

**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
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DATE: July 23, 2015

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

As evidenced in the June 2015 HealthLeaders' cover story "Fueling Top-Line Growth – Healthcare leaders are seeking outpatient market share and other strategies to ensure long-term viability", the acute care/hospital businesses continue planning to position as the leaders in addressing healthcare efficiency and effectiveness. As Edward Prewitt, HealthLeaders Editorial director opines, "The center of gravity is shifting away from expensive acute care hospitals and toward retail and outpatient medicine." Blue Ridge Bone & Joint (BRBJ) physicians understand, and have understood, that perspective for years. To that end we have petitioned the State Health Coordinating Council (SHCC) since 2009 asking the SHCC to approve a demonstration project for a single specialty, two room, ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties.

In the preceding June 2015 HealthLeaders editorial paragraph Cleveland based MetroHealth System President and CEO Akram Boutros, MD says, "Our aim is, within the next three and one-half years, to have 50% of our revenue from risk-based or shared savings contracts." On April 1, 2015 BRBJ began participating in CMS' and CMMI's bundled payment for care improvement initiative. BRBJ is the only orthopedic physician

practice, let alone physician practice, in western North Carolina (WNC) participating in this risk based demonstration project. BRBJ physicians consider active pursuit and participation in programs designed to increase healthcare efficiency and effectiveness integral to their focus on making a significantly positive impact on the care they provide WNC citizens.

The petitioners respectfully request the North Carolina Proposed 2016 State Medical Facilities Plan (NCSMFP) include support of a demonstration project for a single specialty, two operating room, ambulatory surgical facility in Buncombe County.

The 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. (Attached 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, 2013, 2014, 2015 and 2016 NCSMFPs. The proposed 2016 NCSMFP does include reference to, but does not include reconsideration of, the approved demonstration projects. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015 and 2016) respectively.)

Having a demonstration project of this sort approved for Buncombe County would create the opportunity for an entity to build a new ambulatory surgical facility. BRBJ physicians understand that interested entities would have to make their case to the SHCC as to why their certificate of need (CON) application for such a project would secure SHCC approval vis a vis other interested entities.

That said and understood, BRBJ physicians seek the 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 patient care. 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 NCSMFP. Nor did it reconsider such a project for Buncombe County in the 2011, 2012, 2013, 2014, 2015 and the proposed 2016 NCSMFPs. That, in light of the facts that:

- The unadjusted OR tally in the proposed 2016 NCSMFP shows the eight hospital managed inpatient (IP) ORs and the thirty hospital controlled shared ORs which are the vastly more expensive ORs versus the fifteen ambulatory ORs.
- The standard OR methodology does not accurately reflect the OR supply and demand for Buncombe County because the inventory includes six dedicated open heart operating rooms that are severely underutilized and cannot be used for other purposes. It also includes two dedicated C-section operating rooms
- Three of the fifteen ambulatory ORs are designated for non-orthopedic surgeries.
- There is a lack of enhanced choice in Buncombe County – one hospital manages the majority of all the unadjusted operating rooms (ORs) in the service area - 47 of 53. Eight of these ORs are dedicated ORs reducing the available ORs to 39.
- The majority of the OR inventory in western North Carolina are hospital-based inpatient or shared ORs.
- It appears the SHCC does not consider Buncombe County citizenry in a way which is consistent 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, 2013, 2014, 2015 and 2016 NCSMFPs. The SHCC does reference but does not reconsider or update the single specialty, ambulatory surgical facility demonstration project in the proposed 2016 plan. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015 and 2016) respectively.)

In previous years the NCSMFP and the 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 inpatient and shared (inpatient and outpatient) operating rooms. Buncombe County has thirty shared and eight 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.

BRBJ has submitted similar petitions since 2009, all of which the SHCC denied. We believe that since our last petition submittal (in July 2014 on the proposed 2015 NCSMFP), the environment has changed to further enhance many of BRBJ’s previously presented local/regional deficiencies and needs with regard to choice, accessibility and cost effective alternatives. Additionally, we believe that the environment has changed since the local Buncombe County hospital’s comments regarding our 2014 petition.

II. RATIONALE FOR THE REQUESTED SPECIAL NEED DETERMINATIONS

The proposed 2016 NCSMFP 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 2016 NCSMFP. The current circumstance does not maximize relevant opportunities for patient and physician choice which have 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 patient choice while reducing cost.
- Gives little or no consideration to changes in surgical technology that create higher outpatient demand for surgical specialties including orthopedic and orthopedic spine surgery. As a member organization of the Orthopedic Forum and national orthopedic associations, BRBJ physicians know that orthopedic surgeons are now successfully performing what used to be only IP joint procedures in ASCs for select patients.
- Appears the SHCC does not consider Buncombe County citizenry in a way which is consistent 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, 2013, 2014, 2015 and the proposed 2016 NCSMFPs. The SHCC does reference but does not reconsider or update the single specialty, ambulatory surgical facility demonstration project in the proposed 2016 NCSMFP. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015 and 2016) respectively.)

Numerous Communities Lack Adequate Access 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 patient access and patient and physician choice. At a time when the North Carolina population is steadily growing and healthcare costs are rising, increased choice can enhance opportunities for patients and physicians to be more focused on quality, access and cost efficiencies. Given the excessively expensive impact of inpatient and shared ORs on healthcare costs, alternate surgical environments should receive increased attention and opportunity – single specialty, ambulatory surgical facilities.

As mentioned earlier, forty-seven of the fifty-three unadjusted Buncombe County ORs are managed 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, quality care and/or the needs of the surgeons wanting to offer those services. It has been almost eighteen 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, 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, since 2006 the CON schedule allows proposals for gastrointestinal endoscopy rooms without a determinative limit.

In Buncombe County 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' choices but

instead due to the prevalence of IP and shared operating rooms that represent 71.8 percent of the total unadjusted planning inventory in Buncombe County. Three of the 15 ambulatory ORs are designated specialty specific (therefore cannot be used for orthopedic surgical care) ORs meaning the actual percentage of ambulatory ORs available for orthopedics is 24.0 percent, or 12 of 50 ORs. (See the table below.)

Existing Unadjusted OR Inventory	Inpatient	Shared	Ambulatory	Total
Buncombe-Madison-Yancey Total OR Inventory	8	30	15	53
	15.1%	56.7%	28.3%	100%
	Inpatient	Shared	Ambulatory	Total
Buncombe-Madison-Yancey Total OR Inventory – Three Non-Orthopedic ORs Excluded	8	30	12	50
	16%	60%	24%	100%

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

Buncombe County OR Cases in the Proposed 2016 Plan	Cases	Percentage
Inpatient	12,067	30.0%
Outpatient	28,120	70.0%
Total	40,187	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.

New to orthopedics is the increasing number of orthopedic surgeons who are performing total joint for patients in the ASC setting. Physician patient selection remains an integral part this option to patients.

Recent developments include successful 23 hour stays for hip replacement patients who had their procedure performed in an ASC. According to James T. Caillouette, MD, in the American Association of Orthopedic Surgeon magazine, joint replacement success in the ambulatory setting relies on careful patient selection, surgical expertise and technique, and judicious pain management.

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.

Due to the cost efficiencies of ambulatory surgical centers, the Medicare facility reimbursement rates for ASCs remain significantly lower than hospital reimbursement rates. Medicaid, the State Health Plan, and commercial insurance typically reimburse ASC facilities at substantially lower rates than hospitals. Patient co-payments are also lower for ambulatory surgery centers.

Current NC CON law makes it very difficult for new ASCs to be developed. NC citizens have far less access to ASCs. Changing the CON law to allow additional ASCs will shift more cases from the hospitals to the lower cost ASCs.

The following table outlines three scenarios for the projected cumulative costs for Medicaid and the State Health Plan related to ambulatory surgery. The more cases that can be shifted to the lower cost ASCs, the greater the savings.

Healthcare consultant, David French, prepared the following analysis for the North Carolina Orthopedic Association presentation to NC State legislators as they assessed approval of House Bill 177 during the 2013 legislative session.

	2014 to 2020
Scenario 1 - No Changes to CON Law , Ambulatory Cases Remain at 80% Hospitals and 20% ASCs	Scenario 1
Total Medicaid + SHP Amounts Paid	Cumulative \$2,520,532,219
Scenario 1 Savings	\$0
Scenario 2 - Add 50 ASCs w 100 ORs (2 per ASC) Changes Ambulatory Cases to 70% Hospitals and 30% ASC	Scenario 2
Total Medicaid + SHP Amounts Paid	Cumulative \$2,450,542,562
Scenario 2 Savings	\$69,989,568
Scenario 3 - Add 100 ASCs with 200 ORs (2 per ASC) Changes Ambulatory Cases to 60% Hospitals and 40% ASCs	Scenario 3
Total Medicaid + SHP Amounts Paid	Cumulative \$2,172,694,165
Scenario 3 Savings	\$147,473,862

Medicaid Ambulatory Surgery Historical Data		
	2011	2012
Hospital Medicaid Ambulatory Surgery Paid Amounts	\$74,799,293	\$85,191,372
Hospital Medicaid Ambulatory Surgery Cases	164,489	172,673
Average \$ Paid per Case	\$454.74	\$493.37
ASC Medicaid Ambulatory Surgery Paid Amounts	\$13,597,774	\$14,589,820
ASC Medicaid Ambulatory Surgery Cases	46,951	43,895
Average \$ Paid per Case	\$289.62	\$332.38
Combined ASC and Hospital Paid Amounts	\$88,397,067	\$99,781,192
Combined ASC and Hospital Ambulatory Cases	211,440	216,568
Average \$ Paid per Case	\$418.07	\$460.74
Variance between Hospital and ASC per Case Paid Amount	\$165.12	\$160.99
Percentage Variance of Hospital and ASC Paid Amount	36.31%	32.63%

NC Medicaid Surgery Utilization Mix of ASC and Hospital Cases		
	2012	% Mix
Hospital Medicaid Ambulatory Surgery Cases	172,673	80%
ASC Medicaid Ambulatory Surgery Cases	43,895	20%
Total NC Medicaid Surgery Utilization	216,568	

State Health Plan Ambulatory Surgery Historical Data		
	2011	2012
Hospital SHP Ambulatory Surgery Paid Amounts	\$186,272,164	\$186,586,774
Hospital SHP Ambulatory Surgery Cases	60,847	58,383
Average \$ Paid per Case	\$3,061.32	\$3,195.91
ASC SHP Ambulatory Surgery Paid Amounts	\$14,216,247	\$15,714,905
ASC SHP Ambulatory Surgery Cases	14,798	13,485
Average \$ Paid per Case	\$960.69	\$1,165.36
Combined ASC and Hospital Paid Amounts	\$200,488,411	\$202,301,679
Combined ASC and Hospital Ambulatory Cases	75,645	71,868
Average \$ Paid per Case	\$2,650.39	\$2,814.91
Variance between Hospital and ASC per Case Paid Amount	\$2,100.63	\$2,030.55
Percentage Variance of Hospital and ASC Paid Amounts	68.62%	63.54%

NC SHP Surgery Utilization Mix of ASC and Hospital Cases		
	2012	% Mix
Hospital SHP Ambulatory Surgery Cases	58,383	81%
ASC SHP Ambulatory Surgery Cases	13,485	19%
Total Combined SHP Ambulatory Surgery Cases	71,868	

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 payer insurance and persons dependent on charity care. Most recent payer mix information substantiates BRBJ's commitment to all patients, regardless of ability to pay. Very consistently during the last several years almost 55% of BRBJ's patients have been government payer or charity care patients. BRBJ physicians are dedicated to the care of government payer 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 be addressed.

III. REQUESTED CHANGE

The petitioners' requested change to the proposed 2016 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 create the opportunity for an entity to build a new 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 expansive patient and physician choice.

IV. ADVERSE EFFECTS IF REQUESTED CHANGES ARE NOT MADE

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

- The lack of effective patient and physician choice 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 region'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 remains an unacceptable alternative because of the lack of more effective patient and physician choice both of 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 2016 NCSMFP 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 unadjusted inventory is approximately 71.8 percent IP and shared operating rooms. The adjusted total operating room inventory is approximately 76 percent. 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 promotes 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 NCSMFP 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 2018 OR oversupply in service areas approved for the demonstration projects. See Table 1.

	2014 <u>Plan</u>	2015 <u>Plan</u>	2016 <u>Plan</u>
➤ Charlotte Area (Mecklenburg, Cabarrus, Union)	+21.6	+32.7	+29.7
➤ Triad Area (Guilford, Forsyth)	+28.9	+32..1	+33.8
➤ Triangle Area (Wake, Durham, Orange)	+16.9	+23.6	+24.9

- Buncombe's projected oversupply was and is as seen below. Significantly lower than that of the areas approved for the demonstration projects.

	2014 <u>Plan</u>	2015 <u>Plan</u>	2016 <u>Plan</u>
➤ Buncombe Area (Buncombe, Madison, Yancey)	+3.2	+3.7	+4.3

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 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 PRINCIPLES 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 sixteen 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 the SHCC approved the requested demonstration project and if BRBJ were to be awarded a CON, BRBJ would 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 71.8 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 2016 NCSMFP 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 choice that persists in many communities and supports unrestrained increases in healthcare charges. Greater patient choice will also result in physicians being able to enhance their focus on improved quality and patient outcomes.

Need Determination

Application of the methodology indicated need for three additional operating rooms in one operating room service area. In addition, the North Carolina State Health Coordinating Council has determined that there is a need for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each. Therefore, there is a need determination for one facility to be located in each of the following areas: Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), Triangle Area (Wake, Durham, Orange counties). The demonstration project facilities must meet the criteria described in Table 6D. It is determined that there is no need for any additional Operating Rooms anywhere else in the state and no other reviews are scheduled “Operating room” is defined in G.S. 131E-76(9) as “...a room used for the performance of surgical procedures requiring one or more incisions and that is required to comply with all applicable licensure codes and standards for an operating room.”

Table 6C: Operating Room Need Determinations

(Scheduled for certificate of need Review Commencing in 2010)

It is determined that the counties listed in the table below need additional Operating Rooms as specified.

OPERATING ROOM SERVICE AREA	OPERATING ROOM NEED DETERMINATION*	CERTIFICATE OF NEED APPLICATION DUE DATE**	CERTIFICATE OF NEED BEGINNING REVIEW DATE
Wake	3	February 15, 2010	March 1, 2010
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	2 (Pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project)	July 15, 2010	August 1, 2010
Triad Area (Guilford, Forsyth counties)	2 (Pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project)	March 15, 2010	April 1, 2010
Triangle Area (Wake, Durham, Orange counties)	2 (Pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project)	November 15, 2010	December 1, 2010
It is determined that there is no need for additional Operating Rooms anywhere else in the state and no other reviews are scheduled.			

From the NC 2010 State Medical Facilities Plan, page 90.

Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	2010 Need Determination	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	2010 Need Determination	2
The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON # G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad Area.		

From the NC 2011 State Medical Facilities Plan, page 99.

Table 6C: Inventory for Single Specialty Ambulatory Surgery Demonstration Project

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	2010 Need Determination	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	Triangle Orthopaedics Surgery Center	2
<p>The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON #G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad area. On 6/1/2011, CON #J-008616-10 was awarded to Triangle Orthopaedics Surgery Center to develop a single specialty (orthopaedic) ambulatory surgical facility in the Triangle Area.</p>		

From the NC 2012 State Medical Facilities Plan, page 102.

Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	University Surgery Center, LLC	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	Triangle Orthopaedics Surgery Center	2
<p>The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON #G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad area. Piedmont Outpatient Surgery Center received its license effective 2/6/2012. On 6/1/2011, CON #J-008616-10 was awarded to Triangle Orthopaedics Surgery Center to develop a single specialty (orthopaedic) ambulatory surgical facility in the Triangle Area. University Surgery Center, LLC received CON #F-008543-10 on 7/18/2012 to develop a single specialty (orthopaedic) ambulatory surgical facility in the Charlotte Area.</p>		

From the NC 2013 State Medical Facilities Plan, page 106.

Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	University Surgery Center, LLC	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	Triangle Orthopaedics Surgery Center	2
<p>The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON #G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad area. Piedmont Outpatient Surgery Center received its license effective 2/6/2012. On 6/1/2011, CON #J-008616-10 was awarded to Triangle Orthopaedics Surgery Center to develop a single specialty (orthopaedic) ambulatory surgical facility in the Triangle Area. University Surgery Center, LLC received CON #F-008543-10 on 7/18/2012 to develop a single specialty (orthopaedic) ambulatory surgical facility in the Charlotte Area.</p>		

From the proposed NC 2014 State Medical Facilities Plan, page 90.

Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project – 2015 SMFP

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	University Surgery Center, LLC	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	Triangle Orthopaedics Surgery Center	2
<p>The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON #G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad area. Piedmont Outpatient Surgery Center received its license effective 2/6/2012. On 6/1/2011, CON #J-008616-10 was awarded to Triangle Orthopaedics Surgery Center to develop a single specialty (orthopaedic) ambulatory surgical facility in the Triangle Area. Triangle Orthopaedics Surgery Center received its license effective 2/25/2013. University Surgery Center, LLC received CON #F-008543-10 on 7/18/2012 to develop a single specialty (orthopaedic) ambulatory surgical facility in the Charlotte Area.</p>		

From the proposed NC 2015 State Medical Facilities Plan, page 93.

Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project – Proposed 2016 SMFP

Operating Room Service Area	Provider	ORs
Charlotte Area (Mecklenburg, Cabarrus, Union counties)	University Surgery Center, LLC	2
Triad Area (Guilford, Forsyth counties)	Piedmont Outpatient Surgery Center	2
Triangle Area (Wake, Durham, Orange counties)	Triangle Orthopaedics Surgery Center	2
<p>The North Carolina 2010 State Medical Facilities Plan included need determinations for a Single Specialty Ambulatory Surgery Demonstration Project, consisting of three facilities with two operating rooms each to be located in the Charlotte Area (Mecklenburg, Cabarrus, Union counties), Triad Area (Guilford, Forsyth counties), and the Triangle Area (Wake, Durham, Orange counties). On 9/28/2010, CON #G-008477-10 was awarded to Piedmont Outpatient Surgery Center LLC and Stratford Executive Associates LLC to develop a single-specialty ENT ambulatory surgical facility in the Triad area. Piedmont Outpatient Surgery Center received its license effective 2/6/2012. On 6/1/2011, CON #J-008616-10 was awarded to Triangle Orthopaedics Surgery Center to develop a single specialty (orthopaedic) ambulatory surgical facility in the Triangle Area. Triangle Orthopaedics Surgery Center received its license effective 2/25/2013. University Surgery Center, LLC (dba Mallard Creek Surgery Center) received CON #F-008543-10 on 7/18/2012 to develop a single specialty (orthopaedic) ambulatory surgical facility in the Charlotte Area and was licensed on May 1, 2014.</p>		

From the proposed NC 2015 State Medical Facilities Plan, page 96.

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Healthcare Planning and CON Section

		<u>Table 1</u>			
<u>SHCC Plan</u>	<u>Measure</u>	<u>Buncombe</u>	<u>Charlotte</u>	<u>Triad</u>	<u>Triangle</u>
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
	Standard Hours/OR per Year	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
	Standard Hours/OR per Year	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
	Standard Hours/OR per Year	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
	Standard Hours/OR per Year	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	2.3%	11.1%	16.0%	16.3%

		<u>Table 1</u> <u>(con't)</u>			
<u>SHCC Plan</u>	<u>Measure</u>	<u>Buncombe</u>	<u>Charlotte</u>	<u>Triad</u>	<u>Triangle</u>
2014 Plan- 2016 Need	Projected IP/OP Surgical Hours 2016	83,939	285,348	271,685	357,678
	Adjusted Planning Inventory	48	174	174	208
	Oversupply	3.2	21.6	28.9	16.9
	Surgical Hours/OR	1,749	1,640	1,561	1,720
	Standard Hours/OR per Year	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	6.6%	12.4%	16.7%	8.1%
2015 Plan- 2017 Need	Projected IP/OP Surgical Hours 2017	79,414	281,631	264,040	328,589
	Adjusted Planning Inventory	48	187	178	212
	Oversupply	3.7	32.7	32.08	23.59
	Surgical Hours/OR	1,654	1,506	1,483	1,550
	Standard Hours/OR per Year	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	7.7%	17.5%	18.0%	11.1%
2016 Plan- 2018 Need	Projected IP/OP Surgical Hours 2018	81,858	290,783	270,002	352,154
	Adjusted Planning Inventory	48	185	178	213
	Oversupply	4.3	29.7	33.8	24.9
	Surgical Hours/OR	1,705	1,572	1,516	1,653
	Standard Hours/OR per Year	1,872	1,872	1,872	1,872
	Percent Oversupply to Adj Planning Inv	9.0%	16.1%	19.0%	11.7%

Source: Table 6B: Projected Operating Room Need for 2012, 2013, 2014, 2015, 2016 from 2010, 2011, 2012, 2013, 2014, 2015, 2016 NCSMFP.