***Draft* Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Monday, October 1, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance
Randolph Sergent, Chair
Regina Bodnar
Ellen Cooper
Lou Grimmel
Elizabeth Hafey (by phone)
Andrea Hyatt
Adam Kane
Ben Lowentritt
Brett McCone
Mark Meade
Michael O'Grady (by phone)
Barry Rosen
Dawn Seek
Andrew Solberg
Harsh Trivedi
Renee Webster

MHCC Staff in Attendance
Paul Parker
Megan Renfrew
Ben Steffen
Catherine Victorine
Cathy Weiss
Suellen Wideman

MHCC Consultants in Attendance
D. Patrick Redmon
Samantha Sender
Thomas Werthman

Others in Attendance
Pat Cameron
Joseph DeMattos
Barbara Fagan
Donna Jacobs
Danna Kauffman
Anne Langley
Dan Shattuck
Steve Wise

Agenda Item 1: Call to Order, Welcome and Introductions

Chairman Randolph Sergent opened the meeting, noting it was the third meeting of the second round of the project. He stated his appreciation for attendees' input, insight and comments.

Task Force members, staff, and those who attended by phone identified themselves.

Agenda Item 2: Approval of September 7, 2018 Task Force Meeting Summary

Mr. Sergent asked the Task Force if there were any comments on the September 7, 2018 meeting summary. None were received.

Agenda Item 3: Ambulatory Surgical Facility (ASF) Services

Paul Parker provided a brief introduction to the subject of CON regulation of ASFs. He noted that CON regulation of licensed ASFs is unique in that some licensed ASFs are subject to regulation and others are not because CON law only includes ASFs with two or more operating rooms (ORs) that seek payment as surgical facilities in the definition of regulated "health care facility." This has been a major factor in shaping the industry in Maryland, channeling most facility development into the unregulated sector. MHCC calls outpatient surgical centers that fall below the threshold of CON regulation (because they have only one OR or no ORs, just non-sterile procedure rooms) "physician outpatient surgical centers (POSCs)."

Establishing an ASF with two or more operating rooms, relocating such a facility, or adding ORs requires a CON or, in some cases, an exemption from CON review, both of which involve review of an application and a decision by the Commission. There is also an applicable capital expenditure threshold requiring CON approval for capital projects that do not involve facility establishment, relocation, or the addition of OR capacity but do involve a capital project exceeding an expenditure threshold.

State Health Plan regulations were amended earlier this year to allow review of a request from physicians for an exemption from CON to establish a two-OR ASF through the addition of a second OR to a POSC or establishment of a two-OR facility. A request for exemption from CON is intended to be an easier form of review than actual CON review, with a more limited set of criteria and without opportunities for project opponents to join the review as interested parties. Further, hospitals can also seek an exemption from CON to establish two-OR ASFs when they are willing to give up an equal number of existing ORs in the hospital setting. Also, if a hospital converts to a Freestanding Medical Facility, there is an opportunity to establish a two-OR ASF in conjunction with conversion of the hospital through an exemption from CON review.

Mr. Patrick Redmon reviewed issues with respect to CON regulation of ASFs that were included in the Interim Report on CON Modernization earlier this year. He then discussed a series of recommendations for reform, categorized as Minimal, Moderate, or Major reform proposals.

Minimal Reform

- **Eliminate Capital Expenditure Threshold defining need for CON approval**

Mr. Sergent sought clarification on this idea, asking whether it means the threshold above which an entity needs CON approval, and whether eliminating the threshold would negate any CON requirement. He asked what activities currently fall below the threshold. Mr. Parker reiterated that the following actions require a CON:

- Establishing an ASF with 2 or more ORs, regardless of cost;

- Relocating to another site, regardless of cost; and
- Adding ORs, regardless of cost.

If none of the above is occurring through an ASF capital project but the expenditure for an ASF capital project (e.g., renovation of the facility or expansion of space without any changes in OR capacity) exceeds the applicable threshold (currently $6.15 million for an ASF), a CON is required for that capital project. This recommended change would mean that such capital projects would never require a CON but the three "categorically" project types bulleted above, would still require a CON. Mr. Parker noted that eliminating the threshold would not have a material impact on CON because such ASF projects are rare. It is truly a minimal reform.

Mr. Steffen explained that the reform is minimal because ASFs in Maryland are, for the most part, quite small and renovation projects would not usually exceed $6.15 million. Renovation of a larger facility could potentially breach the expenditure threshold. Andrew Solberg asked, rhetorically, why MHCC should care if a larger facility does any of the listed types of project.

Moderate Reform

- **Create an expedited review process for ASF and hospital operating room inventory changes – approve if existing OR capacity is well utilized. Do not include interested party participation in this process. Allow all categories of applicant to use this process (i.e., not just physicians, as allowed under the recent "exemption" changes in the SHP)**

Mr. Parker noted that this proposed reform is different than the "exemption" review process reform added through recent regulatory changes. This is an expedited review process for any OR changes to existing facilities, without ownership limitations. Brett McCone stated his view that interested party participation is still critical to the CON project review process, adding that there is no need to create a new category of review process, just do better with the categories already in place. A Task Force member sought clarification as to whether this new process would apply in cases where existing facilities sought to expand. Renee Webster asked whether a "hospital ASF" is an entity owned by a hospital, or based on the hospital campus. Mr. Parker responded that this recommendation was meant to apply to both ASFs and hospitals adding OR capacity. A Task Force member asked about the categories of applicants. Mr. Parker responded that ASFs in Maryland are owned by individual physicians, physician groups, proprietary corporations, usually in joint ventures with physicians, and hospitals, who are also sometimes in a joint venture with physicians.

Revisiting the question of eliminating contested party commentary in an expedited review process, Barry Rosen asked what benefit the commentary from contested parties serves, if the overarching aim of these reforms is to "lean in" to the ASF setting because of its cost advantages. He was not sure about the benefit of contested party commentary.

Andrea Hyatt stated her belief that consideration should be paid to the multiple types of ASF ownership in the industry, which leads to practitioner and case "swapping," between entities, but no real growth.

Mr. McCone stated that maintaining interested party status is important to determine whether services are needed. He added that while procedural efficiency and encouraging competition are valid arguments for changes like that under discussion, the payer mix for outpatient surgery is quite different between hospitals and ASFs. Changes that accelerate taking more and more commercial payment out of the hospital setting and leaving the hospital as a safety net for Medicaid and charity patients can be a consequence of this change that is not necessarily desirable. Further, physicians who care for commercial patients at ASF may also cover remaining patients at a hospital and could seek a subsidy to do so. If this is the business model

encouraged by CON reform, retaining a role for interested party participation is a necessity. Ben Lowentritt noted that ASFs provide a more cost-effective level of care and, from a physician's standpoint, given that every medical innovation is both expensive and being pushed to lower-cost settings, should we try to hold back ASF development from following this trend. The regulatory system created the one OR ASF as a dominant model in Maryland but this may not be the most appropriate model to encourage going forward. He asked what reasons exist to restrict this type of development, which involves private investment based on logical business plans. Streamlining and creating flexibility in the existing process is important because ASFs are an important part of the health care spending solution and the current process may be too rigid to allow for the solution to be realized.

Mr. Sergent asked, putting aside quality, what is CON regulation providing in this space. Mr. Solberg pointed out the need to recognize the unintended consequences of deregulation. One concern would be overutilization. Medicaid's low payment levels have created the inequity of access to ASFs for Medicaid patients and this is unfair for hospitals. He further opined that data around these concerns should be studied prior to deregulation. Ms. Hyatt responded that overuse of surgery or the delivery of unnecessary procedures is being adequately addressed by ASFs and payers. There have been sharp reductions in payment schedules for ASF services, making ASF reimbursement much lower than hospital reimbursement for the same procedures (with Medicaid paying a percentage of the already lowered reimbursement). She added that there should be no expectation that ASFs will take cases at a loss, until the State addresses the current Medicaid payment schedule.

Mr. Rosen addressed the issue that more ASF development will force hospitals to be burdened with non-commercial business. He noted that Maryland has no charity hospitals and HSCRC allows hospitals to overcharge in order to cover the cost of caring for non-commercial patients. The notion of permitting contested parties to challenge projects elongates the review process. Dr. Harsh Trivedi noted, in his experience in Tennessee and other jurisdictions in which he has practiced, an additional unintended consequence of deregulating the market is that many ASFs develop in close proximity to one another. He noted that, in Maryland, the CON process is designed to provide thoughtful care provision across the State, so that services are accessible and efficient. He had concerns about deregulation in an unthoughtful way. Ms. Hyatt noted, with the current policy of no regulation of the supply of ASF with one OR, the proliferation of facilities in close proximity to one another has already occurred. Ms. Webster noted, when comparing ASF numbers in Maryland to other states, Maryland has larger numbers of facilities than other larger states. Therefore, Maryland's CON policy has not prevented substantial growth in ASF supply. Mr. Steffen added, that when you count the number of ORs, Maryland appears to be in line with other states, whereas when you count the number of facilities, there are far more in Maryland by comparison, as a consequence of the unique policies that Maryland has followed with respect to CON regulation of ASFs.

- **Give MHCC the ability to waive CON requirements for capital projects endorsed by HSCRC as contributing to safe and effective control of TCOC**

Mr. McCone, addressing system efficiency and feasibility of the reform idea, indicated a need to define in regulations how both MHCC and HSCRC would define "safe and effective" and how MHCC would implement the reform. It would require clearly defined rules for the agencies to waive regulatory requirements. Mark Meade agreed. Mr. Sergent stated his view that this reform could resemble a CMS demonstration project. A waiver could be granted under certain payment parameters. He suggested that projects could be treated as HSCRC demonstration projects. Dr. Lowentritt concurred with Mr. Sergent's concept, given Maryland's uniqueness. He suggested it not be limited just to ASFs. Mr. Solberg stated that this may only be applied to hospital-sponsored ASFs, as HSCRC only has regulatory authority over hospitals. Regulatory specificity would be necessary, given the flexibility of the HSCRC process (e.g.,

negotiation of hospital global budget revenue). Mr. McCone agreed, but noted the language in the recommendation was not limited to hospital-sponsored ASFs.

Major Reform

- **Eliminate all CON regulation of ASF development (but retain streamlined regulation of OR capacity of hospitals with reforms proposed in earlier slide**
- **Provide authority and funding for broader and more rigorous ASF regulation by MDH. Require detailed background review of ASF licensure applicants. Deny licensing to persons who have problematic track records. Fund additional MDH staff for more frequent surveys and more monitoring of ASF safety and quality. Enable delicensing for poor quality. Require and enforce design standards. Additional funding could arise from high licensing fees which may also discourage lower capability applicants.**

Ms. Hyatt noted that the Maryland Ambulatory Surgery Association (MASA) recommends eliminating CON requirements for ASFs with two or fewer ORs. However, MASA does not believe in more rigorous regulation, noting ASFs have design standards, regular surveys, and quality reporting requirements. Dr. Lowentritt questioned the comment about under-developed quality measures and monitoring of ASFs, given the regular monitoring and reviews that occur now. Mr. Parker indicated that this idea of "beefing" up MDH regulatory oversight as a necessary adjunct of deregulating all ASF development was in line with similar reform ideas for other types of facilities, assuring an adequate "gatekeeper" can ameliorate any negative impact of having greater numbers of persons entering the ASF field in Maryland if CON restrictions are lifted. With respect to quality measurement, this part of the reform idea speaks to the field of health care facility comparison tools generally. While there are a number of "compare" tools maintained by CMS, there is no CMS "ASF Compare." Ms. Hyatt noted the industry has asked for it.

Mr. Sergent saw two aspects of quality assurance. Quality assurance can be a function of "gatekeeper" style licensing. It can also be achieved through more effective consumer-oriented quality comparison. The first component is related to CON regulation. He asked if ASFs have a concern, in the same way home health agencies were concerned, about the proliferation of bad actors. Ms. Hyatt does not see similar concerns in the ASF world. Mr. Parker added that if CON for ASF was dramatically scaled back, there may need to be moderate expansion of MDH's powers to deal with bad actors. He acknowledged that the idea may not prove popular but it is based on the concept that if you want more of something, you deregulate it. CON deregulation would be expected to encourage service provision to move from a high cost to a low cost setting, but you would need to amend facility licensing to effectively handle potential bad actors. Mr. McCone believed effectively eliminating CON for two or fewer OR ASFs was a good step. Mechanically, some regulatory procedural steps would need to be cleaned up. Broader, more rigorous ASF regulation is not needed. Instead, the entity would need one set of measures and one agency to "own" it. Task Force discussed the necessity of design standards, and procedures for reviewing them when there are no specific standards. A Task Force member noted that ASF design standards are actually guidelines, which are already controlled by surveys and reviews. Mr. Rosen agreed that two OR reform is terrific and a higher number of ORs would require legislative action. The question is what will hospitals look like in the future, in terms of service lines and payer mix. Mr. Rosen also commented on the technical aspects of regulation. Mr. Parker indicated these requirements related to process will be addressed at a future meeting. Ms. Hyatt stated that the ASF industry is one of the few industries that saves consumers' health care dollars. ASFs exist on very strict budgets, given the payment schedules. There are efficiencies that should be considered by increasing the number of ORs, which are subject to applicable requirements and standards, regardless of number.

Mr. Michael O'Grady appreciated the balanced discussion and the willingness of the industry to deviate from a position of maintaining CON regulation in its current form for protectionist purposes.

Agenda Item 4: General Hospital Facilities and Services and Agenda Items 5: Special Hospital Facilities and Services – Chronic, Pediatric, Psychiatric, Acute Rehabilitation

Mr. Parker introduced the next discussion topic of hospitals, specifically general hospitals, special hospitals, and Freestanding Medical Facilities (FMF), which can only be developed and operated by general hospitals. The regulatory scheme for hospitals is more complicated than that of ASFs. CON requirements are more extensive, and capital thresholds are higher. CON can already be avoided by hospitals undertaking capital projects with no categorically regulated elements. This is accomplished by "taking the pledge" that substantive rate increases will not be sought to pay for the depreciation and interest costs associated with the capital project. Multi-hospital systems (called "merged asset systems" in CON regulation) can do some type of projects with exemption from CON review. Further, a new category of review process called certificate of conformance review was created a few years ago for creation of percutaneous coronary intervention (PCI) programs. Special hospitals specialize in providing one type of patient care, such as chronic care, acute rehabilitation, pediatric care, or psychiatric care. Fewer things happen in this environment that would require a CON. The major regulatory focus in the hospital sector is to maintain high levels of capacity use (beds and ORs) or "adequate" program use (for specialized services such as cardiac surgery, organ transplantation, PCI) by limiting growth in capacity and proliferation of specialized programs.

Mr. McCone provided the Maryland Hospital Association (MHA)'s summary of CON reform recommendations. Key recommendations include:

- Change capital thresholds to 25% of revenue, up to $50 million. CON continues to apply if required by statute;
- Capital funding process needs more clarity from HSCRC. Fund capital appropriately through updated capital policy;
- For hospitals, remove requirements for charge information, charity care information, and quality of care documentation. HSCRC measures and enforces and, thus, no need to address these issues in CON regulation;
- Update SHP to align with TCOC. MHCC should review annually for potential updates; and
- Psychiatric services chapter of SHP needs to be reviewed and revised.

Mr. McCone also provided more general ideas for reform, including:

- Adherence to timelines in project review;
- Speed up non-comparative reviews with no interested parties;
- Eliminate requirement for applicants to provide alternative project scenarios;
- Need to focus completeness questions;
- Eliminate Limited Service Hospital regulations, replace with FMF;
- Notification updates;
- Regulatory and policy reference amendments;
- Eliminating construction cost standard;
- Delegate financial feasibility determination to HSCRC;
- Eliminate ED standards;
- Submit one set of financials to agencies;
- Consolidate and simplify CON application:
- Align agency requirements when transformation occurs;
- Clear messaging for right-sizing services; and
- Revisit definitions.

Mr. Sergent asked about the necessity for any capital thresholds, given HSCRC rate regulation policy. Mr. McCone noted the "risk factor" for overbuilding, and the need to limit risk exposure. Mr. Adam Kane noted the biggest factor for aligning TCOC between HSCRC and MHCC is capacity. Some acute care facilities have reduced volume, and still have excess bed capacity. For alignment with TCOC, the question is, as volume drops, how do you align the CON process and capacity to eliminate entitlement to excess capacity. Mr. Solberg responded that it is not MHCC who has the authority over capacity, rather the licensure process. Mr. Rosen asked, in the context of capital thresholds and the capital plan for HSCRC, is age of a physical plant a relevant variable? Is it distinct from a general capital expenditure? Mr. McCone responded affirmatively but was unsure where the line should be drawn. Mr. McCone stated that demand concerns with respect to non-hospital services indicates that CON is needed for the TCOC model to work. Mr. Kane pointed out that hospital global budge revenue accounts for capital costs. Mr. McCone noted that prior to GBR, capital was funded through volume.

Dr. Redmon presented the issue statements from the Interim Report with respect to hospitals. He then discussed a series of reform ideas categorized as Minimal, Moderate, or Major reforms.

Minimal Reform

- **Eliminate fixed dollar amount for capital expenditure threshold. Establish thresholds based on size of hospital revenue base**
- **Require hospitals seeking CON approval of projects only reviewable because of the CAPEX to request a partial rate review in conjunction with the CON application. No review of applications "reserving the right" for extraordinary GBR adjustment at a later date will be allowed.**

Mr. Sergent asked if there is a capital policy that the industry likes, why is it necessary for MHCC to review projects. Is it to make sure the plan is financially feasible for the sponsoring hospital or that the plan will not increase capacity unnecessarily or increase demand for services. Mr. McCone believed that both are bases for review. Mr. Solberg was concerned that due diligence for financial vetting of projects may not occur if CON is eliminated.

Moderate Reform

- **Eliminate capital expenditure threshold defining need for CON approval**
    - **Eliminate "pledge projects" and CON review of projects with no categorically regulated elements. No hospital capital projects is automatically eligible for extraordinary adjustment of revenue base**
    - **Hospitals can request extraordinary adjustment of revenue base related to increased capital costs for any project defined by HSCRC as eligible for such a request. HSCRC can choose to approve, partially approve, or deny at its discretion**
- **Eliminate requirement for review of bed capacity changes**

Mr. Sergent asked if there is a risk built into these recommendations for a potential game of chicken between hospitals and HSCRC. If hospital construction goes unchecked, will we see hospitals seeking rescue by HSCRC, through rate adjustments, if capital plans do not prove successful. Mr. McCone responded that the capital threshold limit serves to protect against this scenario. Mr. Solberg has never seen this circumstance occur.

- **Create an expedited review process for operating room inventory changes – approve if existing OR capacity if well utilized. Do not include interested party participation in the process**

Mr. McCone indicated that this change may be more a regulatory lens change than a capital review change.

- **Update the SHP to reduce standards. Focus CON review on need for project and project feasibility**

Mr. Rosen believes that the SHP should be written in terms that are relevant and should not consist of requirements. Agency discretion could prompt political pressures, however. Mr. Solberg believed applicants' conformance with terms and conditions of prior applications are important but MHCC can ask applicants if they have performed the listed conditions, without requiring applicants to furnish past applications. Dr. Lowentritt agreed that hospitals should not have to provide prior CON applications, but that MHCC should take into account what was promised versus what was developed or removed. Mr. Sergent noted a distinction between a state agency issuing a license or approval following violations of terms in earlier CONs, versus determining whether in fact an applicant did violate terms of a prior CON. Mr. McCone agreed with simplifying the process for MHCC by providing information and considering reasons for the violations. Mr. Solberg noted the violations will vary in scale or degree.

- **Give MHCC the ability to waive CON requirements for capital projects endorsed by HSCRC as contributing to safe and effective control of TCOC**

Major Reform

- **Eliminate hospital CON regulation, with the exception of:**
  - **Establishing hospitals**
  - **Establishing FMFs**
  - **Relocating hospitals or FMFs**
  - **Introducing cardiac surgery, PCI, and organ transplantation as new services**
- **Redirect work of MHCC on developing a new and different type of SHP that will inform HSCRC decisions on providing additional revenue for capital projects – a plan that accesses the need for systems capacity rather than a set of project review standards**

Mr. Rosen raised an issue with respect to the fourth bullet. If hospitals pledge not to seek budget adjustments, why include cardiac surgery and PCI as services that continue to be regulated. Mr. McCone pointed out some minimum volume is required in specialty services. Mr. Rosen noted that not all programs meet these minimum case volume requirements. Mr. Parker noted these three service lines were included within the scope of CON regulation as part of this deregulatory idea because the volume outcome relationship is most clearly indicated in the literature for these services.

Mr. Sergent noted the interesting nature of Mr. Rosen's point. Mr. McCone noted the HSCRC fixes revenue for entities, which creates a need to look at demand for services. Dr. Trivedi noted, in looking at service lines, what service in the CON ecosystem will help someone do well? He used the example of organ transplantation in another geographic area and mitigation of service failure. Just taking the pledge doesn't benefit an entity or patients. Lou Grimmel asked if all CON for special hospitals would be eliminated. Mr. Parker responded that this proposal was meant to apply to all hospitals, so a CON would still be needed to establish or relocate a special hospital. Mr. Grimmel asked the Task Force to specifically address chronic and acute hospitals before addressing CON in other special hospitals. As an example, Mr. Parker stated that he could not imagine a scenario in which MHCC would approve additional chronic care hospitals in Maryland, given their recent history and, for that reason, it made sense to keep establishment of any hospitals in the scope of CON regulation. Mr. McCone pointed out that discretion without rules will cause problems.

Dr. Trivedi provided an example of his experience in Tennessee, in the context of private psychiatric and addiction treatment facilities, as a "cautionary tale" with respect to deregulation. Private funding will germinate in Maryland as it has in Tennessee, putting existing high-quality entities at risk. Private entities will also expand into services outside of psychiatric and addictions treatment. Mr. Parker asked about the CON requirements in place in Tennessee. Dr. Trivedi responded that Tennessee has a much looser CON process.

Mr. Sergent asked to what extent CON would be eliminated, aside from renovation and bed capacity expansion under this reform idea. Mr. Parker responded that the bulleted service lines in the document he circulated describing the scope of hospital CON regulation would be eliminated from CON requirements. Mr. McCone stated MHA members couldn't reach consensus on how to reform CON and what service lines to eliminate from CON requirements. Mr. Grimmel was unclear about the nature of the major reform being outlined. Mr. Parker provided that, under this reform, generally speaking, the following actions could be taken without a CON: general and special hospitals could add bed capacity, general hospitals could change their operating room capacity, general hospitals could undertake capital projects that do not involve any categorically regulated elements, they could introduce new acute care services. (They couldn't introduce new special care hospital services since this would be tantamount to establishing a new special hospital and would continue to require a CON.) Mr. Steffen simplified, stating an existing facility can add services without CON approval, but not add a new hospital.

Dr. Trivedi spoke about the possible disruption that psychiatric services at a special hospital (like Sheppard Pratt) could suffer if CON requirements for service line expansion were eliminated (lack of access, more treatment in the ED or acute hospital setting, etc.). Mr. Rosen noted that outside entities don't come to Maryland, because of the expense and unknown outcome of MHCC decisions. In the context of the TCOC model, this construct could be leveraged to force entities to take the pledge in exchange for CON exemption.

Mr. Parker acknowledged that CON reform as proposed would, in some respects, shift some of the CON "work load" to HSCRC and a blanket "take the pledge" policy doesn't consider the circumstances of specific hospitals. The ultimate arbiter in these circumstances is and would continue to be HSCRC. With less CON project review responsibility, MHCC can be a consultant for HSCRC in determining what to pay for. It could focus on development of a State Health Plan that identifies resource and investment needs to guide HSCRC in determining when a GBR should be adjusted to account for project costs. If the investment does not align with the SHP and no additional revenue is allowed by HSCRC to support project costs, hospitals will accept that risk and proceed with the project or cancel the project. In either case, a cumbersome external project review process would be avoided.

Agenda Item 6: Plans for the October 12 Meeting – Review of CON Project and Exemption from CON Processes

Mr. Sergent noted the agenda for the next meeting would discuss process and procedure reforms. Mr. Steffen indicated that the cross-cutting recommendations would be considered, as well as process changes in terms of the statute and accompanying regulations. Mr. McCone noted that MHA materials touch on statute and regulation reform.

Agenda Item 7: Adjournment

Mr. Sergent thanked the Task Force for the discussion of a very complicated issue in a very compressed time. Mr. Steffen addressed the agendas of future scheduled meetings, with draft recommendations to be presented to the Task Force on November 9, 2018, with presentation to the Commission at the November 15, 2018 meeting. The meeting was adjourned.