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MARYLAND PATIENT CARE AND ACCESS COALITION

June 20, 2018

VIA ELECTRONIC MAIL & OVERNIGHT DELIVERY
Ms. Frances Philips and Mr. Randolph Sergent
Co-Chairs, CON Modernization Task Force
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Comments on MHCC Interim Report on CON Modernization

Dear Ms. Philips and Mr. Sergent:

On behalf of the more than 300 physicians whose medical practices are members of the Maryland Patient Care and Access Coalitions (MPCAC), I want to thank you and the other members of the CON Modernization Task Force for your hard work during the first phase of MHCC's CON modernization study and for the opportunity to submit comments in response to MHCC's June 1, 2018 Interim Report. MPCAC shares MHCC's commitment to modernizing the State's CON regulatory program that has been in effect for more than 40 years. As we explained in our January 12, 2018 comment letter submitted to Mr. Paul Parker, MHCC's Director, Center for Health Care Facilities Planning & Development, MPCAC believes that any effort to modernize CON regulation should include significant reform of CON regulation as applied to ambulatory surgery facilities (ASFs).

We are even more convinced after studying MHCC's Interim Report that CON regulation of ASFs should be eliminated or, at the very least, liberalized to exempt ASFs with four or fewer operating rooms from CON review. In this letter, we provide comments on various aspects of the Interim Report and present three specific recommendations that we ask MHCC to consider as it begins work on phase two of the CON modernization study.

The Maryland Patient Care and Access Coalition

As you know, for nearly 15 years, MPCAC has been the voice of independent physician specialty practices in the State that deliver integrated, high quality, cost-efficient care to patients in the medical office and ASF setting. With more than 300 physicians drawn from the fields of gastroenterology, orthopaedic surgery, urology, pathology, radiation oncology and anesthesiology, MPCAC's member medical practices treat more than 500,000 Marylanders each

year in over 1,000,000 patient encounters. In addition, and of greatest relevance here, the physicians in MPCAC's member practices perform tens of thousands of procedures in ASFs and endoscopy centers each year.

Comments on MHCC's Interim Report

We agree with MHCC's assessment that CON regulation "primarily functions as a mechanism to influence the supply and distribution of certain types of health care facilities and services." Interim Report at 1. Unfortunately, as applied to ASFs, CON regulation is anti-competitive, creating a barrier to entry into the marketplace. MHCC seized on this concern in its October 2017 "Study of Maryland's CON Program," noting that "[b]y restricting market entry and making it more expensive, CON regulation limits competition and the potential for more competitive markets to enhance value [and] limits potential innovations in service delivery." It is no surprise then, as MHCC observed, that industry comments, "which generally favor continuing CON for their particular facilities, must be weighed in light of a natural tendency to protect existing interests to the potential detriment of new market entrants." Interim Report at 5.

We also agree with MHCC that CON modernization needs to be examined through the prism of the All-Payer Model and, in particular, the Total Cost of Care model. Interim Report at 1, 6-7. This is why we believe it is critical, in phase two of the CON modernization study, for MHCC to recommend solutions that will liberalize CON regulation as applied to ASFs. MHCC correctly recognized that in order for Maryland to "stay within the Total Cost of Care guardrails," it will be important to move "more demand to the least costly setting in which demand can be appropriately handled," which, in turn, will "likely require contraction of systems capacity in some areas and expansion in others." Interim Report at 7.

Academic and government studies have shown that shifting care into ASFs can result in significant cost savings compared to similar services and procedures provided in the hospital setting. As we pointed out in our January 2018 comment letter:

- A study conducted by the University of California at Berkeley found that during the period 2008 to 2011, ASCs saved the Medicare program and its beneficiaries $7.5 billion and were projected, as of publication in 2013, to save the Medicare program and its beneficiaries nearly $60 billion over the next decade;[1]

- A study conducted by the United States Department of Health and Human Services estimated cost savings at $12 billion between calendar years 2012 and

[1] University of California Berkeley, "Medicare Cost Savings Tied to Ambulatory Surgery Centers, (2013) available at http://www.ascaconnect.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0 (last accessed June 15, 2018).

2017 because the rates for surgery centers are lower for performing the same procedures as their hospital outpatient department counterparts;[2] and

- A review of commercial claims data found that health care costs are reduced by more than $38 billion annually due to availability of ASCs as an alternative to hospital outpatient departments, with more than $5 billion of cost reduction accruing to patients through lower deductible and coinsurance payments.[3]

We agree with MHCC's assessment of the literature, which shows that, "in the abstract, the overall benefit of CON regulation is debatable" and does "not provide strong evidence that CON reduces health care costs or improves quality." Interim Report at 6.

We also share MHCC's view that health care quality "is an issue that may be best addressed through licensure regulation, rather than the one-time, front-end review offered by CON regulation." Interim Report at 8. Continuing an anachronistic CON regulatory regime under the guise of trying to safeguard health care quality would be a mistake. MHCC said it perfectly: "ensuring quality of health care and ensuring that 'bad actors' remain outside of the system, are appropriate regulatory goals but using CON regulation may be a problematic and inefficient approach." Interim Report at 8.

We believe it is time for Maryland to replace its CON regulatory framework—at least as applied to ASFs—with an alternative approach that ensures patient access to high quality care without creating barriers to market entry. Specifically, we believe that ASFs should not be subject to CON regulation, regardless of the number of operating rooms and, instead, should be subject to the "determination of coverage" process MHCC currently uses to evaluate physician outpatient surgical centers that contain one operating room. At a minimum, we believe that CON should be liberalized so that ASFs with four or fewer operating rooms are not subject to CON review.

Recommendations for Phase Two of MHCC's CON Modernization Study

We have three specific recommendations to make as MHCC begins its work on phase two of the CON Modernization Study.

[2] HHS OIG, "Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates," Report # A-05-12-00020, (April 2014), *available at* https://oig.hhs.gov/oas/reports/region5/51200020.pdf (last accessed June 15, 2018).

[3] Healthcare Bluebook and HealthSmart Analysis, "Commercial Insurance Cost Savings in Ambulatory Surgery Centers," (2016) available at http://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=829b1dd6-0b5d-9686-e57c-3e2ed4ab42ca&forceDialog=0 (last accessed June 15, 2018).

First, we recommend including additional physicians on the phase two Task Force. We note that of the 16 members of the phase one Task Force, only one of the members, Dr. Ben Lowentritt, is a practicing physician. To be clear, all of the members of the phase one Task Force have brought (and will continue to bring) an important perspective to the issue of CON modernization and we appreciate the importance of not creating too large of a Task Force for phase two. But, as MHCC moves to the stage of proposing solutions, we think it is critical to have additional physicians, particularly from surgical specialties that care for patients in ASFs and other facility settings, at the table for these discussions.

Second, with respect to the application of CON to ASFs, we recommend revising the first of the three "ASF problem statements" (see page 16 of the Interim Report) to capture more directly the concerns of physicians practicing in ASFs. MHCC explained that it will use the "problem statements" outlined in the Interim Report "as an agenda for generating ideas to address the problems, obtain input and engage stakeholders in discussion of those ideas, and attempt to reach consensus on the best ideas and the best ways in which to implement the needed changes." Interim Report at 18. We are concerned that the "problem statements" for ASFs, particularly statement #1, are crafted too narrowly. The first "problem statement" reads:

> 1. The scope of ASF CON regulation may be outdated. In particular, the use of a capital expenditure threshold should be reconsidered.

We agree that ASF CON regulation is outdated and, although we support reconsideration of the capital expenditure threshold, we believe that there are more fundamental problems with the application of CON to ASFs that are not captured in this statement. We ask MHCC to revise this "problem statement" as follows:

> REVISED 1. The scope of ASF CON regulation may be outdated. In particular, the use of a capital expenditure threshold should be reconsidered ***as well as the application of CON regulation to ASFs or, at a minimum, the application of CON regulation to ASFs with four or fewer operating rooms***.

Additionally, given the emphasis that MHCC appropriately placed on the need to ensure that CON regulation fits with Maryland's broader objectives of implementing the Total Cost of Care model, we believe it is important to include an additional "problem statement" as related to ASFs:

> New #4. CON regulation of ASFs potentially undermines Maryland's ability to succeed under the Total Cost of Care model by inhibiting the State's ability to move more demand to the least costly setting in which demand can be appropriately handled.

Third, we support MHCC's decision to begin phase two of the CON modernization study with the development of a set of "guiding principles" and recommend that those principles include the following concepts—all of which are in keeping with the Interim Report and come directly from the language of the Interim Report:

- A robust licensure process, rather than front-end review offered by CON regulation, is the appropriate mechanism for safeguarding health care quality and for ensuring that health care facilities and providers are operated soundly and under responsible ownership.

- It is important to modernize CON regulation in ways that will enable Maryland to succeed under the Total Cost of Care model, including the movement of demand to the least costly setting in which demand can be appropriately handled.

- Maryland must guard against the risk of maintaining CON regulation as a mechanism for protecting existing interests to the potential detriment of new market entrants.

- Modernization of CON regulation must take into account the implications of such regulation on care delivery furnished outside of the hospital setting, particularly in independent ambulatory surgery facilities.

* * *

As Chairpersons Middleton and Pendergrass noted in their June 2017 letter to MHCC's Ben Steffen, the All-Payer Model "[c]alls for dramatic changes in health care delivery and spending, and the Certificate of Need (CON) program must also recognize these changes." The kind of "dramatic changes" needed will not happen by modifying CON around the edges but, rather, through elimination of CON regulation as applied to ASFs. The State's "determination of coverage" process is an appropriate regulatory framework to promote access to high quality, cost-efficient care while eliminating artificial barriers to competition and innovation. At a minimum, ASFs with four or fewer operating rooms should not be subject to CON regulation.

We look forward to continuing to engage with MHCC as it develops recommendations for modernizing CON regulation. If MHCC would consider it helpful, I would be honored to serve on the phase two CON Modernization Task Force to offer my perspective as President of MPCAC and President and CEO of The Centers of Advanced Orthopaedics, Maryland's largest independent orthopaedic surgery practice. Please reach out to me at any time at ngrosso@cfaortho.com or (443) 520-5770.

Sincerely,

Nicholas P. Grosso, M.D.
Chairman of the Board & President, MPCAC

cc: Paul Parker, Director, MHCC Center for Health Care Facilities Planning & Development
Joe Bryce, Manis Canning & Associates