Operating Rooms

Petition:

Carolina Ophthalmology

Carolina Ophthalmology, P.A.

DISEASES & SURGERY OF THE EYE

Marion P. Van Kirk, M.D.
Charles A. Shaller, M.D.
Clayton H. Bryan, M.D.
Samuel E. Navon, M.D., Ph.D.
Mark A. Joseph, M.D.
Robert I. Park, M.D.

March 4, 2008

North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina, 27699-2714

RE: PETITION FOR A CHANGE IN THE BASIC POLICIES AND METHODOLOGIES FOR THE 2009 STATE MEDICAL FACILITIES PLAN

Dear Planning Board:

In accordance with the instructions in the 2008 State Medical Facilities Plan (SMFP), Carolina Ophthalmology, P.A., is submitting the enclosed petition for consideration of a change in the current planning policies and methodologies regarding allowance of new ambulatory surgery centers (ASCs) for the upcoming 2009 SMFP. It is our contention that current Certificate of Need (CON) laws are not only outdated, but used in their current broad application, they do not best serve the overall needs of the citizens of North Carolina.

Throughout the country, CON laws are being reviewed, adjusted, and in many cases, repealed as a result of trends being seen in our health care system. The overwhelming volume of data to support the growth of ASCs is undeniable. As you will see, our petition focuses on the three basic planning principles used in the SMFP, cost, quality, and access to care, as the basis for our arguments. Our request is not without precedent, as our neighboring state of Georgia (among others) has already seen the efficacy in allowing single specialty ASCs to proceed without the demonstration of need.

We hope that the state will view our request as an attempt to move our statewide system forward in the spirit of the planning guidelines. We encourage the planners to take a fresh approach to this issue and to consider the benefits to the citizens of North Carolina above all else. Should you to need further information or have questions regarding our petition, please feel free to contact us. We look forward to discussing this request with the members of the Medical Facilities Planning Division.

Sincerely,

Richard P. Holmes, Administrator
Carolina Ophthalmology, P.A.

1701 Old Village Road
Hendersonville, NC 28791
828-693-1773
800-624-6575 toll free

One Vanderbilt Park Drive, Ste, 150
Asheville, NC 28803
828-277-8233
800-624-6575 toll free

36 Westgate Plaza
Franklin, NC 28734
828-369-4236
800-624-6575 toll free

PETITION FOR A CHANGE IN THE BASIC POLICIES AND METHODOLOGIES FOR THE 2009 STATE MEDICAL FACILITIES PLAN

TO: North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

PETITIONER: Carolina Ophthalmology, P.A.
Richard P. Holmes, Administrator
1701 Old Village Road
Hendersonville, NC 28791
(828) 693-1773
rholmes@carolinaophthalmology.com

DATE: February 28, 2008

RE: Petition for A Change in the Basic Policies and Methodologies for the 2009 State Medical Facilities Plan

I. INTRODUCTION

Carolina Ophthalmology, P.A., submits this petition to request that the state implement a change to the current policy for Certificate of Need (CON) for the specialty of Ophthalmology as it relates to building an Ambulatory Surgery Center. Current policy requires that all ambulatory surgery operating rooms must first be justified by an "adjusted needs determination formula". A need must be determined by this formula before the CON application process can be initiated. It is our contention that this policy is not only outdated, but is no longer supported by data which originally bolstered the premise of CON ideology. By this petition, we request that the state consider a policy change which more closely promotes the utilization of sites of service providing more affordable care while maintaining high quality and safety standards. This request follows along with the state's documented planning principles of cost control, access to care and quality of health services. We request that the state issue an exemption to the CON process for ambulatory surgery centers for the discipline of Ophthalmology based upon the logic and arguments that follow. While other specialties may also have some validity within these same contexts, we contend that the discipline of Ophthalmology is unique in its surgical service mix and lends itself more completely to the ambulatory surgical setting.

Over the last three decades, there is no doubt that Ambulatory Surgery Centers have demonstrated an exceptional ability to improve quality and patient satisfaction while concurrently reducing costs. Physicians opened the first ASC in 1970 because of the frustrations they faced with local hospital operating suites, including scheduling delays, staffing inadequacies, limited OR availability and outdated or inadequate technology. Those same frustrations still exist today. Since then, ASC growth has been exponential with the number of Medicare certified ASCs growing from 2786 in 1999 to over 4700 in 2007. ASC settings allow

physicians to exercise professional autonomy over their work environment and allow them more control over the quality of surgical outcomes. Not only are they able to design these facilities to better accommodate their specialty, but they are also able to schedule procedures more conveniently, control technology and supplies that are suited to their specialties, and they are able to put together specially trained and highly skilled teams familiar with the surgical techniques being performed. The end result is high quality, convenient, more cost efficient care for the patient.

Though the statistics are an increasingly moving target, in a report by the National Conference of State Legislatures in November, 2007, fourteen states have discontinued their CON programs and have opted to control costs through other measures. Of the 37 states with some form of CON regulation, only 27 states regulate ambulatory surgery services. Just because the CON process has been in place in North Carolina for decades does not mean that the process is working for the people of North Carolina. In 2005, The John Locke Foundation, a North Carolina based nonprofit, nonpartisan public policy research institute, provided a compelling case for the repeal of CON laws in the state. In a series of reports called *"The Macon Series"* the author concludes that "The idea that in the area of health care services, free market competition can't work as a means of cost control is not grounded in either economic theory or empirical evidence." While we are not suggesting a wholesale repeal of the CON laws, we are suggesting that the state consider these valid arguments for change.

We submit this petition along with the following premises/arguments and ask the state to consider the logic and empirical evidence that follows to support this request:

Premise (1) The current outpatient surgical system serving our population is a poor value for the North Carolina consumer. There is a large potential for reduced costs and overall health care savings if eye surgical procedures are done in a freestanding ASC vs. a Hospital Outpatient Surgical Department.

Premise (2) Ophthalmology represents a unique specialty in the provision of efficient, high-volume surgical services in an ambulatory surgical setting.

Premise (3) Ophthalmology can provide improved quality of care for eye surgery, including outcomes, convenience and increased patient satisfaction through the delivery of surgical services in a single specialty ambulatory surgical environment.

Premise (4) Ophthalmology can provide improved access to care for patients through the delivery of services in a single specialty ambulatory surgical environment.

Premise (5) Ophthalmology can provide increased efficiency and improved utilization of facility and professional resources through the delivery of services in a single specialty ambulatory surgical environment.

Premise (6) Current North Carolina state health planning policies are outdated and promote unfair competition between surgical practices.

The surgeons of Carolina Ophthalmology are subspecialty trained in cornea, refractive surgery, retina, glaucoma, and oculoplastics as well as general ophthalmology. Patient volume for surgical eye cases in our practice equals about 6,000 procedures per year. We have been serving the eye surgery needs of the people of Henderson County for over 27 years and are the largest provider of cataract services in the county. We have seen it become increasingly difficult to schedule patients efficiently in the current shared hospital OR system. We have also seen it become increasingly costly for our patients to receive these eye surgery services. In addition, we have seen competitive practices that have been allowed to build ambulatory surgery centers utilize this in a marketing capacity to create unfair competition. Approval of this request will allow patients a choice of delivery modes for their eye surgery, thus allowing them a choice in the value they receive for their health care dollar, and will allow us to pursue a more cost effective, higher quality and more efficient mode of delivery for eye surgery in our county and the surrounding areas.

II. RATIONAL FOR A CHANGE TO CURRENT POLICY FOR ALLOCATING OPERATING ROOMS BASED UPON A NEEDS BASED FORMULA

Poor Value of the Current System

It has been well documented that services provided in ambulatory surgery centers are more cost effective than when performed in the hospital outpatient setting. The very first stated goal/principle governing the development of the State Medical Facility Plan (SMFP) is to "promote cost-effective approaches" to health care in North Carolina. Across the country, eye surgery cases are now performed almost exclusively in ambulatory surgery settings and the opportunities for cost savings are impressive. In the United States, according to the National Eye Institute (NEI), cataract surgery is the most frequently performed surgical procedure among 30 million Medicare beneficiaries. Approximately 1.35 million cataract operations are performed annually at an estimated cost of $3.5 billion.

The cost saving trends for ambulatory surgical centers are undeniable and account for one of the key reasons for their exponential growth. As an example, the Medicare Payment Advisory Commission (MedPac) found that a cataract operation cost only $942 at an ambulatory surgery center in 2001 as opposed to $1334 at a hospital. Patients typically pay less coinsurance for procedures performed in an Ophthalmology specific ASC. For example, a Medicare beneficiary could pay as much as $496 in coinsurance for a cataract extraction in a hospital setting vs. that same beneficiary co-pay would be $195 in an Ophthalmology specific ASC. Studies have shown the Medicare program would pay approximately $464 million more per year if all procedures performed in an ASC were instead furnished in a hospital. {Source: *Ambulatory Surgery Centers, A Positive Trend in Health Care*, ASCA and ASC Coalition, November, 2006}

In a separate study conducted by The Moran Company for the Federated Ambulatory Surgery Association (FASA), they found a similar result. The study identified and analyzed about 5 million hospital outpatient department claims as those Medicare would reimburse if performed in an ASC. It found that in 2005, claims in an outpatient hospital setting would cost Medicare about

$4.4 billion versus the same claims done in an ASC setting would total about $2.8 billion, or about $1.6 billion in savings. On average, claims cost $320 less in an ASC as compared to a hospital outpatient department {Source: Press release; Federated Ambulatory Surgery Association, April 5, 2005}. The *Prevent Blindness North Carolina* organization estimates that 562,051 people in North Carolina age 40 and over have cataracts. Using The Moran Company study findings above, the savings for these cases alone could be over $179 million if they were all performed in a dedicated ambulatory surgery center rather than a hospital setting.

Recently, President Bush stated that ASCs are on the "leading edge of health care". On February 16, 2006, the White House invited Jerry Henderson, a board member of the Federated Ambulatory Surgery Association, to address transparency in health care. Ms. Henderson outlined for the President the growing importance of ambulatory surgery centers and explained why more and more Americans are opting for surgery in these more patient-friendly environments. She explained that the co-payment for Medicare beneficiaries is 20 percent of the cost of the procedure at an ASC compared to 40 percent out of the patient's pocket at a hospital. And generally speaking, the costs of procedures at hospitals are higher which means the patient pays more. So, an ASC is less costly for an individual patient, but it's also less costly for the government. {Source: Press release; Federated Ambulatory Surgery Association, February 16, 2006}

Many high ranking government officials recognize the importance that ASC growth has in our country's health system. On February 28, 2007, Centers for Medicare and Medicaid Services (CMS) Acting Administrator Leslie Norwalk opened the FASA Legislative and Compliance Seminar in Washington, DC by stating that "Our goal is to provide the right care for the right patient every time, and ASCs [ambulatory surgery centers]are a critical element of doing just that." Predicting that the future of health care will turn on the quality of care patients receive, she also recognized that ASCs have an edge when patient convenience, physician preference and cost control are involved. {Source: Press release; Federated Ambulatory Surgery Association, March, 2007}

Mark McClellan, former Administrator of the Centers for Medicare and Medicaid Services, has said "ASCs play a very important role in creating a modern, innovative health care system by providing care at a lower cost with better patient satisfaction. With the challenge of rising health care costs, it is clear to me that innovation and creativity in ASCs can make a big difference in the quality and cost of health care." {Source: Press release; Federated Ambulatory Surgery Association, February 16, 2006}

Unfortunately, hospitals have been unable to realize the cost savings of stand-alone, single specialty surgical centers due to a variety of factors, including the acuity of cases which are done in the shared hospital OR setting. The resources required to cover this increased acuity are greatly elevated including on-call staffing and increased numbers of cross-trained nursing professionals to handle the various surgical needs. Ambulatory surgery centers, on the other hand, have historically achieved higher productivity and shorter room turnover times due to streamlined processes that are not disrupted by inpatient and emergency cases. Their staffing ratios are typically lower due to the decrease in acuity of the case mix. The resulting operation of

a stand-alone eye surgery center is higher quality at a much reduced cost of care to the patient and to the health delivery system.

Value can be measured in more ways than simple dollar savings. Some of the less touted but equally important values of ASCs include improvements in technology and medical advances due to ambulatory surgery, improved efficiency for physicians, contributions to their community tax base, and they make stellar employers. Endoscopic and laparoscopic techniques, as well as faster-acting anesthesia drugs were either pioneered in ASCs or gained widespread acceptance because of their use and refinement in ASCs. Availability of ASCs in communities attracts the best surgeons who seek out such independent and autonomous control over their specialties. ASCs typically contribute to their communities' tax base through state, federal, property, unemployment and other special taxes. ASCs also provide flexibility in staffing which often maintains some critical employees in the work force, e.g. nurses, where they might otherwise be lost to the profession due to burn-out or other competing needs. ASCs also provide management opportunities for nurses that also keeps them progressing in their careers. (Source: FASA, *"Meeting America's Surgical Needs and So Much More"*}

In summary, an Ophthalmology specific ASC would be an overall better value for the citizens of Henderson and the surrounding North Carolina counties, not only for the real dollar savings that can be realized, but also for the intangible values that such a facility can bring.

Ophthalmology Is Uniquely Positioned for Efficient ASC Operation

The discipline of Ophthalmology is unique in their needs for an ASC in that almost every surgical case is capable of being performed in an ambulatory setting. Ophthalmology is one of a few specialties that are considered "high-volume surgical specialties" because of the nature and acuity of the surgical cases that are performed. In the 2004 MedPac Commission *"Report to Congress: Medicare Payment Policy"*, ophthalmic procedures accounted for a combined 52% of the share of Medicare payments for high-volume ambulatory surgical services. No other specialty came close to performing this number of procedures in an ASC setting. This report also noted that in 2002, over one third of all high-volume, Medicare certified ASCs specialized in Ophthalmology. Lastly, the MedPac report noted that during 2002, Ophthalmology procedures accounted for 38.7% of the ASC services provided to Medicare beneficiaries with the next closest specialty at 19.5%. These procedures accounted for 56.8% of Medicare payments as a percent of the total ASC payments made in that year.

A study reported by the Agency for Healthcare Research and Quality (AHRQ) that included databases for the Healthcare Cost and Utilization Project (HCUP, Fact Book No. 9) stated that lens and cataract surgery was the most commonly performed ambulatory surgery in 2003. It also went on to report that lens and cataract surgery was the most common ambulatory surgery billed to Medicare.

As evidenced in the studies below, it is critical to note that much eye surgery case volume is driven by factors associated with aging. According to *Prevent Blindness America, 2002,* cataract affects 20.5 million (1 in 6) Americans age 40 and older. By 80 years of age, more than one half

of Americans have cataract. The Mayo Clinic reports that about half of Americans older than 65 have some degree of clouding of the lens (cataract). After age 75, as many as 70 percent of Americans have cataracts that are significant enough to impair their vision. The Journal of the American Medical Association, JAMA, states that 1.5 million cataract surgeries are performed in the United States alone each year. The success rate for these surgeries is about 98%.

Citing a federally funded study, in "Older Americans 2000: Key Indicators of Well Being – Federal Interagency Forum on Aging-Related Statistics", the government study states that health care expenditures and use of health services among older people are closely related with age and disability status. For all health services received, the DHHS (Medicare website) reports that approximately 62% of expenditures, or approximately 656 billion dollars occurred for those aged 45 and older. Those aged 55 and older accounted for 79% of this amount for a total of approximately 520 billion dollars in personal health expenditures.

This correlation between aging and health service utilization highlights further the uniqueness of Ophthalmology relative to surgical demands. A study through the UCLA School of Medicine et.al, published in the *Annals of Surgery* in 2003, reported that the aging of the U.S. population will result in significant growth in the demand for surgical services over the next twenty years. In the study, *"The Aging Population and Its Impact on the Surgery Workforce,"* the lead author predicts the sharpest increases in demand will be in ophthalmology and cardiothoracic surgery, which will see 47% and 42% increases in demand respectively by 2020, compared with 2001 (See Figure 1). Some of this growth could outstrip the current supply of resources. The report states that "Surgeons need to develop strategies to manage an increased workload without sacrificing quality of care". In this report, Ophthalmology was also noted as having the highest proportion of work based in those individuals >65 years of age at 88%, the highest percentage of all specialties reported (See Figure 2, Table 4). These figures closely correlate with the incidence of cataract surgery as noted in the above paragraphs. It is conceivable that unless proper planning (including facility planning) is accomplished at the state levels to provide for this impending growth, this aspect of health care could encounter more serious delays and impacts to quality. To further support the >65 population growth specific to North Carolina, according to the AARP Public Policy Institute report, "*State Profiles, Reforming the Health Care System*", from 1995 through 2005, North Carolina experienced a 14.6% growth in individuals >65 years of age versus the overall U.S. growth of 9.2%.

The data from these studies clearly supports the uniqueness of the specialty of Ophthalmology as it relates to the high numbers of ambulatory surgery cases performed and the potential for economic impact with the available cost savings for these cases. Based upon all available data, no other specialty has the demand for performing such a large volume of ambulatory based surgical procedures, thus a key reason we are asking for an exception to be made for our discipline. Also, given these statistics and the well documented influx of an older population in Henderson and surrounding counties, it stands to reason that we will continue to see growth in the prevalence of cataracts, along with a concomitant growing demand for cataract and other age-related eye surgeries. Even with existing volumes, it is important to note that we have experienced scheduling issues around competition for block time in local hospitals. Over the past few years, due to competition for OR block time, we have seen this problem worsen. It is our

position that patients will ultimately be deprived of timely, high quality and cost effective ophthalmic surgical services unless changes are allowed in the current supply side of the system.

Improved Quality of Care/Patient Satisfaction in Ambulatory Surgery Settings

ASCs are highly regulated facilities whereby the safety and quality is evaluated periodically. This is done through three processes: state licensure, Medicare certification and voluntary accreditation. Almost all accrediting organizations require ASCs to engage in external benchmarking to assist in measuring quality. Studies have shown that ASCs consistently perform as well, if not better than, hospital outpatient departments (HOPDs) as it relates to quality and safety. One study, reported in the Archives of Surgery in January 2004, showed that rates of inpatient hospital admission and death were lower in freestanding ASCs as compared to HOPDs, even after controlling for factors associated with higher risk patients (See Figure 3)

In a MedPac Commission study to Congress released in 2006, the data for 77,294 patients who underwent cataract surgery were analyzed (procedures done in 2001). Of these, 47 percent were performed in a hospital outpatient setting and 53 percent in an ASC. A set of 22 patient characteristics was selected based on clinical expert opinion, including general medical and ophthalmologic comorbidities that might increase the facility cost of performing cataract surgery in an outpatient setting. Of the 22 characteristics, 18 were more common among HOPD patients than ASC patients, 11 of which were significantly more common. From the list of 30 possible adverse outcomes following cataract surgery that was assembled during the Phase 1 study, four conditions were selected for further analysis. The rate of endophthalmitis, a sight threatening eye infection, was significantly higher in the 30 days after cataract surgery among patients in the hospital outpatient setting than in the ASC. The rates of the other three outcomes (cataract fragments, persistent corneal edema, and iris prolapse) were slightly but not significantly higher in the OPD patients.

Quality can also be measured by patient satisfaction with a particular service. Recent surveys through Press Ganey Associates show average patient satisfaction levels in ASCs exceeding 90%. Safe and high quality services, ease of scheduling, greater personal attention and lower costs are among the reasons cited for the growing popularity of ASCs over the alternatives. {Source: *Ambulatory Surgery Centers, A Positive Trend in Health Care*, ASCA and ASC Coalition, November, 2006}

Single specialty ASC settings allow physicians to exercise professional autonomy over their work environment and allow them more control over the quality of surgical outcomes. Not only are they able to design these facilities to better accommodate their specialty, but they are also able to schedule procedures more conveniently, control technology and supplies that are suited to their specialties, and they are able to put together specially trained and highly skilled teams familiar with the surgical techniques being performed. The end result is high quality, cost efficient care for the patient.

Improved Access to Care For Patients

Access to care can fall into two categories: (1) the wait time for needed procedures based upon availability of OR space; and (2) the ability to receive procedures based upon one's ability to pay. Freestanding single specialty ASCs have improved flexibility with scheduling over current hospital based ORs due to the lack of competition for OR space. The constant "juggling" in the hospital OR system to maximize profits and satisfy a large surgeon base can create contentious feelings between surgeons and between the hospital and its customers. The end result can frequently be undesirable and often untenable surgical start times for the surgeon. Besides creating inefficiency for the surgeon's schedule, it also can create quality issues for some patient populations required to fast for long periods of time prior to their surgery. The end result is simply poor medicine.

Proponents of the CON process often cite access to care, both geographical and financial, as a primary reason to maintain these programs. Our physicians currently offer a significant amount of free and reduced fee care through various programs such as Project Access and North Carolina Services for the Blind. We also routinely treat Medicaid patients and frequently provide unreimbursed emergency care whereby we do not benefit from the Indigent Care Trust Fund as do hospitals. In addition, we also offer many free or reduced fee services to individuals in our community who have demonstrated the inability to pay for these needed services but are unable to receive any financial assistance. However, we can only control the professional fees for such services and are dependent on the area hospitals to follow through with similar policies on the surgical fees. Unfortunately, our patients frequently report problems along these lines. The availability of a single specialty ASC would increase our ability to offer indigent and reduced fee access by allowing surgeons an additional stream of revenue increasing their financial flexibility. The end result is improved access to care for many patients that would not receive this in the current system.

Efficient Use of Facility and Professional Resources

Two hospitals, Pardee Hospital and Park Ridge Hospital, account for the entire compliment of operating rooms available for use for all eye surgery cases in the immediate service area. Though we sympathize with the plight of hospitals in these financially challenging times, unfortunately, the efficiency of the hospital systems varies widely. Because the hospital systems are stretched regarding staffing, fully qualified and trained support staff are not always available for eye surgery cases, particularly for emergency cases. Not only can this delay the scheduling of eye cases, it can increase the risk for patients and thereby results in an argument that the level of quality is less than desirable (or acceptable) for these cases. As a recent example, the need for an emergency eye case was recently identified in the early afternoon, but we were unable to schedule the case in a local hospital until 7:30 PM. The patient needed to travel quite a distance from a rural area in order to receive the surgery. The case was ultimately delayed due to an emergency C-section and the surgeon was not able to start the case until after 10:00 PM in the

evening. Being an outpatient case, the patient was discharged very late in the evening and faced and uncomfortable and undesirable drive home.

Efficiency of staff also presents a constant issue in the current system. Staff turnover appears to be high in the shared hospital OR system, resulting in a frequent lack of expertise among the newer personnel. This expertise is vitally important when a complication arises in eye surgery cases and quality of care can be affected. Dedicated single-specialty ambulatory surgery centers, due to their unique focus on specialization, are able to assemble a compliment of staff that is more highly trained to deal with the cases being performed. The staff of an ASC works diligently with the same physicians in a repeated fashion and can not only anticipate the needs of the surgeon, but are frequently capable of assisting at a higher level when needed.

High-volume surgeons clearly prefer "uninterrupted repetition" when performing a daily volume of surgery cases. Some in Ophthalmology would even argue that it improves the quality of their surgery to minimize interruptions between cases. ASCs, because of their efficiency and flow do allow surgeons this benefit. With the ability to turn over operating rooms, the streamlined pre-operative processes and the overall lack of bureaucracy, ambulatory surgery facilities allow surgeons to virtually continuously operate with very little downtime, frequently utilizing two rooms for maximum efficiency.

Lastly, competition for surgical time in the shared hospital OR system can be fierce with multiple specialties having their own unique patient populations and their own unique needs. Hospital OR systems in Henderson County and surrounding areas are frequently unable to accommodate this wide range of surgical needs in an efficient manner. Block time that may have been utilized for years is frequently cancelled in lieu of higher acuity cases. In addition, block time that has historically been utilized for years can be quickly taken away in favor of other specialties seeking "equal time". The result can be cancellations of patients already scheduled for surgery and resultant delays in providing care to eye surgery patients that may be perceived as having less emergent needs

Current CON Laws Are Outdated and Frequently Promote Unfair Competition

Current CON laws in our state are outdated, broad in their context and no longer serve the original purpose for which they were intended. Our request to exempt Ophthalmology from requirements for a CON for a single specialty ambulatory surgery center is not without precedent. Our neighboring state of Georgia has already recognized the value in allowing single specialty disciplines to pursue ambulatory surgery centers. Georgia law exempts surgery centers focusing on a single specialty from demonstrating need. Other states, including Mississippi, Florida, Texas, and Massachusetts (among others), have similar exemptions or policies which do not require CON for physician owned surgery centers. Currently, only 27 states have CON laws that apply to physician owned ambulatory surgery centers.

According to The Locke Foundation in *"The Macon Series"* reports, it is not surprising that "the evidence matches the economic theory" when looking at CONs and their general ineffectiveness. "If CON were "working" as advertised, then one would expect to see a rise in health care costs

when the laws were eliminated. But in fact this is not the case." The reports note one of the most recent and widely referenced studies by Duke University Professors Christopher Conover and Frank Sloan. Published in 1998 in the *Journal of Health Politics, Policy, and Law,* their results are "consistent with "orthodox" economics. Output restrictions lead to higher, not lower costs". These authors point out that for hospitals, CON laws resulted in a 2 percent reduction in bed supply *and* "higher costs per day and per admission, along with higher hospital profits," exactly what economic theory would predict. Interestingly, the study "was unable to detect a statistically significant effect of removing CON on these same expenditures." But overall, the study found no decrease in per capita health care spending attributable to CON. An earlier study showed even more dramatic results. This study examined data through 1982 and found that CON was associated with a 20.6 percent increase in hospital spending and a 9 percent increase in spending on other health care. Overall, the study found that CON was responsible for a 13.6 percent increase in per capita spending on personal health care services (Lanning, Morrisey, et.al., 1991).

"The Macon Series" reports further state that "it is quite clear that all important aspects of the production, distribution, and sale of health care services in North Carolina, and most other states, have been removed from the competitive free enterprise system and placed under the authority of a command and control government bureaucracy. And like all other bureaucracies, it promotes factionalism and division and allows some groups and institutions to suppress the activities of others." The report goes on to cite East Carolina University researchers Campbell and Fournier, who found that "there are reasons to suspect that CON may have been adopted for other purposes...the states most likely to enact CON...were those with a highly concentrated hospital industry and increasing competitive pressures...hospitals were largely in favor of CON regulation, which is understandable considering that it protected them from competition."

In our own experience, we feel the current CON laws allow local competitors to exercise a marketing advantage over other specialists in the area. By allowing one CON and preventing others, the state has essentially endorsed the users of one local ambulatory surgery center by allowing that facility to be built, while stifling all other competition to provide the same opportunities and cost savings for their patients. Although we have reviewed the CON submitted and approved for this specialty eye surgery center for the Asheville area back in 2002, we are still unclear as to the relevance and justification of allowing this center to proceed given the current regulations in place. Our concern, one of fostering an "anticompetitive barrier to entry" into the market, is strongly supported by the findings and conclusions of the 2004 joint report of the Federal Trade Commission (FTC) and the Department of Justice (DOJ), *"Improving Health Care: A Dose of Competition"* described in the next paragraph.

While major supporters of CON tout the "cost saving ability of CON programs", it is important to note here that numerous studies have been done over the last three decades that provide strong evidence that CON laws are not effective in controlling costs. Federal support for CON ended in 1986 with the repeal of the National Health Planning and Resources Development Act of 1974. The following year, The FTC stated in a press release (August 10, 1987) that "market forces generally allocate society's resources far better than decisions of government planners". This statement was included as part of a letter to the state of Virginia recommending that the state eliminate COPN regulation of health facilities. In July, 2004, the FTC and the DOJ issued a joint report titled *"Improving Health Care: A Dose of Competition"*. Their study and report were an

attempt to "improve the balance between competition and regulation in health care". Following extensive testimony from industry representatives, legal, economic and academic experts on the healthcare industry and health policy, both agencies concluded that "CON programs can pose serious competitive concerns that generally outweigh CON programs' purported economic benefits". The agencies went further and suggested that there was "considerable evidence that they (CON programs) can actually drive up prices by fostering anticompetitive barriers to entry". The agencies conclusions recommend that "there appear to be other, more effective means of achieving this goal (cost containment) that do not pose anticompetitive risks". The agencies urged states with CON programs to "reconsider whether they are best serving their citizens' health care needs by allowing these programs to continue".

Dr. Michael Morrisey, Professor, School of Public Health at the University of Alabama, Birmingham, a participant in the FTC-DOJ hearings, writes that studies show that CON does not lower hospital costs. This has been shown in a "series of rigorous multi-state econometric studies in the 1970s, 1980s and 1990s. Conover & Sloan (1998) further concluded that CON repeal had no effect on hospital costs". Dr. Morrisey notes that there is some evidence that shows that CON actually raises hospital costs. He cites the same studies as mentioned above showing that hospitals in states with CON had costs that were 20.6% higher (Lanning et al, 1991).

In summary, the petitioners request that the state consider these numerous studies and the overwhelming collection of expert opinions which contradict conventional use of need determination as a means of cost and other health care resource control.

III. STATEMENT OF ADVERSE EFFECTS

If this requested change to allow Ophthalmology an exemption to the CON process for ambulatory surgical service is not made, the petitioners anticipate the following adverse effects for our community:

- Patients and the healthcare delivery system will continue to have higher than necessary costs for eye surgery services.
- The ongoing high demand for services, combined with the lack of efficiency of the current shared OR system will continue to cause delays in patient's receiving timely and efficient eye surgical services.
- Given the projected growth in Ophthalmology surgery cases as demonstrated in the studies herein, it is likely that the shortage of efficient "high-volume" operating rooms in our area will only worsen. This will result in further declines in the quality of care for eye surgery patients due to extended wait times for procedures, poor and undesirable scheduling processes, inadequate technology, and inadequately trained OR staff.
- Eye surgery candidates will be forced to seek out ambulatory surgery in areas in less convenient and distant areas outside Henderson County where they can receive more timely and more cost effective care.

- The goals of the SMFP will continue to go unmet given that this option for better access, higher quality and more cost effective care will have been denied to the residents of Henderson County.

IV. ALTERNATIVES

One alternative to providing an exemption for Ophthalmology, as some states have done, would be to establish a cap on expenditures for proposed single specialty surgical facilities. All facility requests that exceed the cap would be required to undergo a needs determination process. Those which fall beneath the cap would not be required to undergo a needs assessment. Under this alternative, all multi-specialty ASC requests would still be subject to a needs determination process, although current SMFP policies may not be the most practical to follow.

The petitioners have explored other alternatives and find that currently, no viable alternatives exist to resolve the cost issues, the quality issues, or the operating room utilization issues within the current system in Henderson County. Only two providers, Park Ridge Hospital and Pardee Hospital are available to provide this service for patients. While both hospitals provide good quality, the nature of the shared OR system does not lend itself to efficient or cost effective operation for high-volume outpatient cases such as cataracts and other eye surgery procedures. Options to transfer existing OR capacity into this type of setting are currently not feasible given the volumes and demand of other complex surgeries provided by the two hospitals.

Maintaining the current system as an alternative is obviously not an option since patients will continue to experience these same issues. We have worked within the hospital OR system for years and have seen little improvement in efficiency or cost-effectiveness. Dr. Jack Egnatinsky, past president of FASA, has stated that "ASCs consistently save patients and payers money. But more important, they are safe, efficient and focused on the well being of the patient. In a health care system plagued by inefficiency, excessive costs and a general lack of responsiveness, ASCs offer a better alternative for surgical care." Simply put, if permitted, we can provide a better service and a better alternative for eye surgery patients than the current hospital system.

V. EVIDENCE THAT THE PROPOSED ADJUSTMENT WOULD NOT RESULT IN DUPLICATION OF HEALTH RESOURCES

Allowing an exemption of Ophthalmology in regards to a CON process for ambulatory surgery services will not result in a duplication of services, but rather it will clearly meet the goals of the state medical planning board for a cost effective approach to care that is both accessible and provides for the delivery of quality health services. Current demand for operating room time in the petitioner's service area is high, with intense competition for a limited number of rooms. Hospital surgical suites in the service area have demonstrated that this demand for OR time can easily be filled with higher acuity cases. In fact, this realignment of block surgery time will likely improve the quality of surgery for those higher acuity cases. In order to consider this request a duplication of services, one would have to support the contention that CON prevents unnecessary

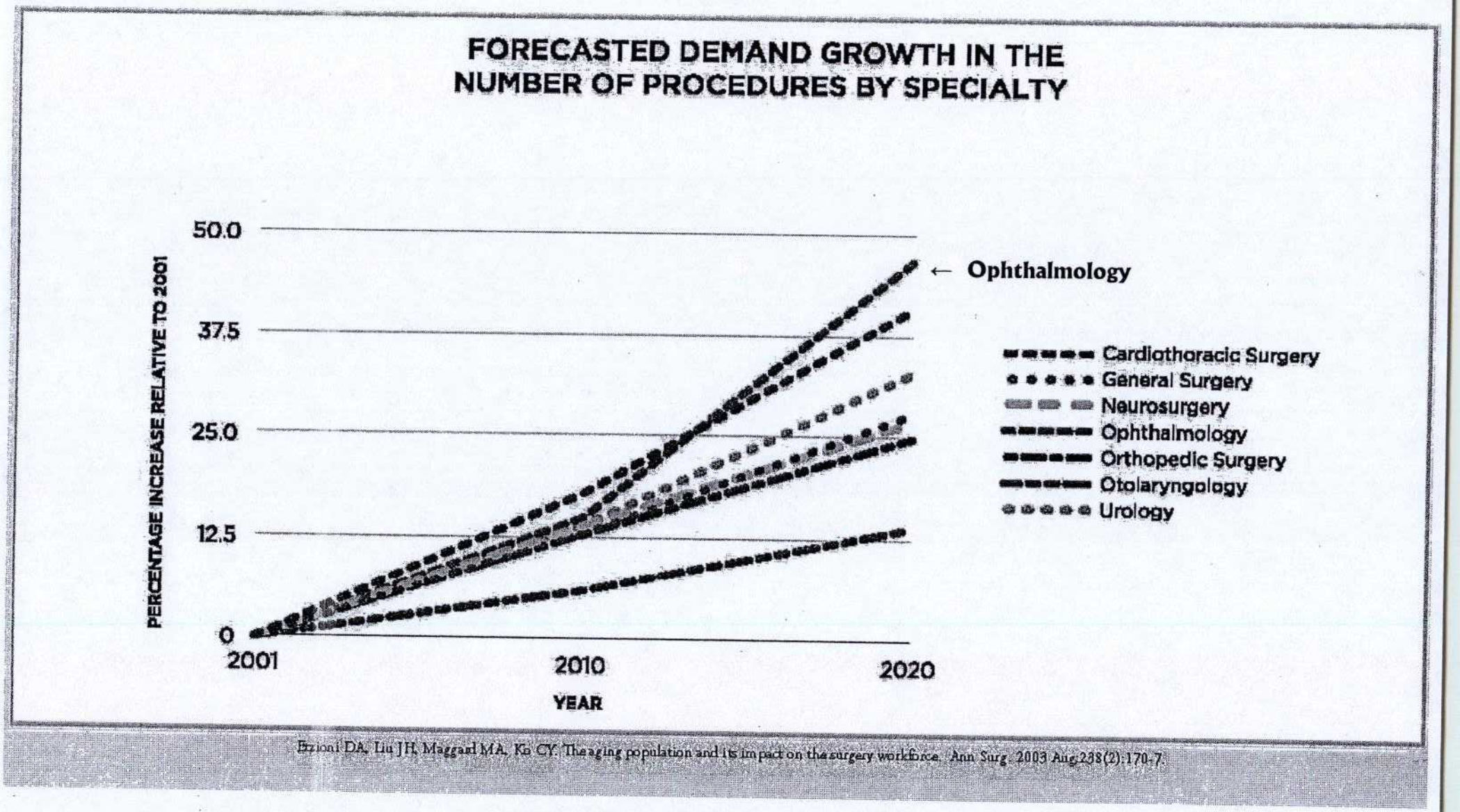
duplication of services above all other reasons. Our proposal will allow for the state planning goals to be met without impacting the current health delivery system.

While we agree that duplication of services is important and has a place in the state health planning process, this concept has been applied "across the board" for decades as one means to prevent entry into the market and to protect certain aspects of the health system. Rather than a broad sweeping application of a needs determination policy as currently used by the state, we feel the policy should be reexamined and selectively applied based upon existing data and current precedents. Only then will the state demonstrate that it is applying its own planning concepts to their fullest measure.

VI. SUMMARY

We clearly understand that by our petition, we are asking the state to consider a new paradigm in health planning that more closely considers the aspects of cost savings, access to care and the quality delivery of Ophthalmology surgical services in North Carolina. We also recognize that this is a departure from decades of following the same planning laws and guidelines. Still, we remind the board that this request is not without precedent in our neighboring states. Our analysis herein clearly shows that Certificate of Need regulations have been under scrutiny for years, and in fact are changing throughout the country to better serve the needs of its citizens. We have provided a strong argument regarding the need for change, and it is time for our state to consider a fresh and innovative approach to health care that reflects the current philosophy and direction of our country. We are confident that approval of this petition will allow us to pursue an ambulatory surgical service delivery system for eye surgery patients that better serves the needs of the citizens of Henderson County and the surrounding Western North Carolina areas.

FIGURE 1



Ezzati DA, Liu JH, Maggard MA, Ko CY. The aging population and its impact on the surgery workforce. Ann Surg. 2003 Aug;238(2):170-7.

FIGURE 2

TABLE 4. Proportion of Work Within Surgical Specialty by Age Group

Specialty	<15 y	15–44 y	45–64 y	65+ y	Total
Cardiothoracic*	0%	0.3%	29.4%	70.3%	100%
General surgery[^]	2.6%	12.3%	25.5%	59.6%	100%
Neurosurgery	2.8%	12.9%	39.1%	45.2%	100%
Ophthalmology	0.6%	0.7%	10.8%	88.0%	100%
Orthopedic surgery	0.6%	16.1%	31.8%	51.4%	100%
Otolaryngology	39.6%	22.1%	29.9%	8.4%	100%
Urology	4.0%	6.3%	24.9%	64.8%	100%

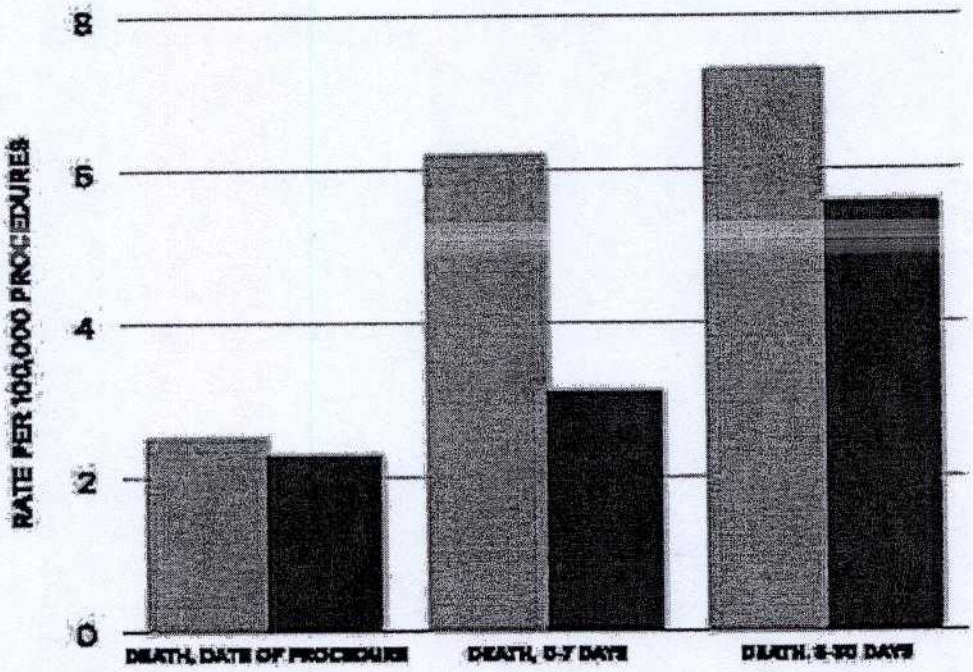
Source: NHDS and NSAS 1996.

*In the 1996 NHDS sample, the incidence rate for specific cardiothoracic procedures in pediatric patients was too small to allow an accurate incidence rate to be reported.

[^]Category includes vascular, breast, hernia, abdominal, gastrointestinal, and pediatric procedures.

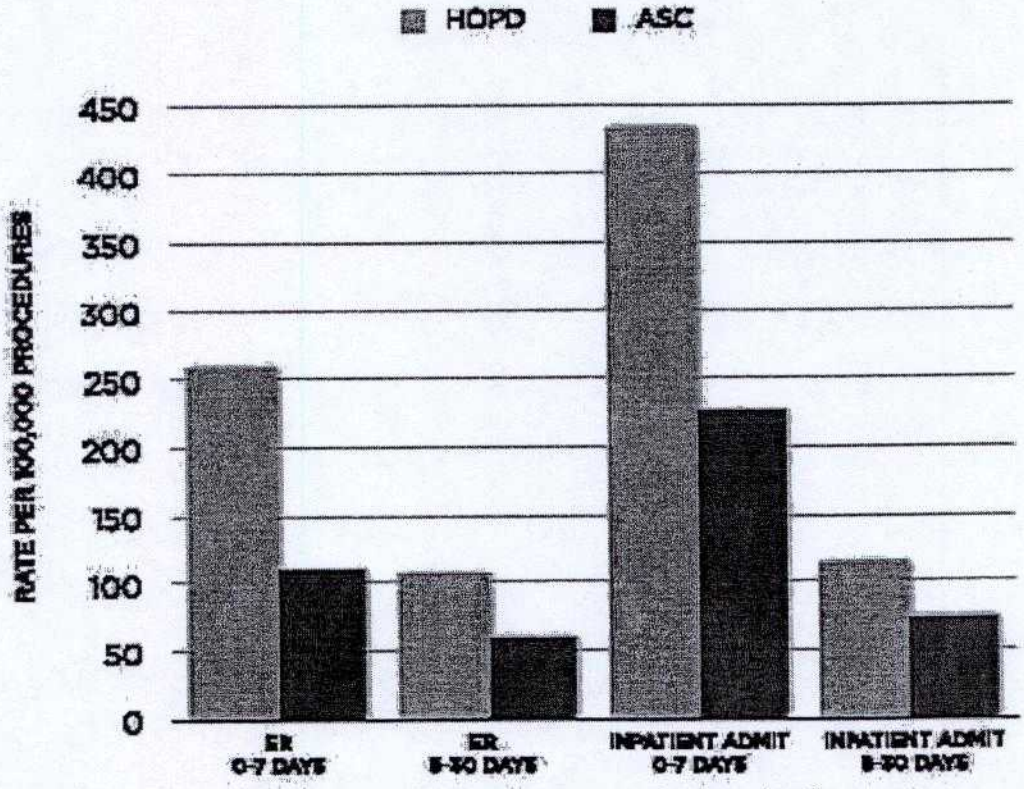
RATE OF ADVERSE EVENTS: DEATH

FIGURE 3



leisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly atients: importance of patient and system characteristics and location of care. Arch Surg. 2004 Jan;139(1):67-72.

RATE OF ADVERSE EVENTS: ER VISIT OR INPATIENT ADMISSION



leisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly atients: importance of patient and system characteristics and location of care. Arch Surg. 2004 Jan;139(1):67-72.