RECEIVED
By K Fisk at 8:02 am, Jul 31, 2012

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

TO: North Carolina Division of Health Services Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714
(919) 855-3865 (FAX)

PETITIONERS: Paul Saenger, MD, President
Stefan Magura, CEO
Blue Ridge Bone & Joint Clinic
129 McDowell Street
Asheville, NC 28801
(828) 281-7129
smagura@brbj.com

DATE: July 23, 2012

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

I. INTRODUCTION

The petitioners request the proposed 2013 North Carolina State Medical Facilities Plan (NCSMFP) include support of a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties.

The State Health Coordinating Council (SHCC) determined to assess the impact single specialty ambulatory surgical facilities can have in North Carolina in that the 2010 NCSMFP included approval for such facilities in the Charlotte, Triad and Triangle areas. (See Table 6C (2010) Operating Room Need Determinations and Inventory for Single Specialty Ambulatory Surgery Demonstration Project). Additionally and separately, 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, ambulatory surgical facility in Buncombe County is consistent with the SHCC approval of such demonstration projects as proposed in the 2010 and referenced and updated in the 2011, 2012 and 2013 NCSFMPs.

Having a demonstration project of this sort in Buncombe County would potentially create the opportunity for an entity to build a new orthopedic ambulatory surgical facility. Blue Ridge Bone & Joint Clinic (BRBJ) physicians understand that interested entities would have to make their case to the SHCC as to why their application for such a project would secure SHCC approval vis a vis other interested entities.

That said and understood, BRBJ physicians would appreciate that opportunity understanding the need to bring their existing expertise of focusing on improving quality, cost and access to such a project. BRBJ physicians believe an opportunity of this nature would enhance and promote increased positive competition. We understand the need to meet the specific criteria, the criteria basic principle and the rationale required by the NCSMFP.

The SHCC did not consider and therefore could not approve a demonstration project for Buncombe County in the 2010 NCSFMP. Nor has it reconsidered such a project for Buncombe County in the 2011, 2012 and the proposed 2013 NCSFMPs. That, in light of the facts that:

- There is a lack of effective competition in Buncombe County – one hospital controls the majority of all the unadjusted operating rooms (ORs) in the service area - 47 of 53.

- The unadjusted 2013 OR tally shows the twenty-one hospital controlled inpatient (IP) ORs and the thirteen hospital controlled shared ORs which are the vastly more expensive ORs versus the nineteen ambulatory 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.

- Three of the nineteen ambulatory ORs are designated for non-orthopedic surgeries.

- Proportionately, in Buncombe County there are fewer freestanding ambulatory surgery facilities, and ORs, when compared to the Charlotte, Triad and Triangle areas.

- The majority of the OR inventory in western North Carolina are hospital-based inpatient or shared ORs.

- It appears the SHCC does not treat Buncombe County citizenry on equal footing with the Charlotte, Triad and Triangle service area citizenry as evidenced by the

SHCC's 2010 approval of single specialty ambulatory surgical facility demonstration projects for those service areas. The SHCC did reference and update this decision in the 2011, 2012 and the proposed 2013 NCSFMPs. (See Table 6C (proposed 2013) and Table 6D (2011 and 2012) respectively.)

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 orthopedic and orthopedic spine surgery capabilities. In many North Carolina communities, the represented 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 thirteen shared and twenty-one IP ORs.

Rather than seeking to change methodologies, the petitioners are simply strongly encouraging the SHCC to consider and approve a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe County – consistent with the SHCC's approval of the single specialty, ambulatory surgical facility projects for the Charlotte, Triad and Triangle areas.

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, ambulatory surgical facility for Buncombe County in the proposed 2013 NCSFMP. 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 variation in the number of operating rooms per capita attributed to different operating room service areas.

- 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 orthopedic and orthopedic spine surgery.

- Appears to not treat Buncombe County citizenry on equal footing with the Charlotte, Triad and Triangle service area citizenry as evidenced by the SHCC's 2010 approval of single specialty ambulatory surgical facility demonstration projects for those service areas. The SHCC did reference and update this decision in the 2011, 2012 and the proposed 2013 NCSFMPs. (See Table 6C (proposed 2013) and Table 6D (2011 and 2012) respectively.)

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-seven of the fifty-three unadjusted 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 almost fifteen 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 orthopedic spine surgeons have very limited options as to where they can practice and when related specialty procedures can be scheduled. These specialties combined comprise a significant percentage of the Buncombe County service area non-surgical and surgical patient care activity.

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.

Many 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 64.2 percent of the total adjusted planning inventory in Buncombe County. Three of the 19 ambulatory ORs are designated specialty specific (cannot be used for orthopedic surgical care) ORs meaning the actual percentage of ambulatory ORs available for orthopedics is 32 percent, or 16 of 50 ORs. (See the table below.)

Existing Unadjusted OR Inventory	Inpatient	Shared	Ambulatory	Total		ORs Pending
Buncombe-Madison-Yancey Total OR Inventory	21	13	19	53		1.1
	39.6%	24.6%	35.8%	100%		
	Inpatient	Shared	Ambulatory	Total		
Buncombe-Madison-Yancey Total OR Inventory – Three Non-Orthopedic ORs Excluded	21	13	16	50		1.1
	42%	26%	32%	100%		

This in light of the fact that over 70% of the cases performed in Buncombe County were outpatient cases.

Buncombe County OR Cases 10/2010 – 9/2011 in 2013 Plan	Cases	Percentage
Inpatient	12,619	29.6%
Outpatient	30,689	70.4%
Total	42,671	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 and increased resource utilization than outpatient cases performed in ambulatory surgery facilities.

In response to these circumstances, the petitioners' request SHCC consideration and approval of a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe County which will enhance quality, cost, access and does not change the OR methodology. The petitioners understand that interested entities would have to make their case to the SHCC as to why their application for such a project would secure SHCC approval vis a vis other interested entities.

Changes in Technology Create Higher Demand for Outpatient Orthopedic Surgery

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 orthopedic spine surgery procedures that are performed on an outpatient basis include:

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

Other newer orthopedic 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.

Dr. Michael Redler with the Surgery Center of Fairfield County who was quoted in Becker Orthopedic and Spine Review in May 2011 said, "Spine surgery is the next great horizon for the ASC." He went on to discuss the fact that performing procedures in an ASC allows for expedited surgery and lower equipment costs, thereby improving quality and reducing costs.

Focusing on ASC operations Dr. Redler said, "arthroscopic procedures are now often the gold standard for surgery on most major joints." Additionally he offered, "we have been able to help pioneer arthroscopic repairs in the wrist with cases done almost exclusively in an ambulatory surgery center."

Also as reported in Becker in their July 6, 2011 publication, because of DHHS' 2010 Health Resources and Services Administration report discussing an unmet baseline requirement of orthopedists in the United States, there are concerns about the shortage of available orthopedic surgeons. These needs are increasing because of the growing number of elderly patients and their commensurate demand for orthopedic services. Considering that projected concern, circumstances which improve orthopedic surgeon efficiency and effectiveness have a potentially positive impact on helping address some of the issue.

Cost Effectiveness

The superior cost effectiveness of ASCs also supports approval of the petitioners' request. CMS, OIG, HHS and the ASC Association have all published numerous reports highlighting the fact that the cost associated with care for Medicare beneficiaries is less at an ambulatory surgery center as compared to the cost at a hospital inpatient, but more importantly a hospital outpatient department (HOPD). Recent analyses by the Ambulatory Surgery Center Association have concluded that Medicare pays 49% less per orthopedic surgery when that orthopedic procedure is performed in an ASC rather than a HOPD.

In 1991 and again in 2003 OIG, HHS reported that CMS paid more for surgical care provided in a HOPD than an ASC. In its 2003 report OIG concluded that in 2001 CMS paid $1.1B more to HOPDs for services which could have been offered in ASCs, $107.3M of which were orthopedic and musculoskeletal related.

Access

BRBJ physicians have an excellent, decades-long history of treating patients representing the entire spectrum of individual economic circumstance. BRBJ physicians routinely provide care for persons covered by government insurance and persons dependent on charity care. Most recent payer mix information substantiates BRBJ's commitment to all patients, regardless of ability to pay. Year-to-date 2012 over 54% of BRBJ's patients are government or charity care patients. BRBJ is dedicated to the care of government and charity care patients.

In addition to the above, BRBJ physicians have demonstrated their commitment to enhance access for the medically underserved. BRBJ physicians routinely and annually agree to care for Project Access patients. Project Access links people without health insurance into a local network of, among other things, physicians willing to see these individuals at no charge. BRBJ physicians provide Project Access patients all of their care to include office visits, diagnostic imaging, needed surgery(ies) and rehabilitations at no charge.

Depending on the SHCC decision about a demonstration project in Buncombe County and the potential of BRBJ's securing a related certificate of need, additional issues related to improved geographical access could perhaps be addressed.

III. REQUESTED CHANGE

The petitioners' requested change to the proposed 2013 NCSMFP is that the SHCC include support of a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe County. Having a demonstration project of this sort in Buncombe County would potentially create the opportunity for an entity to build a new orthopedic ambulatory surgery facility. As stated above BRBJ physicians believe such an opportunity will enhance 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:

- The lack of effective competition throughout much of western North Carolina will cause continued increased healthcare charges and costs which will not necessarily result in patients experiencing improved quality or service from these higher costs. Patients will have little choice but to continue paying high hospital deductibles for surgical procedures which could be performed in outpatient facilities.

- As noted above because CMS paid, and continues to pay, more to HOPDs for services which could have been offered in ASCs, we are not having a positive impact on reducing the cost of this portion of our country's healthcare costs.

- With continued population growth, aging of the baby boomers and the increased focus on embracing an active lifestyle, there could be an unmet need for orthopedists. An unmet need which, in published reports, is projected to result in compound annual growth rates close to 8% through 2016. And, an unmet need which could be positively impacted by increasing physician efficiency and effectiveness through access to ASC ORs.

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 which would increase quality and decrease cost.

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. Rather than try to change the present OR methodology, the petitioners propose the SHCC's support in the proposed 2013 NCSFMP of a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties consistent with the SHCC's approval of such projects for the Charlotte, Triad and Triangle service areas. Blue Ridge Bone & Joint Clinic physicians understand that interested entities would have to make their case to the SHCC as to why their application for such a project would secure SHCC approval vis a vis other interested entities.

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

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

- The total operating room adjusted inventory is approximately 64.2 percent IP and shared operating rooms. As explained previously these ORs are inefficient and more costly to operate than ambulatory operating rooms. In western North Carolina, patients and surgeons lack access to efficient and cost effective ambulatory surgical operating rooms.

- The requested additional demonstration project 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 NCSFMP the SHCC approved demonstration projects in service areas which currently have, and are projected to have, an excess of ORs. SHCC's plan projects the following 2015 OR oversupply in service areas approved for the demonstration projects. See Table A.

    - Charlotte Area (Mecklenburg, Cabarrus, Union) (20.6)
    - Triad Area (Guilford, Forsyth) (27.4)
    - Triangle Area (Wake, Durham, Orange) (36.9)

- Finally, in comparison to Durham County which has an adjusted inventory of 91 ORs in the 2013 plan for a population of 267,587 and an oversupply of (23.7) ORs for 2015, Buncombe County has an adjusted inventory of 50 ORs for a population of 276,900 and a projected 2013 oversupply of (1.1) ORs.

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 SHCC approved demonstration projects. It would follow that the SHCC support a demonstration project for a single specialty, two operating room, 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 physicians understand the need to meet the specific criteria, the criteria basic principle 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 more than thirteen years ago into its daily practice operations. BRBJ physicians have, and do, enjoy(ed) local hospital staff privileges and provide extensive emergency department coverage for the sixteen county western North Carolina service area. 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 Orthopedic 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. If SHCC approved the requested demonstration project and if BRBJ were to be awarded a CON, BRBJ 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 64.2 percent in Buncombe County. BRBJ physicians would be the owners of the proposed demonstration project - a single specialty, two operating room, ambulatory surgical facility.

BRBJ physicians will meet the requirement to provide annual reports on compliance to the appropriate regulatory bodies. BRBJ physicians will submit to annual evaluations and address corrective actions, should they occur subsequent to the review of the annual compliance reports

VIII. CONCLUSION

BRBJ appreciates the SHCC's consideration of its request to include in the proposed 2013 NCSFMP support of a demonstration project for a single specialty, two operating room, 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 result in providers increasing their focus on improved quality and patient outcomes.

		Table A			
SHCC Plan	Measure	Buncombe	Charlotte	Triad	Triangle
2010 Plan-2012 Need	Projected IP/OP Surgical Hours 2012	85,477	303,191	283,200	366,408
	Adjusted Planning Inventory	50	183	178	205
	Oversupply	4.3	21.0	26.7	9.3
	Surgical Hours/OR	1,710	1,657	1,591	1,787
	Surgical Hours/Adjusted OR	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	8.7%	11.5%	15.0%	4.5%
2011 Plan-2013 Need	Projected IP/OP Surgical Hours 2013	85,499	292,612	274,353	365,682
	Adjusted Planning Inventory	50	183	178	208
	Oversupply	4.3	26.7	31.4	12.7
	Surgical Hours/OR	1,710	1,599	1,541	1,758
	Surgical Hours/Adjusted OR	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	8.7%	14.6%	17.7%	6.1%
2012 Plan-2014 Need	Projected IP/OP Surgical Hours 2014	85,199	298,063	273,680	364,723
	Adjusted Planning Inventory	48	185	177	208
	Oversupply	2.5	25.8	30.8	13.2
	Surgical Hours/OR	1,775	1,611	1,546	1,753
	Surgical Hours/Adjusted OR	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	5.2%	13.9%	17.4%	6.3%
2013 Plan-2015 Need	Projected IP/OP Surgical Hours 2015	87,758	307,843	268,863	355,824
	Adjusted Planning Inventory	48	185	171	227
	Oversupply	1.1	20.6	27.4	36.9
	Surgical Hours/OR	1,828	1,664	1,572	1,568
	Surgical Hours/Adjusted OR	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	2.3%	11.1%	16.0%	16.3%