Meeting Summary
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, April 20, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance:
Frances Phillips, Co-Chair
Randy Sergent, Co-Chair
Ellen Cooper
Lou Grimmel
Elizabeth Hafey
Anne Horton
Andrea Hyatt
Ben Lowentritt, M.D.
Brett McCone
Mark Meade
Michael O'Grady (Phone)
Jeff Metz (Phone)
Barry Rosen
Andrew Solberg

MHCC Staff in Attendance:
Paul Parker
Ben Steffen
Suellen Wideman

Others in Attendance:
Brian Ackerman
Daniel Carter
Erin Dorrien
Peggy Funk
Keith Hobbs
Danna Kaffman
Anne Langley
Pat O'Connor
Laura Russell
Noson Weisbord

Co-Chair Frances Phillips kicked off the meeting by asking task force members who are on the phone to identify themselves.

Commissioner Michael O'Grady stated that he had joined the meeting by phone.

Ms. Phillips asked visitors from Johns Hopkins University to introduce themselves. The group consisted of Professor Thompson accompanied by three Master in Health Care Management students (Prateek, Jessica, and Marvin) and Emanuel, Program Manager.

Ms. Phillips asked everyone to review the meeting minutes from February and March and provide feedback. Ben Lowentritt and Elizabeth Hafey noted that they were not on the list as having attended the March meeting but had been present; the minutes will be updated to reflect this change.

Ambulatory Surgery Facility Discussion

Ms. Phillips introduced the process of the meeting. She stated that MHCC staff would provide a brief introduction and an industry representative would expand and elevate issues for the Task Force to discuss. Ms. Phillips then turned to Paul Parker for an introduction of Ambulatory Surgery Facilities (ASFs) from the staff perspective.

Mr. Parker provided a brief introduction to the Ambulatory Surgery fact sheet and compared/contrasted Ambulatory Surgery Facilities in Maryland to that of other states. Lou Grimmel then requested feedback from the group regarding what impact the waiver has on Maryland's ASFs. Mr. Parker responded that the most powerful effect was there was no perennial warfare between hospital and physicians. In contrast, the main point of contention between Virginia physicians and hospitals was to loosen up regulation to let more physicians have the ability to do surgery in ASFs. So far, physicians had lost because hospitals didn't have rate regulation to fall back on. Hospitals were hanging on to the regulation because they needed ambulatory surgery profitability to offset other hospital losses. Ms. Hyatt commented that one of the negatives to Virginia's set-up was that no oversight or quality reporting exist when a case is completed in an office-based setting.

Andrew Solberg responded to Mr. Grimmel's question by stating that the waiver incentivizes hospitals to develop off-campus sites.

Barry Rosen also responded to Mr. Grimmel stating that the waiver allowed Maryland hospitals to charge higher prices for Medicare and Medicaid patients because HSCRC required it. He also made the point that one-room ASFs are not particularly efficient, and questioned why there were regulatory barriers of any sort in place for those?

Mr. Parker addressed Mr. Rosen's question by stating it is not difficult to get an additional operating room added to a one-room ASF. The Commission has recently reformed the ASF chapter of the State Health Plan (SHP) so there is now an updated exemption process for some types of providers. The Commission also now allows hospitals to swap out decommissioned hospital ORs for a two-room ASFs.

Andrea Hyatt, representing Maryland Ambulatory Surgery Association (MASA), introduced herself and gave her background. She thanked the Commission for the opportunity to participate and comment. She stated that the ASF industry had promoted Institute for Healthcare Improvement (IHI) Triple Aim and had helped Maryland providers cut costs without compromising safety and quality. MASA had chosen to not take a single position on need and CON regulation given multiple different opinions from ASF operators in the State. Ms. Hyatt noted that the one-room ASF approach had caused increases in single room ASFs in the State, much more so than surrounding states. She stated that MASA supports a competitive environment, and that the growth over the past few years had been relatively flat, serving as evidence that the competition had been weeding out those facilities that were not competitive enough.

Ms. Hyatt highlighted several MASA comments and recommendations as the following:

- MASA supports recent changes in the SHP, which have eliminated many barriers to entry.
- MASA believes that exemptions should not be eliminated.
- MASA recommends certain criteria about alternatives and elimination of minimum utilization.
- MASA supports more emphasis in place for operational requirements.
- MASA supports the elimination of capital expenditure threshold, providing the example that an increase in construction cost beyond 15% should not delay the project.
- MASA endorses the use of technology to submit automated and form-based applications.
- Relative to duplication of CON with other agencies. MASA recommends:
    - Removal of requirement of application to address quality of care in other locations.
    - Removal of entire section of transfer agreements.

Dr. Lowentritt, who acknowledged he was speaking on behalf of the physician community, then raised several issues with current CON oversight from his perspective, including:

- Lack of clarity within the ASF chapter of the SHP relative to any clear delineation between hospitals and ASFs, particularly related to applicable standards.
- Regarding the new two-room ASF exemption, lack of clarity regarding the amount of work necessary for the exemption process, noting that information on items such as need and charity care were still necessary.
- Amount of regulations and quality monitoring in place outside of CON is already significant, so what is the biggest concern from the Commission's standpoint that CON helps to address?

- Inefficiencies and limited economies of scale associated with one-room ASFs given certain basic minimums associated with sterility and staffing.

Dr. Lowentritt concluded by stating that ASFs have much lower cost. From an efficiency standpoint, given that a considerable amount of infrastructure and staffing are required to operate an ASF, one solution might be to allow two-room ASFs as the starting point.

Randolph Sergent thanked Ms. Hyatt and Dr. Lowentritt for their comments. He acknowledged that the group's desire seemed to be to make the starting point of regulation for two-OR facilities. He asked, what was the magic number of rooms to optimize efficiency? What would be the maximum number of rooms, if there was one?

Ms. Hyatt responded to Mr. Sergent's question. She agreed that there was more efficiency in increasing from one to two ORs, noting that two rooms give physicians more flexibility in scheduling procedures. She also noted that ASFs performing multiple specialties would achieve even further increased efficiency with additional rooms beyond two. She observed that biggest efficiency gains occur when facilities expand in increments of two.

Mr. Rosen commented that he didn't believe there was a need for regulation for this industry given the resource requirements associated with the CON process and the lack of efficiencies associated with smaller ASF locations. He questioned why there is such a "deli-counter ticket" requirement at all.

Ellen Cooper asked if there was a limit to what could be done in ASFs compared to what could be done in the hospital? Ms. Hyatt responded by saying that there had been a lot of pressure on ASFs to perform appropriate cases for appropriate patients. She noted that Medicare and private payers define the range of surgical procedures that they will reimburse at an ASF. Mr. Parker commented, ASFs are required to admit and discharge a patient in under 23 hours. There are also certain procedures that payers, including Medicare, don't have codes for and therefore reimbursement does not exist.

Mr. Solberg stated that if there were no regulation for ASFs, there would be a proliferation of ASFs based on aspiration alone, many of which would be forced to shut down due to insufficient volume. Mr. Sergent questioned why it mattered if many ASFs open and then close? Dr. Lowentritt agreed that there was no real justification for CON given numerous financial check points. If no CON regulation existed, many existing facilities would go out of business.

Mr. Sergent addressed the group, stating that we've heard the case against regulation, so he wondered about the reasons for regulation.

Commissioner O'Grady commented that providers generate demand in this industry. Without CON, ASFs would not go out of business but find ways to fill their waiting rooms. Demand had been dictated by the provider and it would be unlikely that that market would take care of that if CON went away. Commissioner O'Grady expressed his concern that ASFs would be able to prop up inefficient operations for years on the backs of taxpayers and premium payers.

Mr. Solberg countered by stating that many ASFs have been built based on private dollars and that it wouldn't be that easy to switch gears and generate a different business and maintain or pass many accreditation/requirements. He stated that many centers were in fact closing now due to competition.

Commissioner O'Grady responded to Mr. Solberg's comments by saying that there was a provider has a tremendous amount of discretion in the timing of a procedure. These factors affect utilization but didn't fall into the category of medically unnecessary. Deregulation would provide motivation to take action to perform surgeries instead of watchfully monitoring, which would put upward pressure on insurance premiums.

Mr. Sergent commented that it would be great to understand empirically how CON would impact demand. Today payers are much more assertive in assessing whether surgical services are necessary. In the current environment, Mr. Sergent questioned the impact of CON and asked staff to provide evidence. Ms. Hyatt in agreeing that payers were becoming more assertive, stated that Medicare had strict criteria that must be met when someone sought cataract surgery, for example. Commissioner O'Grady stated that he agreed with Ms. Hyatt from that perspective. He acknowledged that payers are more pro-active in assessing surgical appropriateness. He clarified that he objected to the notion that opening the market for surgical services would necessarily produce market equilibrium where supply balances with real demand.

Brett McCone stated that the group certainly needs to think about how to change/transform care. He noted that from the commercial payer perspective utilization was managed; however, that isn't the case for Medicare. He acknowledged that as transformation takes place the Commission must monitor ASF volume increases relative to hospital volume declines.

Ms. Hyatt observed a reason for the overall ASF volume increase was likely to because doctors have backlogged cases in hospitals. She contended that sometimes physicians could only block time one day a week in the hospital OR, but that same physician could block considerably more time an ASF. Ms. Hyatt also stated that some hospitals are trying to direct patients to their ASF, but some payers were putting up roadblocks because they believed they were already paying the hospital under the global budget arrangement.

Mr. McCone stated that all members needed to rethink what was regulated by the HSCRC on the outpatient side as services were moving to unregulated side of the organization.

Ben Steffen restated that one-room ASFs were not regulated and that the outcome of the current policy overall should be taken into account current impact, including the view that one OR ASFs are not the best site from vantage point of OR efficiency and patient safety.

Ms. Hyatt stated that the work done previously regarding amendments to the State Health Plan for Surgical Services that went into effect in January should be revisited in relation to this topic. Mr. McCone agreed, stating that he believed the amendments to State Health Plan for Surgical Services was well thought out, but further changes were needed.

Ms. Phillips concluded that ASFs were going through significant transformation/innovation and that the staff should crystalize ideas and circulate back to the group. She concluded this segment of the conversation and moved to the next item on the agenda.

Other Provider Categories Discussion

Mr. Parker introduced the discussion first on Residential Treatment Centers (RTCs), noting that until recently the sector that was in decline. Mr. Parker noted that there were only 470 beds in the State now, and geographic distribution was very limited. He also noted that within the past two years there had been only one application, which was withdrawn but recently has been re-submitted again.

Mr. Parker then discussed CON regulation Alcohol and Drug Rehabilitation Facilities. He noted that data limitations exist as these facilities. Many do not report utilization or patient-level data. He observed that the treatment spectrum for substance abuse withdrawal management includse outpatient, inpatient, and acute inpatient care. Although these facilities cover a wide spectrum of care, Mr. Parker noted that the only the medically-monitored intensive inpatient treatment level of care (which is not acute hospital care) and acute hospital-level care is regulated through CON. Mr. Parker stated that there were 18 acute inpatient substance treatment facilities in the State, referred to as Level 3.7 facilities, using the American Society for Addictions Medicine definitions of levels of care. He noted that there had been hardly any activity in this field for years, but over the past eighteen months, four new facilities were approved.

Ms. Hyatt asked the group, given the recent experience, was there any public policy reason to continue to regulate them? Mr. Parker responded by stating that the Commission had proposed to remove acute inpatient substance treatment from the scope of CON, given that these facilities constituted a small share of the treatment spectrum. He stated that most development activity in this treatment segment was arising from for-profit companies that did not participate in Medicare or Medicaid. He noted that the federal government had announced in August 2017 that Medicaid would pay for this level of inpatient drug treatment in facilities of any size. He suggested this change would likely not deter the Commission from its assessment that CON regulation was not the appropriate regulatory stance.

Ms. Phillips commented that access to acute inpatient substance abuse treatment was an issue because of the opioid crisis in the State. She stated that people needed treatment and CON appeared to be imposing unneeded barriers. It was noted that the Commission proposed to remove acute inpatient substance abuse treatment from the scope of CON, but the proposal was challenged in the House of Delegates because facilities that currently operate do not want new market entrants or competition.

Mr. Solberg then asked about whether the regulation for residential treatment centers was necessary? Mr. Parker reported that the Commission hasn't studied that in order to take a position. He stated that it was likely that the existing providers would oppose an effort to deregulate.. Mr. Parker agreed that, given current trends in this field, it was his opinion that regulating Residential Treatment Centers was of questionable necessity.

Mr. Parker then addressed the topic of regulated Special Hospitals, which include special medical rehab, special psychiatric, pediatric, and chronic care. Mr. Parker noted that applications for these facilities are relatively rare. Ms. Cooper questioned whether the reason for this might relate to reimbursement, to which Mr. Parker noted that most acute inpatient rehabilitation patients, the most common form of special hospital patient, are Medicare.

Mr. Sergent asked the group for reasons why these services were regulated when regulation wasn't necessary. In response, Mr. Parker stated that there had been explosive in this long-term care hospitals (in Maryland, chronic care) and, to a less extent, in acute rehab, over the last 20 years in some non-CON states. This was not seen in Maryland

Ms. Cooper then shifted the conversation back to the previous discussion, by asking about withdrawal management (detox) and if outpatient withdrawal management or rehabilitation is covered by CON? Mr. Parker answered by saying no, outpatient substance treatment was not governed by CON.

Ms. Cooper made the point that there should be a balance between access, fraud protection, and quality. Fraud, as the group has discussed before, had been an issue in Florida. Ms. Phillips noted that the rigorous review of quality and data was still in infancy stage right now.

Ms. Hyatt asked whether the group would recommend deregulation of CON across the board? Mr. Parker responded by saying that the Commission would let this process play out and that aside from inpatient detox, the Commission hadn't taken a formal position on reducing the scope of CON regulation in recent years.

Mr. McCone confirmed that recommendations from the Task Force on this topic was a required part of Phase II.

Given available time, the topic of alignment between CON regulation and the Maryland payment model was discussed briefly, but the Task Force agreed sufficient time wasn't available to discuss fully, and Ms. Phillips directed the group to the next agenda item, lessons from other states.

CON Reform – Lessons from Other States Discussion

Mr. Daniel Carter from Ascendient Healthcare Advisors provided a brief history of CON reforms that had taken place in other states. Mr. Carter prefaced his comments by stating that any discussion of reform from other states was highly dependent on the current regulatory scheme in each state. Most states, Mr. Carter continued, had initiated CON reform for a handful of reasons, such as:

- External factors related to the impact of ACA and associated/expected responses.

- Internal factors like challenges from physicians or responses to specific issues, such as challenges in rural health care or behavioral health access issues.

Mr. Carter stated that reform efforts generally fall into three categories:

- What services were regulated
- How those services are regulated and planned
- The CON process itself, including pre-submission, application submission, limiting the review periods, limiting who may comment/oppose on the applications, limiting the appeal periods, discovery, or number of depositions.

Mr. Carter then provided several examples of CON reforms, including:

- Georgia passed a bill recently to define a microhospital and provide definitions with regard to what geographies might qualify for an exemption process for development of a microhospital.

- North Carolina now has provisions associated with hospitals that close in rural areas, including ability of applicants to apply to open a microhospital or operate a freestanding ED in lieu of the full-service acute care hospital.

- North Carolina also has loosened regulations and developed a more streamlined process for applicants proposing to operate psychiatric beds in lieu of acute care beds, or providers who want to convert hospital-based ORs to freestanding ORs.

- South Carolina has eliminated per se regulation for equipment such as PET and MRI, but capital threshold requirements still exist.

- Florida deregulated virtually all outpatient services many years ago largely due to growth in the senior population, which was driving increased demand. Florida was seeking to remove barriers for those that wanted to move patients from higher to lower cost settings.

Brian Ackerman from Ascendient then introduced himself and provided more specific examples of other states' CON modernization efforts in light of healthcare transformation, noting that given recency some of the outcomes/details were yet to be finalized.

- **Kentucky**:

  Rather than attempt to eliminate CON, Kentucky has focused on trying to understand how to embrace CON to drive systematic change in healthcare delivery, improve care coordination and ensure access for all. Mr. Ackerman provided a few specific examples of what Kentucky has done, including:

  - Established uniform review criteria related to participation in state-wide health information exchange and required documentation of a plan for treatment of indigent and underserved.
  - On the outpatient side, removed large outpatient centers, or hospitals without beds, from its SHP. These centers are considered hospitals without beds and include their own medical staff, primary care providers, operating rooms, imaging services, and 24-hour emergency department.

- Removed certain need methodologies from the SHP, including for ASFs.

- **Connecticut:**

  - Proposed to incorporate reviews of mergers/acquisitions into the CON process in an effort to ensure that mergers don't impact cost dramatically.
  - Recommended to limit/eliminate the majority of medical equipment requirements.
  - To assist with expediting decision timelines, proposed allowing the agency to hire subject matter experts as needed to assist with the preview process.

Ms. Phillips asks if any research has been done on Skilled Nursing Facilities (SNF), home health and hospice? Mr. Carter responded that there has been a trend among CON regulations in making it easier to shift toward lower cost of care. There was a balance between understanding that there needed to be some degree of control for SNF, assisted living, and home health, and improving the availability of these facilities to allow more patients to be treated in a lower cost setting.

Ms. Phillips discussed the need for a comprehensive literature review process to understand the impact of CON vs. non-CON in states across the country.

Interim Report Outline and Next Steps Discussion

Ms. Phillips initiated discussion of the interim report outline. Mr. McCone began the discussion by commenting on items included in the outline relative to Hospitals by stating that MHA strongly disagreed with the conclusion in #7, and would prefer instead that clear rules are established and followed rather than developing alternatives for CON project reviews. Relative to item #9, Mr. McCone disagreed with the use of the word "inadequate," preferring that the Task Force focus more on refining the community input process based on what makes the most sense relative to care transformation and CON.

Ms. Horton commented that it would be helpful if this group could review and/or reconfirm the process before any discussions of details. Ms. Steffen summarized the overall process stating that by December 2018 the group would deliver recommendations to the Committee chairs. Upon identifying problems during this current phase (Phase I), the staff would develop the draft interim report and share with the Task Force prior to the May 11th meeting. The May 11th meeting would be devoted to review of the report. The final interim report would be presented to the Commissioners at the May 17th meeting. The interim report would be submitted to the Committee Chairs shortly after the May meeting. Mr. Steffen stated that Phase II of the Task Force would commence in June.

Mr. Rosen suggested the articulation of some guiding principles for Phase II, stating that efforts in Phase II could be greatly enhanced if principles were in place. He also suggested having a matrix in place to guide decision making during Phase II. Mr. Rosen recalled that during similar efforts in 2005, the group had adopted a scorecard to keep track of details and that the same should be done for this process.

Ms. Horton agreed with the need for guiding principles. Mr. Sergent added that if the Task Force could agree on the purposes of CON, then each purpose could be tied with a principle, and problems could be related back to them.

Ms. Cooper raised the point that consumers want to know if CON had accomplished the correct goals such as quality, access, innovation, cost, and charity care. If CON isn't accomplishing this, Ms. Cooper wondered if the group should recommend an alternative?

Mr. Solberg stated that so far, the group had been in information gathering mode and would agree that going forward criteria for evaluating industry-based issues should be established. Mr. Steffen stated that the Commission should circulate those 2005 documents/principles.

Mr. Steffen agreed that principles should be established for Phase II but acknowledged that sufficient time was not available to include those within the interim report. Instead, those principles should be considered the first priority with the start of Phase II.

Mr. Parker noted that the current focus was setting an agenda for Phase II. The goal was to have well-articulated problems that could be focused on; however, much of the minutia should be excluded. The report should include problems that were identified as well as supporting information on why these problems must be addressed.

Mr. Solberg asked whether the Commission expected this group to adopt some form of the problem statements as final? Mr. Parker confirmed that was the goal and Mr. Steffen suggested that the Task Force should not attempt to reach full agreement on each problem statement, but to instead focus on determining if a broad consensus is in place for the problem statements.

Ms. Phillips thanked the Task Force for the day's discussion and concluded the meeting.