**Duke University Health System**

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March 22, 2013

Ms. Nadine Pfeiffer
Medical Facilities Planning Branch
North Carolina Division of Health Service Regulation
Medical Facilities Planning Branch
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Public Comments on SMFP Petition from MedCapital Advisors

Dear Ms. Pfeiffer:

Duke University Health System hereby submits these comments in opposition to the petition submitted by MedCapital Advisors regarding the regulation of ambulatory surgery services (the "Petition"). The Petition seeks relief that is beyond the scope of the SHCC's planning role and that would increase utilization and duplicate services unnecessarily.

**The Relief Sought Is Not Within the Purview Of The SHCC.**

The Petition does not expressly set forth the policy or need methodology change that it endorses. However, it generally advocates for changes that would make it easier for surgeons other than plastic surgeons, maxillofacial surgeons and otolaryngology surgeons to provide ambulatory surgery procedures without certificate of need and licensure regulation:

> It is requested that CON and licensure exceptions be applied equally to all ambulatory surgical facilities, regardless of medical/surgical specialty. The request is that orthopedic surgery, ophthalmology, urology, OB/GYN, general surgery, and other medical/surgical specialties be allowed to develop and operate single specialty ambulatory surgical facilities, not subject to the requirements of CON and state licensure, equally as plastic surgery, oral maxillofacial surgery, and otolaryngology (ENT) do presently.

This request would require the SHCC to exceed its statutory role in the healthcare planning process. The SHCC plays no role in the enforcement of CON or licensure requirements for particular providers. Rather, the SHCC's role is to prepare, with DHHS, the State Medical Facilities Plan. N.C.G.S. 131E-176(17). As set forth in the Plan itself, "the major objective of

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the Plan is to provide individuals, institutions, state and local government agencies, and community leadership with policies and projections of need to guide local planning for specific health care facilities and services." 2013 State Medical Facilities Plan, p. 1.

Therefore, it is the SHCC's role to determine the number of licensed operating rooms that need to be developed, not whether certain procedures may or may not be provided in unlicensed facilities. The CON Law, not the SHCC, determines the facilities, services, and equipment that are subject to CON regulation. By statute, "[a]n ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1c) of this section and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility." N.C.G.S. 131E-176(1b). Nothing in the CON Law limits the ambulatory surgical procedures performed in physician office settings to plastic surgery, oral surgery, or ENT procedures.

As a practical matter, factors such as the applicable standard of care and payor requirements may dictate which specialties are best suited to offering procedures in unlicensed settings. For example, the Medical Board has promulgated a Position Statement on "Office-based procedures" detailing factors that should be considered in offering such procedures, including infection control, patient selection, and equipment maintenance. See N.C. Medical Board Position Statement: "Office-Based Procedures" (http://www.ncmedboard.org/position_statements/detail/office-based_procedures).

Similarly, government payors regulate the conditions for payment of a "technical" or "facility" fee, generally paying such fees only for procedures conducted in licensed facilities. Managed care payors can impose similar requirements for such reimbursement for their patients' surgery procedures. This may deter surgeons with primarily Medicare, Medicaid, or commercially insured patients from performing surgical procedures in unlicensed settings, while surgeons providing significant procedures on a self-pay basis (such as plastic surgery) may have more flexibility and incentive to offer those procedures in unlicensed settings. This is a function of payor requirements, however, not the SHCC's planning role.

**Increasing Ambulatory Surgery Centers Would Unnecessarily Increase Utilization and Spending.**

Even if the changes requested by the Petition were within the SHCC's jurisdiction, allowing the creation of additional ambulatory surgery facilities without regard to the need for such facilities is not warranted. The expansion of ambulatory surgery facilities could increase overall spending for those services. Even assuming that the costs of certain individual procedures might come down, studies have shown that with the development of additional facilities leads to increased utilization. The increased procedure volume can increase total spending for such services overall and the costs that all payors – and therefore insured patients

and taxpayers – must bear, and can also lead to the provision of unnecessary or marginal services.

For example, research has shown that the expansion of ambulatory surgery centers in Florida led to increased procedure use beyond the simple addition of capacity to the market. The new ASCs did not merely shift volumes from hospitals, but also led to "volume growth . . . in the marginal patient," reflecting increased procedures and lowered treatment thresholds. J.M. Hollingsworth et al., *Opening of Ambulatory Surgery Centers and Procedure Use in Elderly Patients*, Arch/Surg 146, no.2 (February 2011): 187-2267. A study of Idaho ASCs similarly found that the frequency of three common outpatient orthopedic procedures was significantly higher for physician owners of ASCs than for nonphysician owners, including arthroscopic knee surgery, a treatment that has been found to yield no improvement in outcomes compared with physical and medical therapy, which costs half as much. J.M. Mitchell, *Effect of Physician Ownership of Specialty Hospitals and Ambulatory Surgery Centers on Frequency of Use of Outpatient Orthopedic Surgery*, Arch/Surg, 145, no. 8 (August 2010): 732-38. That is, when ASCs are built, overall utilization increases.

Moreover, not all patients appear to get the benefits promised by the advocates of ASCs. One study found that physician owners of ASCs directed 92% of their commercially covered patients, 91% of Medicare patients, and 98% of "self pay" patients (who primarily received cosmetic surgery not covered by their health plan) to their own ASCs – but only 55% of their Medicaid patients, referring the remaining 45% of Medicaid patients to hospital outpatient departments. J.R.Gabel et. al., *Where Do I Send Thee? Does Physician-Ownership Affect Referral Patterns to Ambulatory Surgery Centers?,* Health Affairs, 27, no. 3 (March 18, 2008): w165-w174. Similarly, a study found that in Pennsylvania, 8% of general acute care hospital outpatients were Medicaid patients, compared to only 1% of physician-owned ASC patients. *Critical Condition: The State of Health Care in Pennsylvania, p. 18 (Critical Condition: The State of Health Care in Pennsylvania*, Pennsylvania Health Care Cost Containment Council (October 2007). "Just as 11 a.m. on a Sunday morning might be the most segregated hour of the week in the United States, perhaps ASCs are the most payer-segregated component of our health care system." *Gabel et al., w173-174.* Ambulatory surgery facilities thus can have the effect of siphoning off well-insured patients with favorable reimbursement, while leaving Medicaid and other underserved patients for hospitals to treat.

**Releasing Single Specialty Ambulatory Surgery Facilities From Need Determinations Would Unnecessarily Duplicate Services.**

There have been suggestions that single specialty ambulatory surgery facilities should be treated like endoscopy facilities which are no longer subject to need determinations. The differences between the two services are critical, however. First, the change in the regulation of endoscopy rooms in 2005 was the result of a statutory amendment, not merely a change in the SMFP. Moreover, in enacting that change the legislature specifically found "[t]hat demand for gastrointestinal endoscopy services is increasing at a substantially faster rate than the general

population given the procedure is recognized as a highly effective means to diagnose and prevent cancer." N.C.G.S. 131E-175 (12). Expanding access and procedure volumes to this potentially life-saving service was the specific goal of this statutory change.

There is no similar need to expand access and volumes statewide for ambulatory surgical procedures. As set forth above, increased utilization of ambulatory surgery facilities may come at the expense of the "marginal" patient who may need the service at all. Moreover, North Carolina currently has significant excess capacity in ambulatory surgery facilities. Out of the 42 licensed ambulatory surgery centers reporting any volume in the 2013 SMFP (excluding those who reported 0 procedures):

- Only 22 had procedures sufficient to exceed 1000 hours per procedure per room, based on the 1.5 hours per ambulatory procedure assumed in the operating room methodology.

- Only 5 would have exceeded 1872 hours per year per room (to be considered at or above 80% of OR capacity) based on the 1.5 hours per procedure assumption; however, these five facilities had average procedure times between 15 and 60 minutes. None actually exceeded 1872 hours of procedures based on their reported procedure times in their licensed renewal applications.

- 14 were designated as "chronically underutilized" and thus excluded from the need determinations (while only 2 hospitals were chronically underutilized).

Therefore, the existing ambulatory surgery centers have significant excess capacity. Where a need may arise for additional capacity in individual service areas, current law and regulations provides the opportunity. In the last two competitive operating room reviews in Wake County, for example, the first resulted in a CON for an orthopedics specialty ambulatory surgery center (which is under development). The second decision approved an application for an ambulatory surgery center in Holly Springs (recently affirmed by the Court of Appeals). In addition, the SHCC has created three demonstration projects for single-specialty ambulatory surgery centers, subject to carefully crafted reporting requirements to enable the SHCC to determine the effect of such facilities on patients and other providers. However, those projects are only just now coming on line, and have not yet provided the information needed to evaluate them.

In conclusion, the SHCC does not have the authority to make the changes requested in the Petition. In any event, further increasing the number of ambulatory surgery facilities without regard to need in individual service areas would lead to the unnecessary duplication of services.

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As set forth above, it can lead to unnecessary increases in volume. It can also lead to the shift of well-insured patients away from hospitals to physician-owned facilities. For all these reasons, Duke urges the SHCC to deny this Petition.

Very truly yours,

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