Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Friday, February 23, 2018
4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:

Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Ann Horton (Phone)
Andrea Hyatt
Adam Kane
Brett McCone
Mark Meade
Michael O'Grady (Phone)
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:

Ben Steffen
Courtney Carta
Linda Cole
Theressa Lee
Kevin McDonald
Paul Parker

Others in Attendance:

Brian Ackerman
Patricia Cameron
Daniel Carter
Bob Gallion
Anne Langley
Adam Malizio
Bruce Richey (Phone)
Laura Russell
Howard Sollins

Call to Order

Co-Chair Philips called the meeting to order.

Ben Steffen remarked that most input received to date has been from health systems. He suggested that the most efficient way to move forward regarding the comments, given the time limitation of the day's meeting, was to let Brett McCone provide input from hospitals and health systems on behalf of the Maryland Hospital Association (MHA) rather than having individual health systems speak. Mr. Steffen clarified that there will be opportunities for all stakeholders to comment as the group moves forward in the process.

Paul Parker informed the attendees that the draft January meeting summary will be open to input and comments for the next couple of days. Moving forward, meeting summaries will be provided prior to the meeting for input and comments.

Mr. Parker introduced Ascendient Healthcare Advisors, the vendor who will provide technical support to the task force. Brian Ackerman provided a brief introduction to Ascendient and noted that he will be attending all task force meetings as the primary point of contact on behalf of Ascendient.

Andrea Hyatt informed the group that she has access to CON information from other states. Mr. Parker volunteered to be the point person to distribute to the vendor and those who are interested. He also informed the group that there two binders had been put together, one of which contains copy of journal article from the research literature on CON regulation compiled by Robert Moffitt, the Commission Chairman and Barry Rosen, and one with hard copies of the comments received to date in response to MHCC solicitation of comments for the Task Force's review. The literature will soon be posted for the task force members.

Comments to Date

Mr. Parker reported on the hospital comments that were received and made note of the point that in general those providing comments were interested in retaining CON regulations with a focus on establishing a more modernized and streamlined process. Questions and concerns largely related to how the Task Force might refine the scope and depth of the process, while modifying procedures to allow for simpler and more timely reviews.

Mr. Parker indicated that the focus for today's meeting will be on the hospital sector and describing the key problems and issues for hospital CON regulations that may also be applicable to CON in general. He requested that attendees review the summary of hospital comments for major themes. It was pointed out that eight hospital organizations provided comments, including MHA. Mr. Parker noted that one of the hospitals, University of Maryland Medical System (UMMS), proposed the most significant changes in the scope of hospital and other health care facility CON regulation among hospital commenters. Specifically, with respect to hospital capital projects, UMMS proposed that only establishing and relocating hospitals outside of a hospital's service area should remain within the scope of CON regulation. In addition, UMMS indicated the need to maintain some regulation of inpatient psychiatric services, if such services would not participate in serving Medicaid patients, and also recommended shortening the list of services that need CON if introduced by hospitals as new services.

Mr. Parker also indicated that the MHA has a task force working on reviewing these same issues and anticipates preliminary recommendations associated with that work to be available near the conclusion of the first phase of the Task Force process.

MHA Perspective

Mr. McCone provided a summary of the comments submitted by MHA and also provided a caution against looking at CON in other states as a reference point for CON modification in Maryland due to Maryland's unique payment system. Mr. McCone informed the group that MHA has assembled a CON work group that has been and will continue to meet throughout the year. The group includes representatives who have expertise in health planning, policy, and operations, and will be evaluating the CON program from two primary perspectives: content (what to regulate) and process. Mr. McCone indicated that MHA's recommendations will tackle the CON review process issues first, and then go chapter by chapter through the State Health Plan, focusing first on acute care hospitals and special hospital psychiatric facilities in order to develop recommendations.

Mr. McCone indicated that the current payment model has been a good thing for the state and hospitals would like to extend it as a vehicle for addressing the total cost of care, as planned. However, under this approach, hospitals are the only facilities held accountable for costs from a pricing and volume perspective. Mr. McCone acknowledged that the current focus is on limiting the growth of payments per Medicare beneficiary. That focus, along with the regulation of the supply of services, provides incentives for addressing avoidable utilization.

Mr. McCone noted that the current payment model runs parallel to CON, but also sometimes perpendicular, noting the migration of services out of the hospital and into lower cost settings, e.g., ambulatory surgery centers (ASCs). The ASCs disruption can vary from market to market, with some geographic areas experiencing an increase in competition while others, like Baltimore, experiencing decreased competition.

CON needed with Maryland's unique payer system?

From MHA's perspective, Mr. McCone indicated that CON is a necessary tool to ensure there are high quality, appropriate services available to Maryland residents. He also pointed out that within a payment model focused on total cost of care growth, CON is necessary to regulate supply, which ultimately has an influence on the total cost of care. Mr. McCone made the point that CON is necessary to ensure that there are quality, cost-effective services given. Hospitals are held accountable for hospital revenues under the current payment model.

Andrew Solberg stated that hospitals are trying to have it both ways when it comes to cost and quality, suggesting that if cost and quality are regulated by other entities then it should no longer matter relative to CON. Mr. McCone responded by saying that the CON process is required to establish the initial need for a service, then the HSCRC determines the associated cost, but the CON process must first determine need. For example, in the case of cardiac surgery, there is a minimal volume requirement, so, in that way, the CON serves as a permit that is related to quality assurance. However, going forward operationally, quality and costs are regulated by the Office of Health Care Quality, HSCRC and national quality standards.

Innovation and costs

The Task Force discussed the role of CON, whether it stifles innovation, and its overall impact on the rising cost of care in Maryland. Some expressed concern that CON may set such a high hurdle that it is much easier for existing providers to meet the standards; thereby hindering new market entrants and innovation.

- Mark Meade pointed out the examples of the Aetna/CVS merger and Amazon, which provide a challenge to the market and are driving the location where services are delivered. Mr. Meade made the point that while he favors CON regulaton, he believes that CON limits the response to new market dynamics and asked that the Commission take that into consideration.

- Bruce Richey stated that both free market and non-free market forces play a role in innovation. In a completely free market, the market will determine how much innovation is desired. The

fact that hospitals are regulated and many other entities are not puts hospitals at a disadvantage when considering the entire service line, which may limit the ability to innovate.

- Randy Sergent pointed out the need to understand that sometimes the total cost of care is reduced by having someone other than the hospitals provide the care. As a result, the Task Force needs to look carefully at when CON is being used to protect something at the hospital, rather than looking at the best way to lower the total cost of care. Mr. Sergent requested that we be sure to ask the question as to whether we are protecting institutions rather than reducing the cost of care as the priority.

- Mr. McCone offered that the presence of global budgets and the level of alignment in Maryland is unique and serves as an example of how Maryland hospitals are innovating. He pointed out that CON exists for ASCs and skilled nursing services, and nothing about CON regulation is stifling those services from an innovation perspective. He also pointed out that there is no CON regulation for physician-based services, which is further indication of additional areas for potential innovation.

Members also discussed the connection between CON, the HSCRC, and the current payment model.

Barry Rosen responded to a prior question about the connection between CON and the all payer system, stating that CON helps hospitals on the payment side, as HSCRC struggles to come up with a bundle of funds for new or replacement hospitals (Prince George's and Germantown, for example) because it comes out of the funds for the whole state. Meanwhile, other hospitals still have the same overhead that they had before. Mr. Rosen stated that the HSCRC eventually will need to adopt normative standards and consider lowering rates. The CON process helps HSCRC do its job. In this way the HSCRC and the CON connect with each other and with the global budget payement system. However, it is a real problem that there is not a normative approach for managing hospitals' costs, and Mr. Rosen expressed that this issue needs to be addressed.

Based on Mr. Rosen's comment, Adam Kane made the point that how we manage capacity is also part of the discussion. He stated that compared to rates, capacity is even more important for a hospital. Is it HSCRC or CON's responsibility to address the issue of capacity? Mr. McCone replied that hospitals are getting a CON exemption to change some campuses to outpatient only, but that exemption process needs to be easier. He stated that we must look at those rules to see where we can improve. Mr. Rosen stated that if we are trying to make the system cheaper, then we need to make certain processes easier.

How to streamline the process, including perceived duplication between MHCC/CON and HSCRC

Mr. McCone stated that most hospitals have the opinion that CON is still needed in Maryland, but the process should be modernized by taking into consideration the following:

- Consider eliminating financial feasibility review and the regulation of charity care from the scope of MHCC's work, leaving these tasks to the HSCRC and/or via licensure requirements:
  - Potentially include HSCRC in the process earlier.
  - CON regulation can be likened to the process of obtaining a building permit. After you obtain it, it is still necessary to obtain and maintain an occupancy permit. As such, the CON process itself should exclude items more appropriate for other entities to review/monitor operationally.
- Significantly raise capital expenditure thresholds or eliminate them altogether, particularly for projects not involving introduction of new services.
- Revisit the State Health Plan (SHP) to ensure that its overall goals and purpose and how it addresses demand/need are consistent with the current hospital payment model. Make sure each chapter is up-to-date, particularly for psychiatric services, while also continuing to update other standards, where applicable.
  - The SHP should focus on reducing avoidable and unnecessary utilization with methodologies that are clear, data driven, and consistent.

Meeting attendees also discussed completeness review questions:

Mr. McCone reported that there is a general agreement among hospitals that there should only be one round of completeness review questions which are limited to things that are essential to making the decision. Questions must include only those that are appropriate and useful for decision making. Consideration should also be given to the fact that applicants have different skills related to completing the application itself.

Mr. Steffen pointed out that UMMS provided some data on completeness reviews. He also made the point that the flip side of multiple rounds of questions is trying to get a complete application up front. Without it, some applicants may be rejected. This becomes a dilemma for staff, especially thinking of the varied expertise of the applicants.

Mr. Solberg indicated that there is an opinion that completeness reviews often go beyond the completeness aspect and become more of an opportunity to extend decision making. He suggested that the process should be focused solely on ensuring application completeness and stop there. Any review period extension should be separate and identified as such.

Mr. Rosen stated that there are currently nine standards, each with seven sub-standards, which equals 63 different factors to review. He also pointed out that there is a lengthy appeal process that can take up to three years and provides opposing parties the time to pick apart any of those 63 factors. He suggested that perhaps the SHP should outline and streamline a list of factors that are most relevant and request that applicants write a letter stating why they deserve a CON. Mr. Rosen pointed out that often just one or two items are the real issue, and the remaining 60 are not as critical to the decision-making process.

Mr. Sergent commented that regarding standards, there may be an opportunity to change the general bias from proving that something is needed and feasible, to whether something is not needed or infeasible.

The topic of adjusting the capital expense threshold was also brought up again, with Mr. Parker making the point that obtaining a CON for larger expenditure projects has historically been the way in which hospitals are enabled to go to HSCRC and seek increased rates to cover higher depreciation and interest expenses. He reminded the Task Force that hospitals already have the ability to avoid CON regulation for projects that only require review because of the size of the expenditure by taking the pledge that they will not ask for increased charges above a nominal amount to help in paying for the project. Any changes in this aspect of CON regulation must take that into consideration how this will affect HSCRC policy on when and how hospitals can seek global budget adjustments to account for higher capital costs. If we eliminate the capital expenditure threshold for CON, do we allow all hospitals an ability to request increases in rates whenever they undertake projects and increase their capital costs? Mr. Parker made the point that, from his perspective, addressing this topic involves talking about investment risk and how much risk it is appropriate for hospitals to take.

Mr. Kane then asked the question that if the HSCRC is linking charges to GBR growth, does the CON process even serve as a true gateway or just a scheduling triage?

Members of the meeting then discussed timelines and standards:

- Mr. McCone suggested that the Commission look to improve in the area of maintaining schedules/timelines, understanding that hospitals themselves can be the source of delays, on occasion.
- Mr. McCone pointed out that MHA is not advocating for reducing the standards in the SHP but suggesting that efforts be made to make the standards more explicit, especially in competing applications, making the point that interested parties should have to continue to demonstrate impact and involvement, but in a way that is supported by good, data-driven analysis.
- Mr. McCone suggested that there is potential to eliminate some review requirements and/or provide an expedited review in instances where no interested parties are present.
- In addition, Mr. McCone suggested that the post-approval requirements need to be addressed and either changed significantly or eliminated altogether.
- Mr. McCone also recognized that the MHCC has its own capacity and resource restrictions, and the potential to add incremental manpower with subject matter expertise could help with process times.
- Mr. Solberg commented that any standards should only be in place if they specifically address a demonstrated problem that the Commissioners feel needs to be addressed, and all other standards be eliminated…with the issue of charity care being cited as an example.
- Mr. McCone agreed, saying that charity care is built into prices and part of HSCRC rate-setting authority. It is audited every year and therefore already addressed elsewhere.
- Ms. Phillips acknowledged the apparent duplicative nature of charity care but suggested that there might also be additive information that should not be eliminated given the importance of access.
- Mr. Kane noted that things change over time, so what is important is also changing. Mr. Kane asked if there was a way to have a process that would allow the Commission and applicant to clarify which standards are more relevant to the project to provide some level of flexibility.

- Mr. Steffen pointed out that some states are politics-ridden, so sometimes flexibility can lead to undue influence from powerful stakeholders. He recognized that he too would like to see flexibility but would like to see some protections in place to ensure some foundation upon which decisions can be made on the basis of transparent standards and criteria.

Community Input

Ms. Phillips revisited the building permit (CON) and operating permit (OHCQ/HSCRC) analogy, suggesting that building permits are created with a tremendous amount of local community input; however, consumers do not currently feel they have a sufficient chance to provide input on health planning projects. Ms. Philips noted that we might say community input is provided by board members but wondered if that was truly sufficient.

Mr. McCone agreed that community input needed to be part of the process and commented that the statute changed to say that there had to be public hearings and community input from the local communities.

Mr. Solberg pointed out that historically CON decisions were mostly consumer driven, which often resulted in local area recommendations that did not make sense relative to broader health planning concerns. Mr. Solberg noted that in terms of exemptions, the public hearing process is very effective. People who have concerns or are very active are represented. For those kinds of projects, Mr. Solberg stated that public input is very effective. He also noted that most of the exemption process is not really exemption, but more a CON process, stating that an applicant must still show consistency with the SHP and that exemptions are still regulated by the Commission.

As a consumer representative, Ellen Cooper noted that this area of regulation is difficult to understand for most of the general public, so it is difficult for the general public to know how to make their voice heard. She suggested that there needs to be a less formalized way to make comments, such as a public hearings or some other way, so one can understand and communicate those issues without understanding the entire process.

On Mr. Solberg's point regarding exemptions, Mr. Steffen agreed that he was accurate, but pointed out that the MHCC is simply following the statute that is in place. Mr. Steffen also acknowledged that all of these types of discussions are why we are going through this process, pointing out that raising good questions related to the complexity of exemptions is a good "white board" item for further discussion.

Mr. McCone concluded this line of discussion by making the point that the current statute requires that hospitals must notify the public of changes to key services.

Mergers/Consolidation

Commissioner Michael O'Grady stated that the task force should consider the dynamic of the current market, including the need to be realistic about incentives within the broader context. Mr. O'Grady suggested that the pressures of the current plan and financial constraints can lead to consolidation at a time we want to ensure innovation. Mr. O'Grady asked that we ensure that we

are not creating incentives that may harm innovation and quality. He asked that the committee keep in mind current incentives and goals when recommending any changes.

Relative to consolidation, Ms. Cooper noted that due to the regulatory rate structure in Maryland, the Federal Trade Commission (FTC), Department of Justice (DOJ), and the Attorney General (AG) do not look at consolidation in Maryland like they do in most other states. Those entities defer to local regulatory agencies like the MHCC to ensure that the amount of consolidation achieved in order to achieve better cost, quality and innovation is not excessive or dramatically affecting the competitive environment.

Mr. Kane noted that in other states the FTC looks at the effect of consolidation on contracting with payers, but given the payment model in Maryland that is not a significant consideration.

Ms. Cooper noted that state policy encourages mergers and affiliation, but then supervises those activities through rate regulations.

Howard Sollins agreed but noted that in the instance of for-profit acquisitions of Maryland hospitals the AG has special statutory authority and oversight in those unique instances.

Mr. Parker pointed out that the MHCC has asked for clarity on this but acknowledged that the answer is somewhat "muddled." Specifically, MHCC has the authority to review mergers and consolidations via exemption; however, the acquisition of a facility does not require a CON. As a result, MHCC's authority in this area is dependent on whether a transaction is considered a merger/consolidation or an acquisition.

Mr. O'Grady then stressed that the committee remain realistic about pressures on hospitals and incentives to bend the cost curve, acknowledging that the presence of only two to three health systems in Maryland would fundamentally change this entire process. Mr. O'Grady made the point that we can regulate all we might want, but if only a few control the supply, regulation doesn't really control things any more. Mr. O'Grady concluded by stating that this is clearly an issue that deserves more discussion.

Meeting Conclusion:

Ms. Philips thanked everybody for their time and noted that the next meeting is on March 23 and may be extended by 30 minutes. Mr. Steffen acknowledged that the group also wants to cover freestanding surgery centers but given the scope of hospital conversations they will be deferred to later meetings. He noted that the focus of the March 23rd meeting would be long-term care, including nursing homes, home health agencies, and hospices.