MPCAC

MARYLAND PATIENT CARE AND ACCESS COALITION

January 12, 2018

VIA ELECTRONIC MAIL & OVERNIGHT DELIVERY
Mr. Paul Parker
Director, Center for Health Care Facilities Planning & Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Freestanding Ambulatory Surgical Facilities – MHCC CON Study, 2017-2018

Dear Mr. Parker:

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 for the opportunity to provide input on potential reform of the State's Certificate of Need (CON) program. This is a critically important issue, as the Chairs of the Senate Finance Committee and the House Health and Government Operations Committee recognized in asking the Maryland Health Care Commission (MHCC) to develop recommendations for "modernizing" the CON program. As we explain below, CON regulation of freestanding ambulatory surgical facilities (FASFs) is an anachronism that prevents Maryland from achieving the goals of the Triple Aim—improving the patient experience, improving the health of populations, and reducing the per capita cost of health care. Accordingly, **MPCAC believes that CON regulation of FASFs should be eliminated.**

In response to MHCC's Comment Guidance, we divide our remarks into three sections. First, we discuss the ways in which the State's CON regulatory framework stifles innovation and competition and is at odds with health care delivery in the 21st century. Second, we highlight key takeaways from recent academic studies and government reports about the quality of care delivered in—and cost savings achieved by—FASFs. We believe those findings call into question the value of continuing the State's CON program. Third, we offer a proposal for regulating FASFs that is more consistent with the goals of the Triple Aim than the State's existing CON program.

The Maryland Patient Care and Access Coalition

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 ambulatory surgery center settings. With more than 300 physicians drawn from the fields of gastroenterology, orthopaedic surgery, urology, pathology, radiation oncology and anesthesiology, MPCAC works to promote and protect the integrated model of health care delivery for the benefit of all patients in Maryland. The physicians in 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 FASFs and endoscopy centers each year.

The Current CON Regulatory Framework Is at Odds with the Goals of the Triple Aim

We believe a statement in MHCC's October 19, 2017 "Study of Maryland's Certificate of Need Program" captures the perspective of the physicians in our MPCAC member practices with respect to the State's CON program:

> By 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.

We also agree with the characterization set forth in the MHCC study that the CON "regulatory process is slow, burdensome & overly legalistic."

We fail to see how—in 2018—the continuation of CON regulation of FASFs will advance the Triple Aim's goals of (1) improving the patient experience of care (including quality and satisfaction); (2) improving the health of populations; and (3) reducing the per capita cost of health care. In fact, we believe that continuing the State's CON program as applied to FASFs will undermine Maryland's ability to achieve these goals and, accordingly, we applaud the General Assembly and MHCC for undertaking a reexamination of CON.

Our MPCAC member practices report that the CON process is incredibly burdensome—both in terms of the time it takes as well as the associated costs—and there can be little doubt that the process increases overall health care costs and does not contribute positively to the patient experience. For that matter, the CON program operates as a barrier to entry for independent medical practices seeking to design innovative, cutting edge health care delivery models that would move care out of the more expensive hospital setting. And, the elimination of competition and the associated restraint of trade created by CON programs drives up the cost of care even further. We do not believe that it is worth the time, money and effort to preserve an antiquated CON program, particularly given the absence of data demonstrating that Maryland's CON program is making a meaningful contribution to the containment of health care costs.

We are also concerned that the CON program is at odds with the goal of providing Maryland patients with convenient access to the highest quality and most innovative care. Not only is CON a barrier to entry for health care providers, but it is an impediment to patient choice. Our member practices report a continuing evolution in the preferences of their patients—particularly "millennials" and other young patients—to have procedures done in the non-hospital, community setting offered by FASFs.[1] The evolution in patient preference with respect to *where* their care is delivered should not be ignored as the MHCC Taskforce considers whether CON regulation of FASFs should be eliminated.

State Health Policy Should Be Revised to Encourage the Migration of Care to FASFs

Academic and government studies consistently show that FASFs provide higher-quality care at a lower cost than hospitals. We believe this data provides compelling support for the elimination of CON regulation of FASFs. We highlight some of the key takeaways from recent literature:

- Using data on procedure length, a study found significant time savings for ASC treatment suggesting that ASCs are substantially faster than hospitals at performing outpatient procedures, after controlling for procedure type and observed patient characteristics;[2]

- Physicians who perform a higher volume of particular types of surgery at surgery centers have better surgical outcomes;[3]

[1] In the "Issues and Policies" discussion of the Proposed Permanent Regulation COMAR 10.24.11, MHCC provided extensive statistical support for the migration of care from the hospital to the FASF setting for surgical cases. COMAR 10.24.11.03 (Proposed Permanent Regulation, 2017), *available at* https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/documents/surgical%20services/COMAR%2010.24.11_Proposed_Permanent_%20Regulation_20171027.pdf. Between calendar years 2010 and 2015, the total number of outpatient surgical cases in operating rooms at Maryland hospitals decreased by 2.9% and the total number of inpatient surgical cases decreased by 15.5 percent. *Id*. During that same time period, surgeries at surgery centers in the State increased by 7.5 percent. *Id*.

[2] Munnich, Elizabeth L., Parente, Stephen T., "Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability To Meet Demand Up." Health Affairs. 2014 May; 33(5): 764-769, 768 (finding that, on average, patients who were treated in ASCs spent 31.8 fewer minutes undergoing procedures than patients who were treated in hospitals—a difference of 25% relative to the mean procedure time of 125 minutes).

[3] See, *e.g.*, Borowski, D.W., Bradburn, D.M., Mills, S.J., Bharathan, B., Wilson, R.G., Ratcliffe, A.A., Kelly, S.B., "Volume-outcome analysis of colorectal cancer-related outcomes." Abstract. British Journal of Surgery Ltd. 2010 Sep; 97(9): 1416-1430; Murphy, M.M., Ng, S.C., Simons, J.P., Csikesz, N.G., Shah, S.A., Tseng, J.F., "Predictors of Major Complications After Laparoscopic Cholecystectomy: Surgeon, Hospital, or Patient?" Abstract. Journal of the American College of Surgeons. 2010 Jul; 211(1): 73-80; Wilson, A., Marlow, N.E., Maddern, G.J., Barraclough, B., Collier, N.A., Dickinson, I.C., Fawcett, J., Graham, J.C., "Radical Prostatectomy: A Systematic Review of the Impact of Hospital and Surgeon Volume on Patient Outcome." Abstract. ANZ Journal of Surgery. 2010 Jan; 80(1-2): 24-29.

- ASCs are consistently praised for their potential to provide less expensive, faster services for low-risk procedures and more convenient locations for patients and physicians compared to outpatient departments;[4]

- A study conducted by the University of California at Berkeley found that during the four-year 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;[5]

- A study conducted by the United States Department of Health and Human Services estimated cost savings at $12 billion between calendar years 2012 and 2017 because the rates for surgery centers are lower for performing the same procedures as their hospital outpatient department counterparts;[6] and

- A review of commercial medical 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 the cost reduction accruing to the patient through lower deductible and coinsurance payments.[7]

The overarching conclusion is that FASFs are a high-quality, lower-cost substitute for hospitals as venues for outpatient surgery. Maryland's regulatory framework should be modified to encourage the proliferation of FASFs, not to inhibit their creation.

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[4] See, *e.g.*, Paquette IM, Smink D, Finlayson SR. Outpatient cholecystectomy at hospitals versus freestanding ambulatory surgical centers. J Am Coll Surg. 2008; 206 (2):301-05; Grisel J, Arjmand E. Comparing quality at an ambulatory surgery center and a hospital-based facility: preliminary findings. Otolaryngol Head Neck Surg. 2009; 141 (6):701-09.

[5] 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 Jan. 5, 2018).

[6] 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 Jan. 5, 2018).

[7] 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 Jan. 5, 2018).

CON Regulation of FASFs Should Be Eliminated and Replaced with an Alternative Regulatory Framework

It is time for Maryland to replace its CON program with an alternative approach that ensures patient access to high quality health care without setting up barriers to market entry. In short, we believe that CON regulation of FASFs should be eliminated, regardless of the number of sterile operating rooms. Instead, all FASFs should be subject to the "determination of coverage" process MHCC currently uses to evaluate prospective FASFs with only one sterilized operating room. Beyond the "determination of coverage" process, we believe that oversight of FASFs should continue through existing regulations promulgated by the Department of Health[8] and through quality assessment accreditation (e.g., the Accreditation Association for Ambulatory Health Care, Inc. the Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities).

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As Chairpersons Middleton and Pendergrass noted in their June 23, 2017 letter to MHCC's Executive Director, 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." It is the view of the more than 300 physicians in MPCAC's member medical practices that the kind of "dramatic changes" needed will not happen by modifying the CON program around the edges. CON regulation of FASFs should be eliminated. The State's "determination of coverage" process, coupled with mandatory national accreditation, is an appropriate regulatory framework that will promote access to the highest quality, cost-efficient and convenient care while eliminating artificial barriers to competition and innovation.

We look forward to serving as a resource to MHCC—and to the Senate Finance and House HGO Committees—on the important work ahead.

Sincerely,

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

cc: Joe Bryce, Manis Canning & Associates

[8] COMAR 10.05.01, et seq. The existing regulatory system requires FASFs to renew their licenses every three years (COMAR 10.05.01.03(A)-(B)), to be available for surveys by the Centers for Medicare and Medicaid Services to determine continued compliance and investigate complaints (COMAR 10.05.01.05(A)), and to monitor their own personnel and the quality of services provided at the surgery center (COMAR 10.05.01.07 & 10.05.01.08).