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PETITION FOR SUPPORT OF A DEMONSTRATION PROJECT FOR A SINGLE SPECIALTY, TWO OPERATING ROOM, ORTHOPEDIC AMBULATORY SURGICAL FACILITY IN BUNCOMBE, MADISON, YANCEY (BUNCOMBE COUNTY) COUNTIES

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RE: Petition for Medical Facilities Planning Section support of a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties

I. INTRODUCTION

The petitioners request the 2010 North Carolina State Medical Facilities Plan (NCSMFP) include support of a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County. Having a demonstration project of this sort in Buncombe County will ensure an additional opportunity to establish a new orthopedic ambulatory surgery facility which will focus on improving quality, cost, access and promote positive competition. Blue Ridge Bone & Joint Clinic (BRBJ) physicians understand the need to meet the specific criteria, the criteria basic principles and the rationale.

The State Health Coordinating Council (SHCC) has recognized the positive impact single specialty ambulatory surgical facilities can have in North Carolina in that the proposed 2010 NCSMFP includes proposals for such facilities in the Charlotte, Triad and Triangle areas. (See Table 6C: Operating Room Need Determination.) Additionally, the SHCC has the authority to provide special need determinations for ambulatory surgery operating rooms. The petitioners' request for a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County is

consistent with the SHCC recognition of such demonstration projects as proposed in the 2010 NCSFMP.

The SHCC did not approve a demonstration project for Buncombe County. That, in light of the facts that:

- There is a lack of effective competition in Buncombe County – one hospital controls the majority of all operating rooms (ORs) in the service area - 40 of 46.
- Twenty-one of the hospital controlled ORs are the vastly more expensive to the patient, inpatient (IP) ORs.
- The standard OR methodology does not accurately reflect the OR supply and demand for Buncombe County because the inventory includes six open heart operating rooms that are severely underutilized and cannot be used for other purposes.

In previous years the NCSMFP and the Certificate of Need (CON) process have offered very few opportunities for new providers to develop ambulatory surgery facilities in Buncombe County. At the same time, providers have strengthened their market dominance by working to hamper other healthcare providers from petitioning that need exists by not having ORs in service, as mentioned above.

Among other things, this petition discusses how changes in surgical technology drive the need for ambulatory surgery operating rooms with specific orthopedics and spine surgery capabilities. In many North Carolina communities, these surgical specialists have been unable to achieve optimal quality, staffing efficiencies and cost savings because the specialty procedures are relegated to the shared (inpatient and outpatient) operating rooms. Buncombe County has nine shared ORs and twenty-one IP ORs

Rather than seeking to change methodologies, the petitioners are simply strongly encouraging the SHCC to approve a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County.

II. RATIONALE FOR THE REQUESTED SPECIAL NEED DETERMINATIONS

The 2010 NCSFMP does not include a single specialty ambulatory surgery demonstration project for Buncombe County . BRBJ would ask that the SHCC revisit this decision and approve a single specialty, two operating room, orthopedic ambulatory surgical facility for Buncombe County. The current circumstance does not maximize the opportunity for competition which has been shown to, and will, have a positive impact on quality, cost and access.

Although not focusing on the current OR methodology, it is true that it:

- Generously continues to protect hospitals with “special exclusions” for C-section rooms and ORs related to trauma centers/burn centers. These specialized operating

rooms and their related utilization are not included in the planning methodology calculations.

- Ignores the huge variation in the number of operating rooms per capita.

- Does not facilitate need determinations for new facilities to improve geographic access and enhance competition.

- Gives no consideration to changes in surgical technology that create higher outpatient demand for surgical specialties including orthopedics and spine surgery.

Numerous Communities Lack Adequate Competition and Patient Choice of Surgical Operating Room Providers

There are numerous North Carolina counties where one, or a very few facilities, control the majority of operating rooms, thereby limiting competition. At a time when the North Carolina population is steadily growing and healthcare costs are rising, increased competition can encourage providers to be more focused on quality, access and cost efficiencies. Based on the high cost of healthcare, surgery oligopolies should no longer be protected from competition.

As mentioned earlier, forty of the forty-six Buncombe County ORs are controlled by the local hospital. Those ORs are predominantly IP and shared ORs which do not appropriately address the needs of the patients seeking easily accessible, cost effective, high quality care and/or the needs of the surgeons wanting to offer those services. It has been well over ten years since there has been any potential opportunity for other providers to be appropriately engaged in offering surgical care. Accepting the status quo does not maximize the needs of patients seeking easily accessible, cost effective, high quality care.

Restrictions to Access for High Volume Specialties

Given the market dominance of large providers in many North Carolina service areas, orthopedists and spine surgeons have very limited options as to where they can practice and when these specialty procedures can be scheduled. These specialties combined comprise approximately 20 percent of the ambulatory surgery.

In contrast, other high volume specialties have already developed single specialty ambulatory facilities in North Carolina. For example, the 2006 CON schedule allows proposals for gastrointestinal endoscopy rooms without a determinative limit.

Most of the ambulatory orthopedic and spine surgery procedures are performed in IP and shared operating rooms that are used for both inpatients and outpatients. This arrangement is determined not by patients' and surgeons' choice but instead due to the prevalence of IP and shared operating rooms that represent 79 percent of the total

adjusted planning inventory in Buncombe County versus the North Carolina statewide 34 percent. (See the table below.)

Existing OR Inventory	Inpatient	Shared	Ambulatory	Total	ORs Pending
Buncombe-Madison-Yancey Total OR Inventory	21	13	9	43	4
	49%	30%	21%	100%	
	Inpatient	Shared	Ambulatory	Total	
North Carolina Total OR Inventory	155	282	861	1,298	53
	12%	22%	66%	100%	

Shared and IP operating rooms have frequent schedule changes and delays because emergency and urgent cases often postpone the scheduled elective cases. These shared operating rooms are also routinely used for both "contaminated cases" and "clean cases". This situation extends the time needed for cleaning the operating rooms between procedures. Also, the OR methodology does not recognize the fact that outpatient cases that are performed in shared operating rooms, have, on average, longer turnover times than outpatient cases performed in ambulatory surgery centers.

In response to these circumstances, the petitioners' request for a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County will enhance competition and does not change the OR methodology.

<u>Changes in Technology Create Higher Demand for Outpatient Orthopedic Surgery</u>

Existing and new minimally invasive surgical technologies will continue to shift surgery utilization to the outpatient setting. Historically, orthopedic surgery has achieved high levels of outpatient utilization. For example knee arthroscopy procedures are approximately 80 to 90 percent outpatient, while shoulder rotator cuff repair procedures are typically 50 percent outpatient.

Specific types of spine surgery procedures that are performed on an outpatient basis include:

- Discectomies.
- Laminectomies.
- Spinal fusions/Minimally invasive spinal fusions.

New spine surgery procedures that can favorably impact outpatient utilization include:

- Kyphoplasty – reduces pain and restores height to patients with vertebra compression fractures -- uses catheter/balloon/ bone cement application.
- Vertobroplasty - reduces pain for patients with vertebra compression fractures -- uses bone cement delivered through a catheter.

- Endoscopic Discectomy – removes portions of degenerated disc using fiber-optic endoscopes and/or fluoroscopy.
- Endoscopic Spinal Fusion - fuses spinal segments using implants delivered through small incisions and uses fiber-optic endoscopes and/or fluoroscopy.

As has been noted by the Health Care Advisory Board, "patients receiving discectomies, laminectomies, anterior cervical fusions and even minimally invasive lumbar fusions are being discharged (from ambulatory surgery center (ASC) ORs) in well under 24 hours. Early clinical outcomes have been positive, suggesting that the outpatient approach for much of today's inpatient spine portfolio could become increasingly common across the next decade."

Cost Effectiveness

The superior cost effectiveness of ambulatory surgery centers also supports approval of the petitioners' request. The Federated Ambulatory Surgery Association reports that co-payment for Medicare beneficiaries is 20 percent of the cost of the procedure at an ambulatory surgery center as compared to 40 percent patient responsibility at a hospital.

Also the costs of outpatient procedures at hospitals are higher. Studies have found that Medicare pays on average $320 less per surgery when the procedure is performed in an ASC rather than a hospital outpatient department.

Mark McClellan, the 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."[1]

III. REQUESTED CHANGE

The petitioners' requested change to the 2010 NCSMFP is that the SHCC include support of a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County. Having a demonstration project of this sort in Buncombe County will ensure opportunities to establish a new orthopedic ambulatory surgery facility to improve quality, cost and access and promote more positive competition.

IV. ADVERSE EFFECTS IF REQUESTED CHANGES ARE NOT MADE

The expected adverse effects if the changes are not made include:

[1] www.fasa.org, Washington, DC; February 16, 2006, News Release

- The lack of effective competition throughout much of western North Carolina will result in continued increases in healthcare charges and costs. Patients will have little choice but to continue paying high hospital deductibles for surgery procedures that could be performed in outpatient facilities.

- With continued population growth, aging of the baby boomers and the increased focus on embracing an active lifestyle, the petitioners expect surgery workloads will increase by at least 10 to 20 percent over the next few years based on BRBJ's existing practice and industry projections. Additionally, BRBJ's physician complement will increase this summer further increasing demand on currently available ORs. This growth will make it increasingly difficult to schedule patients for surgery in a timely manner.

- The petitioners expect that scarce operating room time will result in a higher percentage of procedures being delayed or rescheduled. This will cause difficulties for both patients and surgeons. Schedule delays decrease staff efficiency, diminish patient satisfaction and can compromise the quality of care.

- The petitioners would expect greater difficulty in recruiting surgeons should that occur. Surgeons state that they are 20 to 30 percent more productive in an ambulatory surgery center as opposed to a hospital surgery suite.

V. ALTERNATIVES THAT WERE CONSIDERED BUT ARE NOT FEASIBLE

Maintaining the status quo is not an acceptable alternative because of the lack of more effective competition.

Submitting petitions for adjusted need determinations in specific service areas is a potential option; but one that has not been successful in the past. Some previous petitioners have submitted petitions for adjusted need determinations for ambulatory surgery operating rooms in their respective service areas. These petitions were denied without much discussion or explanation.

Many potential petitioners have not filed petitions because relevant opportunities did not present themselves.

Proposing to change the methodology for projecting operating room need does not appear to be feasible because the planning emphasis has been focused on the development of an appropriate endoscopy mechanism to project need separate from the surgery methodology. Rather than try to change the present OR methodology, the petitioners propose SHCC support of a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties.

VI. EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES

The proposed change to the need determination will not result in unnecessary duplication of health resources for several reasons:

- The total operating room adjusted inventory is approximately 79 percent IP and shared operating rooms. As explained previously these ORs are inefficient and more costly to operate than ambulatory operating rooms. In many areas of North Carolina, patients and surgeons lack access to efficient and cost effective ambulatory surgical operating rooms. The requested special need determinations will add ambulatory surgical capacity that promote more cost effective service, lower charges and lower costs as compared to the majority of the operating rooms in the inventory.

- Additionally, in the 2010 draft NCSFMP the SHCC proposes demonstration projects in service areas which currently have, and are projected to have, an excess of ORs. SHCC's plan projects the following 2012 OR oversupply in service areas being considered for the demonstration projects:

  - Charlotte Area (Mecklenburg, Cabarrus, Union) (20)
  - Triad Area (Guilford, Forsyth) (26.7)
  - Triangle Area (Wake, Durham, Orange) (9.3)

  Based on the current and projected oversupply, it would follow that the SHCC should view Buncombe County in at least the same light as the three North Carolina service areas in which the demonstration projects are proposed. It would follow that the SHCC support a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe County.

VII. EVIDENCE THAT THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLIES GOVERNING THE DEVELOPMENT OF THE NCSMFP: SAFETY AND QUALITY, ACCESS AND VALUE

Blue Ridge Bone & Joint Clinic (BRBJ) physicians understand the need to meet the specific criteria, the criteria basic principles and the rationale.

BRBJ physicians have worked in and helped foster systems which incorporated the implementation of systems to measure and report quality which promotes identification and correction of quality of care issues and overall improvement in the quality of care provided. BRBJ implemented electronic medical records ten plus years ago into daily practice operations. BRBJ physicians have, and do, enjoy(d) local hospital staff privileges and provide extensive emergency department coverage. BRBJ physicians have, and will continue, to collaborate(d) with the North Carolina Hospital Association and the North Carolina Medical Society in their efforts to develop quality measures.

BRBJ physicians have, and will continue, to collaborate(d) with the North Carolina Hospital Association and the North Carolina Medical Society in their efforts to increase access to the underserved. BRBJ physicians have, and will, promote(d) equitable access to indigent patients. At this point BRBJ understands the SHCC open access to physicians criteria but would prefer to support the North Carolina Orthopaedic Association proposition that the demonstration projects be ones where applicants be instructed to provide the proposed medical staff bylaws and the written criteria for extending medical staff privileges at the facility. BRBJ will work to meet timely project completion by obtaining a license no later than two years from date of issuance of the CON, unless this requirement is changed by the NCSMFP.

The Buncombe County service area meets the criteria for current population size but not the OR components. That is in large part because of the inordinately large percent of IP and shared ORs at 79 percent in Buncombe County versus the North Carolina 34 percent. BRBJ physicians would be the owners of the proposed demonstration project - a single specialty, two operating room, orthopedic ambulatory surgical facility.

BRBJ physicians will meet the requirement to provide annual reports on compliance. BRBJ physicians will submit to annual evaluations and address corrective actions, should they be offered.

VIII. CONCLUSION

BRBJ appreciates the SHCC consideration of its request to amend the 2010 NCSFMP to include support of a demonstration project for a single specialty, two operating room, orthopedic ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties.

The petitioners are convinced that their patients deserve better options than what currently exist. Approval of this petition can partially remedy the lack of effective competition that persists in many communities and supports unrestrained increases in healthcare charges. Greater competition will also require providers to focus on quality and patient outcomes.