***Draft* Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Monday, January 22, 2018
MHCC Offices, 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 (phone)
Anne Horton
Andrea Hyatt
Adam Kane
Ben Lowentritt, M.D.
Brett McCone
Mark Meade
Jeff Metz (phone)
Michael O'Grady
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:
Linda Cole
Eileen Fleck
Kevin McDonald
Paul Parker
Ben Steffen
Suellen Wideman

Others in Attendance:
Patricia Cameron
Jack Eller
Peggy Funk
Keith Hobbs
Bob Gallian
Donna Kinzer
Anne Langley
Stan Lustman
Jerry Schmith
Katie Wunderlich

1. Introductions and Review of the Charge

Ben Steffen called the meeting to order at approximately 9 a.m. He introduced himself, welcomed and thanked those in attendance, and introduced the two Co-Chairs of the Task Force.

Co-Chair Fran Phillips introduced herself and also thanked everyone for attending. She welcomed a robust discussion of the CON program, stressing that there should be no concern with right or wrong ways to approach CON modernization or reform. She urged everyone to feel uninhibited about asking questions. She noted that she had recently left the Commission because of changes in her employment situation but was honored to serve as Co-Chair of the Task Forces. She noted that people could keep up with MHCC activity via YouTube, where recordings of the monthly meetings could be found.

Co-Chair Randy Sergent introduced himself and also welcomed and thanked the attendees. He asked the Task Force members and principal staff to briefly introduce themselves, which they did.

Mr. Steffen reviewed the charge to MHCC as outlined in the June 23, 2017 letter of Senator Middleton and Delegate Pendergrass, Chairs, respectively, of the Senate Finance Committee and House Health and Government Operations Committee. He noted that the directive is broad but priority of place is given to an assessment of how to assure the alignment of CON and the evolving all payor model of hospital charge regulation, administered by the Health Services Cost Review Commission. He noted that CON had not been standing still. Important changes had been made in recent years in State Health Plan (SHP) regulations for cardiac surgery, PCI, general surgery, organ transplantation, hospice, and home health agency services and these changes represented important updates to MHCC's approach to CON regulation, building in more use of quality metrics and opening up the ability for market entry of new providers into several service categories that were largely closed off under previous iterations of the SHP. MHCC recognizes the need that is often expressed for changes in the regulatory process and, after review, believes that statutory changes are needed to accomplish significant procedural reforms.

Mr. Steffen noted that the CON study will have two phases and that today's meeting kicks off Phase 1 focused on reaching consensus on the problems and issues with CON regulation. This phase will culminate in an interim report to the legislature. Phase 2 will focus on solutions to those problems and changes in law and regulation that will address identified issues. He expressed the view that this process is a good way to start. He noted that anyone describing a problem will usually have some ideas about solving the problem "in their back pocket," but the Task Force should try to keep the initial focus on fleshing out problems without immediately gravitating to solutions as a good way to give everyone a better opportunity for broad input on the best ideas for change. A conscientious approach to first identifying and describing the problems should improve the ability of the Task Force to better think through the best approach to addressing problems and issues in the regulatory program and process.

2. Initial Ice Breaker Discussion

The Co-Chairs introduced this initial area of discussion as an approach to getting a sense of how the Committee understands the purpose of CON regulation, its effects, and its practical value, guided by three questions:

- Why does Maryland need Certificate of Need (CON) regulation?

- What would Maryland's health care system look like without CON regulation?

- How does CON regulation contribute to or detract from furtherance of the Triple Aim? The Triple Aim is defined as:
    - Improving the patient experience of care, including quality and satisfaction;
    - Improving the health of populations; and
    - Reducing the per capita cost of health care

Co-chair Sergent expressed his view that an initial discussion of these broad questions would be a useful prelude to the more complicated debate and discussion on specific program and process reforms that will follow. Co-chair Phillips emphasized that all of the Commissioners are fully engaged on the issue of modernizing CON regulation. She noted that most Commission meetings have at least one agenda item that lends itself to a discussion of the scope and process of CON regulation and this interest in change predates the changes in the hospital payment model or administrations. She also emphasized that everyone is affected by CON regulation even though direct interest and involvement tends to be concentrated in the regulated facility owners, opeators, and their consultants and that the work of the committee should reflect that employers and consumers are stakeholders in the debate as well. She encouraged the Task Force to think about opportunities for doing good with CON regulation, in terms of access and quality of care.

With that, remarks were requested from Task Force members. They provided brief introductions of their relevant professional and public roles and responded to the icebreaker questions, as summarized below.

Michael O'Grady is a Commissioner and said the Commission is often struck by the time and expense imposed by CON. So, it is important to assure that Maryland is getting a return on the investment it is requiring on the part of health care facilities. Striking the right balance is how he perceives the challenge. On the one hand, regulating supply may be important if questionable demand for service is induced by supply, or to assure sufficient volume is maintained at a particular program when volume and quality of outcomes are related, or to avoid duplication of expensive resources. On the other hand, the regulation should not unduly restrain trade, becoming protectionist, and should not diminish access to needed services. CON can serve to keep out bad actors but allowing new market entry also has value because limiting competition and innovation can be costly.

Barry Rosen stated that we need to recognize that CON is designed to restrict supply and we need to ask if such restriction is ever good. He outlined the arguments put forward as to why this is sometimes viewed as necessary and good for controlling cost and controlling overuse of health

care. While restricting supply involves some limits on access, it can also be viewed as, in some cases, insuring access for populations that might otherwise be abandoned. He noted that there should be some ability to use the experience of the 15 states without CON regulation to shed some light on the questions of how CON regulation affects access and overuse. HSCRC needs to weigh in on these questions.

Adam Kane noted that issues of state funding were an important foundation of CON regulation. There was concern that the state would pay for oversupply and overbuilding. The relevance and importance of this concern has changed over time and this is related, to some extent, to the evolution of HSCRC policy. CON regulatory policy must also evolve. With respect to quality, he cautioned against trying to do too much through the CON program. Other agencies have the primary responsibility for monitoring quality on an ongoing basis.

Andrea Hyatt is concerned with redundancy of effort in regulation and quality reporting and wants to check growth in what she perceives as a growing trend in duplicative effort. Having experience in the private ambulatory surgical facility sector and also now working in a hospital system, she has a perspective on how regulation must strike a balance between the differing needs and roles played by different types of providers.

Andrew Solberg noted that, in his role as a consultant, he rarely works on hospital projects that do not start out larger at the beginning of the regulatory process. CON does have that impact. The regulatory process tends to "follow the numbers," it is not aspirational, and we would lose that focus if CON is eliminated. The SHP needs to be a better approach to dealing with the real problems that facilities have – that should be the basis for SHP standards. He does not think CON has a significant role in quality assurance and there are areas that should be deregulated.

Co-Chair Sergent clarified for the participants that reporting on the quality of care and the performance of health care facilities, in general and not in the context of a specific facility interested in a capital project, was a major mandate of MHCC that is separate and apart from discussions of the role that CON regulation might or might not play in quality assurance. He wanted everyone to understand this, given that discussion of quality assurance in the context of CON regulation is obviously a part of the Task Force work.

Lou Grimmel emphasized the importance of the "waiver" (the new payment model, as of 2014, for regulating hospital charges, through an agreement with the federal government) and the next phase of the payment model's evolution to oversee the total cost of care. The Task Force needs to look at how CON can help to make this evolution successful. Secondly, he emphasized the importance of manpower availability and limitations as an important factor in considering the appropriate way in which to regulate the supply of facilities and services.

Ellen Cooper noted that, because of her professional background as an anti-trust regulator, she was primarily interested in the way in which CON regulation affected competition.

Ben Lowenstritt noted that health care delivery is changing dramatically, apart from the direct impact of the hospital payment model changes, and HSCRC must take advantage of these changes to make the payment model work in the way desired. We need to avoid restricting patients from

getting into a less costly environment. With respect to quality, CON is limited to initial assessment of applicants but cannot be a factor in maintenance of quality over time. With respect to eliminating CON regulation, an unfettered ability to move services around within the health care system clearly threatens some individual practitioners and communities and these effects should be a concern of MHCC

Ann Horton reflected on the very different views among her "constituencies." Medicare- certified home health agencies want continued CON regulation as a control on the supply of home health agencies. Some residential service agencies want to become Medicare-certified home health agencies (HHAs) and CON is a major barrier. She is eager to learn about how CON may stifle innovation. She noted that some states without CON controls have had significant problems with Medicare and Medicaid fraud and CON is probably a factor that helps reduce the incidence of this problem. The TF needs to keep in mind the vulnerability of patients engaging with home-based services, often alone in their homes and how changes in regulatory policy may be related to maintenance of a safe patient environment.

Mark Meade stated that a balanced regulatory process is needed. Unfettered access to markets in a changing insurance environment market may have unwanted consequences. Regulatory policy should not limit the ability to control utilization in positive ways. Regulations can be streamlined but CON probably needs to continue to exist in a modified form.

Brett McCone noted that the Maryland Hospital Association (MHA) convened a work group of hospitals to look at CON regulation in 2016 that concluded that CON is necessary to control distribution of limited resources. Maryland hospitals are committed to the program for reform of hospital currently underway and changing the service delivery system. These changes need to continue to control cost of care and improve care. However, CON regulation needs to be modernized and a second work group has been convened to recommend specific changes. The group will have recommendations that will inform the MHCC study.

Regina Bodnar stated that hospice programs support CON regulation but appreciate the need for streamlining the regulatory process. It is costly but not having CON regulation would also be costly in other ways.

Jeff Metz noted that the nursing home industry has long relied on the CON regulatory model because so much of its payment sources are tied to government and regulation is perceived as a necessary check on oversupply and higher cost. He identified himself as "a free market guy who believes some costs of the regulation should be reduced through streamlining the process. However, it would be difficult to apply total free market principles to widely open up nursing home development.

Randy thanked the TF members for their initial remarks. Commissioner O'Grady asked about the literature on CON regulation and the value of comparing a sample of states with CON and a sample of states without CON to gain insights.

Paul Parker stated that, in his view, the literature addressing the effects and value of CON regulation is a "mixed bag" and that some of the research is fairly old with work on CON tapering

off in recent years. But the TF will be considering this literature. He expressed the view that, for many areas of the health care system, it is difficult to see that CON regulation has resulted in clear differences in the supply and distribution of facilities and services, the population's use of services, or cost, when states with and without CON regulation are compared. He attributes this to the fundamental weakness of most CON regulatory systems, as operated in the U.S., to shape the health care system when more powerful market forces and payment systems mitigate against the controls on supply that CON might otherwise achieve. He did note a few areas in which CON regulation clearly resulted in differences in supply and industry characteristics – home health, hospice, specialty hospitals. CON regulation varies from state to state and noted that Maryland's unique approach to regulating ambulatory surgery is an example of how the barrier represented by CON regulation can channel development in a particular direction. In this case, it has resulted in far more ambulatory surgery centers per capita, most with one operating room or no operating rooms, in Maryland than seen in any other state.

Mr. Steffen stated that we will be looking at the research comparing states with and without CON regulation or with differences in their regulatory environments.

Mr. McCone noted that MHA focuses on northeast states that have had some historic experience with rate setting in looking for meaningful comparisons. Ms. Hyatt noted that some state associations may be able to tap into research and data gathered by their national association counterparts for useful information for the TF.

3. Current Authority of MHCC and HSCRC

Mr. Parker presented an overview of the current scope of CON regulation and the status of the SHP, with respect to recent updates and the priority for updating older chapters of these regulations. (His slides can be accessed on the MHCC web site at: http://mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/CON_modernization_workgroup/con_modernization_workgroup_slide_deck_presentation_20180122.pdf

A brief discussion followed in which it was clarified that HHAs and hospices are defined as "health care facilities" in CON law and the origins of the scope of CON regulation were discussed. Mr. Parker said that the list of services that are regulated under CON can be viewed as a legacy of the first two decades of the program's evolution and a reluctance to make changes in statute over time. The presumed relationship between service volume and outcomes was a consideration and this relationship is still considered important in cardiac surgery and percutaneous coronary intervention, organ transplantation, and neonatal intensive care. In Maryland, freestanding diagnostic and treatment centers providing such services as magnetic resonance imaging, computed tomography, nuclear medicine imaging, and radiation therapy are unregulated through the CON program. Other states, such as Virginia, that regulate hospital facilities and services with a CON-style program, like Maryland, often do regulate these services and have much more stringent regulation of all freestanding outpatient surgery centers than Maryland. This characteristic may be related to Maryland's regulation of hospital charges, that blunts the competitive impact on hospitals. Maryland has prohibitions on self-referral by physicians that Virginia does not have and this is a different regulatory barrier on development of physician-owned diagnostic and treatment centers. In short, while the scope of CON has changed over time,

the current scope has changed little since the mid-1990s and represents a balance that much of the regulated facilities have come to accept and support, fearing change. Co-Chair Sergent stated that the TF will need to consider the list. Mr. Rosen stated that one service, neonatal intensive care, is always approved and, in such a case, should be considered for removal. It was clarified that statutory changes would be needed to make substantive changes in the scope of CON regulation. Some additions can be made through regulation.

Mr. Rosen stated that CON largely works to chill development rather than through denying project requests. Mr. Parker agreed, stressing that CON regulation has been around for over 40 years and would be expected to work in this way. Ms. Hyatt noted how avoidance of CON is obviously the basis for Maryland's large number of single operating room surgery centers.

Mr. McCone stressed a need to look at per capita use of services when trying to understand possible impact of CON regulation and the need to look at use rates beyond just the facilities and services that are directly regulated.

b. All Payer Model

Donna Kinzer, Executive Director of HSCRC was introduced and she introduced other HSCRC staff in attendance. She contrasted the consideration of hospital capital projects prior to 2014 and how initiation of the global budget-based payment model has changed interaction between HSCRC and MHCC. Capital expenditures must be supported by revenue available to hospitals in both cases. A pass through of capital is not desirable. Volume increases could support capital expenditures. For very large projects, HSCRC would consider a rate increase related to capital but the hospital would need to have charges at or below the average for similar hospitals.

The new payment model moves to total hospital cost per capita and global budget revenue (GBR) bring that per-capita cost down to the hospital level. Adjustments of the GBR are made for volume adjustments (population change and aging) and market shifts. HSCRC still expects most capital projects to be funded through the existing GBR but will adjust GBRs for very large projects. It looks for cost effectiveness to be demonstrated on a per capita basis in the hospital's service area. Policies are still under development, e.g., how to treat shifts in market share. She gave examples of how MHCC and HSCRC review worked in some recently considered hospital relocation project reviews. In the case of Washington Adventist Hospital, the original project was scaled back and the hospital was given partial funding of its request for additional revenue authority. In the case of Prince George's Hospital, a regional approach to changing the Dimensions system allowed the project to move forward with an expectation that the overall GBR for a relocated hospital and a hospital conversion to an FMF would not require extraordinary expansion of the overall global budget for that capital project. This was a good outcome for a hospital with high costs. More recently, a project went forward without additional consideration for capital funding even though the applicant had sought this as a source of funding for the project. There will continue to be a focus on avoidable admission and reducing excess capacity in the hospital system.

Co-Chair Sergent asked about opportunities to reduce regulatory oversight by eliminating duplication of effort by the two agencies. Ms. Kinzeer noted that HSCRC is relied upon for

financial analysis as part of CON review with MHCC and HSCRC doing "blocking and tackling" in the hospital project review process.

Dr. Lowenstritt noted how hospital reimbursement and the incentives created by the new payment model are quite different from the environment downstream from the hospital and finding a common denominator to make the system respond in a more integrated way is needed. Mr. McCone noted that, historically CON approval has been the key that unlocks the door to getting charges adjusted. The new model is modifying how hospitals ask for rate adjustments.

Ms. Kinzer suggested that CON regulation may need to be more regional in its perspective as inpatient demand continues to decline. Opportunities to shrink the hospital system by saying no to some replacement projects will be necessary.

Mr. O'Grady suggested that the analytic capabilities of MHCC and HSCRC should be considered by the TF. We must ask if we have the best tools to manage a complex system.

Mr. Rosen offered his view that the regulatory system has a difficult time easing out struggling hospitals. If HSCRC props up a struggling hospital it hurts everyone else. Mr. Kane asked about projects that do not expand GBR. Are cost just being reallocated? Ms. Kinzer reiterated the need to look at everything from a per capita cost perspective. Even if GBR is not expanded to assist in funding a capital project, per capital cost in the service area may change because of the changes in service delivery related to the project. There may be a substitution of regulated with unregulated spending. She noted that HSCRC has had set asides for GBR adjustment as part of its annual update process to account for changes such as new hospitals coming on line and this maintains overall net revenue neutrality. It can be thought of as taking a little out of every GBR to fund a new or expanded GBR. CON should be able to work as a cost containment tool within such a system. The GBR system may incentivize systems consolidation but CON may help avoid hospitals becoming "too big to fail." Watching the growth rate is the key consideration.

Co-Chair Sergent asked why CON is necessary if the GBR system constrains growth in hospital costs. Is CON needed to stop someone from doing something foolish? Ms. Kinzer noted that there is still a need to manage supply. Too many hospitals are still convinced that demand for service will decline everywhere but at their hospital but this is changing. There is still some adjustment to the new reality going on and some statutory walls may need to stay in place. A free for all may threaten the bond market. The system still has excess bed capacity.

4. Approach to Conducting the Study – Review of the Work Plan

Mr. Steffen reviewed the preliminary work plan through May of this year. It will undoubtedly be refined and adjusted over time. A small procurement for contract support is underway that extend the ability of MHCC staff to support the work of the TF.

5. Adjournment

The meeting adjourned at approximately 11:10 am.