of CON regulation in: reducing/preventing overcapacity, and facilitating more equitable access to care/appropriate care. Supporters also see limitations on growth and new market entry that are inherit to CON regulation as: protecting existing investment in facilities, reducing fraud opportunities and potential of overwhelming oversight capacity of licensing certification agencies, and by keeping labor shortages from becoming more acute.
- CON regulation imposes a significant direct compliance cost on regulated facilities (as filing and review has become extremely expensive for larger projects).
- CON limits competition which may increase cost, as well as limiting competitors who may have innovative approaches for reshaping care delivery.
    - An interesting comment for discussion on how to overcome this problem: by its nature, CON regulation encourages a "silo" perspective, on appropriate role of particular types of facilities. There may need for more flexibility in approaches to regulating supply and distribution of healthcare facilities, as we're trying to change healthcare delivery system. We want to possibly encourage facilities to break out from their limited traditional roles, to provide different types of services, better managed care, and coordinated care.
- The general perspective is that the role of CON as a tool for quality improvement is limited. Quality Improvement objectives may be better addressed through a more appropriate tool than CON regulation.
- CON regulation is the primary way for the MHCC to implement its objectives for health care facility services. It should be reformed to better focus on achievement of this purpose.

Mr. Parker reviewed problems identified in the interim report, which included:

- Scope of CON regulation is outdated. We need to look at how that should be reformed, across the whole spectrum of regulated facilities. One idea is different process reviews for different projects (not primarily "one size fits all").
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- SHP regulations are in some cases outdated and overly complex; we need to better align SHP with the new All Payer Model.
- Project reviews take too long.
- Need to review information requirements imposed by CON regulations, and eliminate any excessive or duplicative information requirements.
- Performance requirements used to monitor progress; assure that projects approved by MHCC are implemented on a timely, efficient basis are outdated and need to be reformed.
- We may not have a process to determine whether MHCC is receiving all of the community perspective and input on projects.

Commissioner. Sergent talked about reviewing the report with the Commission, from the context of Phase 2:

- Looked at stakeholder mix;
- Guiding principles to apply;
- Solicit specific and detailed ideas from stakeholders to address problems;
- Built meeting agenda for Phase 2 around key areas of reform that were suggested.
    - Slides presented to MHCC:
        - Scope of regulation;
        - Reforming the process;

- Time limits;
- Fitting processes to the project;
- Rethinking SHP regulations;
- Simplifying/better prioritizing items;
- Reforming post-approval process;
- Ideas for how to reform the SHP.

Commissioner. Sergent noted the goals for this phase are to develop consensus on statutory and regulatory changes. The MHCC will develop a final study report by December 1, with recommendations to the committee chairs. The final report will be MHCC recommendations, though the Task Force is offering input into how MHCC should think about these recommendations and the degree of consensus that the Task Force would come to regarding those recommendations.

Mr. Steffen thanked Messrs. Adam Kane and Barry Rosen for presenting their perspectives at the Commission meeting, and asked if Chair/Commissioners present at Task Force would provide perspective on what was said on scope/pace of reform at the meeting.

Commissioner Sergent emphasized that the Commissioners encouraged Task Force members to think broadly. The Task Force has a unique opportunity to look at the foundations of the CON; not just tweaks; if something much larger (not specified) was warranted, it should be proposed.

Mr. Rosen pointed out the importance to make both big and small recommendations, recognizing that MHCC doesn't control legislative process. If the Task Force makes only recommendations that require changes in statute and the General Assembly fails to act, then the Task Force has accomplished very little. Mr. Rosen argued that the Task Force should consider both regulatory and statutory changes. Regulatory changes could accomplish streamlining, even if the General Assembly did not act in 2019. Commissioner. Sergent agreed, supporting the need to get Task Force recommendations and start organizing them, to determine what can be fixed without legislation. He noted it is important to not lose sight of the small things.

Dr. Michael O'Grady stated that the Commission was looking for meaningful changes. No one on Commission is looking to make the process any harder or more bureaucratic for providers than is necessary. Commissioners are struck by the length of time the process takes, the multiple steps required and the significant costs. It is important for the Task Force to be diligent and try to streamline operations of the program. Dr. O'Grady concluded by stating that purpose of the CON program is to protect Maryland patients and taxpayers, not to provide protected markets for existing providers. Lastly, he reminded the Task Force that Mr. Parker had stated that research has found that CON is not a powerful cost control tool.

Agenda 4: The Challenge of Controlling the Total Cost of Care: Where Maryland Currently Stands

Commissioner Sergent introduced Caitlin Cooksey from the HSCRC.

Mr. Steffen introduced the agenda item by referencing the letter from Committee Chairs Sen. Middleton and Del. Pendergrass. The request encouraged MHCC to align CON processes with incentives and priorities in the Total Cost of Care (TCOC) model. To succeed, the Task Force must look at not only providers and patients, but also administrative processes in place, to ensure they align with overarching TCOC model goals.

Ms. Caitlin Cooksey provided background on data received from Medicare, and explained data captured in presentation slides. She and Eric Lindemann presented Medicare fee-for-service data through March 2019, with claims paid through April 2018.

Mr. Rosen asked for clarification as to what the slide actually shows and an explanation of precisely what is represented. He noted that the time series results were not as positive as described by the presenters. There was discussion among the Task Force and questions were asked of the HSCRC as to what the presented data actually represents. Additional discussion points included:

- Maryland performance relative to the nation,
- Utilization of hospital/non-hospital space and related savings,
- Correlation between growth and cost,
- Usefulness of CON in general, if utilization is not lowered,
- Maryland hospital/non-hospital growth.

Mr. Parker stated the purpose of the presentation was to provide context of CON reform under new payment model, and drill-down perspective. The MHCC staff agreed to provide the Task Force with additional information that summarized Maryland's performance under the All Payer Model. Mr. Steffen agreed to provide a longer time series of All Payer Model performance at a future meeting.

Agenda 5: Discussion of Goals for CON Modernization and Guiding Principles for Evaluating Reforms

Commissioner Sergent noted the next agenda item reviews goals and principles for evaluating reforms.

Mr. Steffen and Commissioner Sergent identified three documents for Task Force review:

- 2001 Guiding Principles for CON;
- 2005 Guiding Principles CON Task Force report;
- Set of draft principles for Task Force commentary and revision.

Review of Guiding Principles of CON

The Task Force had a lengthy discussion about guiding principles. There was a general consensus that the guiding principles were too numerous. There appeared to be some preference for a narrower list of principles for CON reform, rather than guiding principles for CON generally.

In reviewing the extensive list, Chairman Sargent stated that he did not believe that the current CON program aligns with some of the principles in the bulleted list. He pointed to the limited ability of CON to police quality and safety. Mr. Rosen agreed, and suggested rephrasing language to state that CON program should attempt to keep bad actors or poor quality providers out of the system, following the notion that CON process serves as a "deli ticket machine;" once ticket is pulled, providers are responsible for licensing and quality. However, the CON process can keep bad actors out with specific questions, such as: have you failed any surveys nationwide, or are you under investigation? Such questions serve as "deli counter" questions, when deciding whether to open or to prevent a facility from opening. These are not deep questions on quality and safety programs, which are in the purview of OHCQ or other agencies.

Mr. Richard Przywara noted that over the past decade drug and alcohol treatment has seen emergence of unsavory/unethical practices; corporate entities will be in one location and incorporate in another state.

CON should look at bad performers and where they are, and bad performances in other states will prevent entry in Maryland. CON is needed to prevent this. The question was also asked: what other agencies affect operator's ability to obtain a CON????

Commissioner Sergent asked how to differentiate a past poor performance from an ongoing poor performance. He argued that an ongoing poor performance should be addressed through licensure. Rene Webster responded that licensure can affect this differentiation, but by then the facility has already been operating in the State, and limiting CON can help the MHCC look at good/bad actors when reviewing competing CON submissions. Additionally, the Task Force member observed that it can take years to remove a license, during which the operator may be delivering poor patient care. Commissioner Sergent stated that he was happy to see recommendations for streamlining where CON and licensure are applied simultaneously, making it cheaper and more efficient. A Task Force member stated that the CON process is needed to promote quality and safety.

Discussions briefly focused on alignment with the All Payer and TCOC Models. A Task Force member observed that CON reform had to be well-aligned with the incentives in the Maryland TCOC Model and other changes resultant of health system transformations, but that this reform effort had to be practical and visionary to have the maximum impact in that environment. He noted that the main point of CON and modernization work and the directions from the Committees was to better align CON with the goals and objectives of these new Models. Ms. Jennifer Witten noted that Maryland has committed in the TCOC Model to drive down cost, improve patient outcomes, and improve quality of care (triple aim), and this triple aim must be kept at the forefront during reform discussions. Alignment of agencies affecting CON is beneficial moving forward, as it relates to quality and improved outcomes for patients.

Turning to the efficiencies of CON processes and the operation of the market, Commissioner Sergent noted that when evaluating recommendations and pieces of the CON process, the question will become whether CON meets any of the guiding principles. If it doesn't, is it needed?

Commissioner Sergent addressed application of CON in circumstances where market forces are likely to result in preferred outcomes. He questioned whether unrestricted entry in the market is likely to result in undesired outcomes. Mr. Steffen noted that a justification for CON has been that supply-sensitive services could proliferate, because the purchaser is removed from the purchasing decision or lacks information upon which to make a sound decision.

Commissioner Sergent noted that, given the way CON works, once someone gets through CON, there isn't a mechanism to allow the MHCC to have direct control, unless there is ongoing oversight (e.g. cardiac services). Hence, CON serves as entry point control for governing market entry, not market conduct. Commissioner Sergent highlighted the conundrum that once a CON is issued, there is no mechanism to request different conduct by the provider, or take back the CON. A Task Force member stated that the challenge with CON is that in a county that is not underserved, a new provider with a new approach will find it impossible to enter that county. This is a significant constraint, because an essential element of the TCOC Model is that Maryland needs to deliver care in a different way, but CON will not permit that new approach, particularly in a jurisdiction where there isn't an actual need for additional capacity.

A Task Force member responded that the way to accomplish this is precisely through the coordination being discussed (HSCRC, providers, etc.). The entry point for CON is, "is there need"? And then can you do it differently?

The Task Force turned to the principle of allowing market entry only when there is a demonstrated need. A member opined that if there is an old facility that needs to be replaced, and the only way to fund replacement is to increase the number of beds, the MHCC should allow the facility to replace itself. Commenters agreed. Mr. Rosen believed the question was wrong: instead of "is there a need?" The question should be "is there a reason to stop (bar) entry?" This is a different question than "do we have enough of something?" The problem with the middle set of guiding principle bullets is the degree; could this entry undermine the ability of an existing facility to maintain financial viability—is that essential? He noted that Maryland may want to stop entry if it will destroy one charitable hospital that is caring for vulnerable population, but that's an extreme.

Mr. Steffen responded that some stakeholders voiced concerns to the MHCC that the proliferation of for-profit providers could overwhelm non-profit essential community providers. Dr. O'Grady sought clarification of the definition: does essential community providers mean safety net (federal definition), or does it mean the provider who is currently there? Mr. Steffen stated that community hospices that serve all community members characterize themselves as essential. Dr. O'Grady wasn't certain this broad definition of "essential providers" rises to the level of being protected through the guiding principles of CON.

Commissioner Sergent would generally frame guiding principles by stating CON will only be applied when benefits of CON outweigh the costs. It is not that CON must meet all principles, but if CON can't meet any of these principles the Task Force should recommend eliminating that element of CON.

A Task Force member noted that the Task Force needs guiding principles to say if the solution to what's being proposed doesn't meet certain criteria (doesn't support TCOC, doesn't increase patient quality and safety, etc.), that's the threshold. Reforms need to meet certain guiding principles. To check every box for granting CON is asking too much of the CON process. Another member noted that one of the guiding principles of free markets is that it creates innovation. If someone has an innovative way of delivering care and there is a need, can that innovation, if viable, be evaluated and permitted?

A Task Force member stated that the stifling of innovation is one of the major criticisms. CON gives such an advantage to existing providers that incentives to innovate are restricted. Ann Horton respectfully disagreed. She stated that she is a member of a national company and that Maryland has been innovative. Maryland is not a fishbowl; states without CON could incubate innovation, and these innovations could diffuse to Maryland. Fears that CON limits innovation should not deter the State from regulating through CON. Commissioner Sergent disagreed with this statement and argued that relying on other states to incubate innovations may mean that Maryland will seldom be an early adopter, and often the early adopters reap the biggest benefits. If CON regulation inhibits innovation, shouldn't we be certain of the programs benefits? Ms. Anne Horton offered a national perspective specific to home health care. She noted that she could not identify any innovation in a non-CON state that is being brought to Maryland. She observed that there are few instances in Maryland where CON is stifling innovation. Reggie Bodnar agreed with Ms. Horton and challenged the Task Force to identify innovations in health delivery that are not occurring in Maryland.

Commissioner Sergent proposed adding a principle that CON should not stifle innovation. Mr. Steffen provided examples of structural innovations in nursing homes, with ability to deliver services across the care continuum and continuing care retirement communities. Examples of CON limiting innovation has been manifested by one provider not being able to offer other services without meeting a set of regulatory requirements. There is a recognition that, post-ACA, Stark rules are hindering innovative models.

Commissioner Sergent asked to amend a bullet to read "decrease inadequate access to care by vulnerable populations."

Mr. Rosen requested to add "not cost prohibitive" to the bullet containing terms "clear, consistent and timely." If there is a way to lessen bureaucratic load, it should be done. The process should be less costly to participants. Also, CON process should be consistent with the TCOC model, which in turn is consistent with silo issue.

Commissioner Sergent asked to add licensing and regulation to local planning and payment reforms bullet. Commenter asked whether this addition contemplated collaboration with community providers, stakeholders and local governments. Mr. Steffen noted that, at one time prior to commissions' merger there was a much closer integration between statewide and local planning initiatives. There may be a need to realign with local planning efforts, given that healthcare transformation is taking place at different paces and in different ways in local communities. Mr. Solberg noted expense and time, without substantive return, was the reason local planning requirements were eliminated. Before we revisit this, it would be important to define what local planning means. Commissioner Sergent advocated for local planning to complement/coordinate, but not to duplicate, efforts.

Mr. Parker returned to the middle section, which structurally provides a test that can be applied as ideas for reforming CON are addressed. This test includes drilling down into what is meant by market forces, adding unrestricted market entry or the unregulated expansion of capacity. This addition effectively encapsulates the primary effect of CON regulation on existing providers: do we want to make this stronger? CON came about because of market failure. Instead of saying CON should apply in cases of an unregulated system producing undesirable outcomes, CON should be limited to instances in which unrestricted market entry or unregulated expansion of capacity is likely to result in specific poor outcomes.

Mr. Rosen believed flexibility made some sense, not necessarily a check box that triggers CON. Commissioner Sergent suggested adding a cost-benefit requirement, and noted that list is not final, and it will be revised.

Closing Remarks

Mr. Steffen concluded by stating there was no discussion of the Work Plan, with a sector-by-sector approach. The Task Force would also like to develop a catalogue of recommended solutions based on the interim report, or other ideas that have come up in discussions, to fit into subsequent meetings. Some proposals will affect multiple SHP chapters, and there will be a list of recommended solutions a week before the next meeting.

Mr. Parker noted scheduling issues with the schedule of discussion topics. It would be helpful if the group could weigh in on schedule as it is currently set.

Comments were made as to when stakeholders will generate comments.

Mr. Steffen thanked the HSCRC, and offered a takeaway that innovations are occurring nationally, and these innovations may want to be incorporated in Maryland.

Commissioner Sergent thanked the Task Force and closed the meeting.