March 21, 2013

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

Dear Ms. Pfeiffer:

NCHA represents over 130 hospitals in North Carolina. For the reasons stated below NCHA opposes the petition from MedCapital Advisors to exempt single specialty surgery centers from the Certificate of Need law. Thank you for the opportunity to comment on the petition they submitted to the State Health Coordinating Council.

- **The Petition's request is unclear**. The MedCapital Advisors petition does not make a specific request to the SHCC pertaining to a policy or methodology, as required by step two of the SMFP "Instructions for writing petitions for changes in basic policies and methodologies." The petition appears to be requesting a change to the Certificate of Need Law that would exempt certain surgery centers from the law. The petition later indicates that "legislative changes may be initiated," and NCHA believes that a change in the law will be necessary in order to authorize the SHCC to invoke a policy that exempts a specific provider from the law.

- **The Petition claims** "That the demand for ambulatory surgery is increasing due to advances in technology and anesthesia, and single-specialty ambulatory surgery operating rooms are recognized as a highly effective means of expanding access while achieving cost savings regardless of the availability and potential underutilization of hospital-based operating rooms." That statement is also found in a CON bill proposed to change the Certificate of Need law now being considered in the legislature. (See http://www.ncleg.net/Sessions/2013/Bills/House/PDF/H177v1.pdf.) However it is not consistent with the findings of fact in the current Certificate of Need law, "That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services."

NCHA disagrees with the MedCapital Advisors petition's claim that removing the limit on new single specialty ambulatory surgery centers would lower costs in North Carolina. Medicare represents the largest payer category in North Carolina hospitals and ambulatory surgery centers. Yet many states without CON laws or limits on the number of ambulatory surgery centers have been shown in reports by the Dartmouth Atlas to have overall higher Medicare costs. Their studies show that differences in spending are almost entirely explained by differences in the volume of health care services received by similar patients. A comparison of "price adjusted Medicare payment per enrollee," ranks North Carolina with lower costs than states without limits to single specialty ambulatory surgery like Texas, Ohio and Florida. http://www.dartmouthatlas.org/. Research published in Health Affairs (HEALTH AFFAIRS 29, NO. 4 (2010): 683–689) was specific to physician owned ambulatory surgery centers, stating "our analysis of Florida data for five common procedures revealed a significant association between physician-ownership and higher surgical volume." And Atul Gawande, MD has written several articles in "The

New Yorker" discussing the differences in Medicare costs across communities, concluding in his article, "The Cost Conundrum Redux" that it is due largely to "a marked expansion in physician-owned imaging centers, surgery centers, hospital facilities, and physician-revenue-sharing by home-health agencies." <http://www.newyorker.com/online/blogs/newsdesk/2009/06/atul-gawande-the-cost-conundrum-redux.html> North Carolina's should not risk its lower Medicare cost ranking by adopting a process that rewards selected providers with a bypass of the state's planning process.

While it is clear that the changes in H1060 resulted in more capacity for gastrointestinal endoscopy, many of those procedures, and especially those on commercially insured patients, were previously performed in hospitals. Yet those hospitals will continue to provide the services to the sickest and poorest patients, as well as those in need of further care if a procedure performed in an endoscopy center develops complications. NCHA does not support adopting this process for surgery by removing operating rooms in single specialty ambulatory surgery centers from the states health planning process.

- **The Petition misconstrues the intention of the endoscopy provisions of HR 1060** in its claim that "the State of North Carolina has not enforced CON legislation equally across all medical/surgical specialties." During the discussions by the SHCC in 2004 it was recognized that endoscopy is not classified as a surgical procedure and that the intent of the process was to increase access to the screening colonoscopy procedure, in the interests of cancer prevention. Gastrointestinal endoscopy rooms were differentiated from surgical operating rooms in the CON law and the SMFP. Therefore the claim that other surgical specialties should also be granted exemption from CON is not logical.

- **The Petition claims "single-specialty ambulatory surgical facilities may be safer than multi-specialty hospital based operating rooms due to lower infection rates as documented in medical literature.**
It is not clear whether the petitioner is claiming that single specialty is safer than multi-specialty or that single specialty is safer than hospital based outpatient surgery. While the petition claims there is documentation in medical literature, none is included in the petition.

Numerous articles have been written to describe the hazards of investor owned single specialty surgical facilities, one of which is overutilization derived from self-referrals. In a recent JAMA study of screening colonoscopies, 23 percent were "potentially inappropriate" because the patients were over age 75 or because they had a repeat screening too soon after the last one for no clear medical reason. The study, from the journal JAMA Internal Medicine, also states "Physician preferences and practice setting may influence colorectal screening rates."

Differences in patient acuity, as well as the disparate application of Federal quality measures and regulatory inspections between hospitals and ambulatory surgery centers complicate comparison of their quality. However, a well-known failure of infection control practice is discussed in a report from the National Institutes of Health <http://www.ncbi.nlm.nih.gov/pubmed/20575663>. In an endoscopy clinic in Las Vegas, NV, a "patient-to-patient transmission of HCV likely resulted from contamination of single-use medication vials that were used for multiple patients during anesthesia administration" in January 2008.

- The Petition claims, "the high cost of outpatient surgery centers in hospital outpatient department settings and hospital owned ASC's clearly limits pat(i)ent access."

Accessing surgery in either hospital or freestanding surgery centers has not been shown to be a problem for those with private insurance. However a review of data from ambulatory surgery center licensure reports indicates that uninsured and Medicaid patients receive screening colonoscopies and ambulatory surgeries at hospital affiliated centers more than twice as often as in non hospital-affiliated ambulatory surgery centers.

The Centers for Medicare and Medicaid Services (Medicare) and other third party payers recognize that more highly acute cases can be cared for in hospital outpatient department surgery settings, and has also established that certain procedures cannot be performed in an outpatient setting other than a HOPD (CMS-1589-P addendum EE). CMS also recognizes that hospitals have a higher regulatory burden and must be more accessible to all comers regardless of their insurance status. The payment rate for hospital outpatient surgery reflects the additional costs incurred in providing these services.

The development of freestanding ambulatory surgery and endoscopy centers is dependent upon the existence of a full service hospital to provide emergency or inpatient care if those procedures fail. Maintaining these services on a 24/7 basis is costly and becomes more so when patients are steered to these other settings.

NCHA Hospitals have supported the State Health Coordinating Council's approach to the expansion of ambulatory surgery through support of the expansion of gastrointestinal endoscopy centers and the SHCC's single specialty ambulatory surgery center demonstration projects, but are also involved in over 20 ambulatory surgery centers, both single and multi-specialty, located throughout the state. These centers hold the same ambulatory surgery center license and are reimbursed under the same payment schedule as the single specialty ambulatory surgery centers proposed in the MedCapital Advisors' petition. However they may be organized with physician partners under joint ventures that enlist and support their continued involvement as members of the hospital medical staff. Most of these centers are not single but multi-specialty ambulatory surgery centers, still offering the convenience of a freestanding surgery center in a safe, cost effective and trusted location.

NCHA agrees with the approach the SHCC has taken, incorporating the principles of quality, access and value into its decision-making, and we believe that these principles will support the SHCC in a denial of the MedCapital Advisors petition.

Please feel free to contact me if you have questions, and thank you for the opportunity to provide comments on the MedCapital petition.

Mike Vicario
NCHA Vice-President of Regulatory Affairs