

**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 Service Regulation  
Healthcare Planning Section  
2704 Mail Service Center

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**DATE:** March 6, 2019

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

**I. INTRODUCTION**

The October 30, 2018 U.S. News and World Report article “Why Private Practitioners Are Still the Best Choice for Consumers” offered the following:

“A recent study published in Orthopaedic Reviews found that orthopedic surgeries cost an average of \$3,225 more when performed in a hospital setting compared to an outpatient clinic (sic, ambulatory surgery center). And that's just the average – the research found that cost savings ranged from 17.6 percent to 57.6 percent. Another study found that ACL (anterior cruciate ligament) reconstruction surgery cost an average of \$9,220 at an inpatient hospital facility and just \$3,905 in an outpatient clinic. But the quality is not poorer because of the lower cost: Additional research has shown that outpatient care is simply more efficient, allowing patients to spend 25 percent less time in the ambulatory surgical center than they would in a hospital setting, while realizing the same clinical outcomes.”

The January 31, 2019 Becker's Orthopedic Review article "North Carolina ASC completed 250 total joints in 2018: 4 things to know" offered:

"The Surgical Center of Greensboro (N.C.) performed 250 total joint procedures in 2018, which was the first year of the ASC's total knee replacement bundle program. After participating in the Bundled Payments for Care Improvement (BPCI) program at his local hospital, a group of total joint surgeons in Greensboro, NC realized they could implement similar bundled payments with their Surgical Care Affiliates (SCA) surgery center."

The January 23, 2019 Becker's Orthopedic Review article "Planned orthopedic surgery cost \$25B in 2017, up 44% in 7 years: 5 things to know" offered:

"A new report from the Blue Cross Blue Shield Association shows spending for planned orthopedic surgeries have grown significantly over the past decade.

The organization examined medical claims data for members who underwent hip and knee surgery from 2010 to 2017. Five things to know:

1. From 2010 to 2017, spending on planned orthopedic surgeries increased 44 percent and accounted for 47 percent of all orthopedic spending. The number of knee implants increased 6 percent and the number of hip implants increased 5 percent over the same time period.
2. The average price for inpatient knee implants in 2017 was \$30,249, compared to \$19,002 in the outpatient setting. There was a significant gap between inpatient and outpatient spending on hip replacements as well; average spending on hip replacements was \$30,685 in the inpatient setting and \$22,078 in the outpatient setting.
3. The outpatient setting represents a 30 percent to 40 percent savings for knee and hip procedures.
4. The outpatient complication rate improved by 23 percent for knee surgeries and 36 percent for hip surgeries from 2013 to 2017; at the same time, there were comparable complication rates in the inpatient setting.
5. The increased number of knee and hip replacements over the study period drove the cost, and the number of joint replacements for patients under the age of 65 years increased sharply. Planned orthopedic surgery cost around \$25 billion in 2017."

EmergeOrtho | Blue Ridge Division (EO | BRD) physicians understand, and have understood, the particulars and perspectives described above for years. To that end we have petitioned the State Health Coordinating Council (SHCC) since 2009 (not 2016,

2017) asking the SHCC to approve a demonstration project for a single specialty, two room, ambulatory surgical facility in Buncombe, Madison, Yancey (Buncombe County) Counties.

Among other things, on April 1, 2015 then Blue Ridge Bone & Joint, now EO | BRD, began participating in CMS' and CMMI's bundled payment for care improvement initiative. EO | BRD was a pioneer as the only orthopedic physician practice, let alone physician practice, in western North Carolina (WNC) participating in this risk based demonstration project.

As of August 1, 2016 Blue Ridge Bone & Joint merged with Carolina Orthopaedics Specialists (greater Hickory area), OrthoWilmington (greater Wilmington area) and Triangle Orthopedic Associates (greater Durham, Raleigh area) to become EmergeOrtho and the EmergeOrtho | Blue Ridge Division (EO | BRD). On January 1, 2019 Greensboro Orthopaedics (greater Greensboro area) merged into EmergeOrtho (EO). EO now includes:

- 51 locations in 25 NC counties.
- 148 physicians.
- 271 mid-level providers.
- 11 MRI locations.
- 21 orthopedic urgent care centers.
- Surgeon-owned ASCs in Brunswick County (under construction), Durham and Greensboro.

With the merger, all EO divisions participated in BPCI Classic and now participate in BPCI Advanced. We also participate in other Medicare Advantage bundle programs and commercial bundle programs.

***(See pages 10 – 13 in the accompanying Blue Ridge Outpatient Surgery Center (BROSC) May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section A – Identification, Question 10.)***

In recent years our experience has been and remains that commercial payers and self-insured employers encourage doctors/surgeons to consider and include site-of-service decision making in the choice as to where surgeons perform surgeries.

All EO doctors and EO | BRD doctors specifically consider active pursuit and participation in value based 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 2019 State Medical Facilities Plan (NC SMFP) 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 NC SMFP 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.

EO | BRD does understand the SHCC's desire and intention to consider the impact of the approved single specialty ASC demonstration projects. We would expect that the SHCC undertook the 5 year review of the single specialty Piedmont Outpatient Surgery Center since the center received its license effective 2/6/2012. And, we would expect the SHCC did the same in its 5 year review of the single specialty, Triangle Orthopaedics Surgery Center (TOSC) since the center received its license effective 2/25/2013. That said, EO | BRD is very familiar with TOSC since, as an EO division, we are uniquely acquainted with a division's operational and functional performance.

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, 2016, 2017, 2018 and the proposed 2019 NC SMFPs. The proposed 2019 NC SMFP does include reference to the 2010 approved demonstration projects and does offer some update. But it does not include reference to the 5 year performance review of the demonstration projects or additionally approved demonstration projects – subsequent to that 5 year review. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015 2016, 2017, 2018 and the proposed 2019) 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. EO | BRD 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, EO | BRD physicians seek the opportunity understanding the need to bring their existing expertise of focusing on improving quality, cost and access to such a project. EO | BRD 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 NC SMFP.

The SHCC did not consider and therefore could not approve a demonstration project for Buncombe County in the 2010 NC SFMP. Nor did it reconsider such a project for Buncombe County in the 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (proposed) NC SMFPs. As mentioned earlier, EO | BRD does understand the SHCC's desire and intention to consider the impact of the approved single specialty ASC demonstration projects. Even so the decision does not consider/reconsider additional demonstration project(s) in the proposed 2019 NC SMFP, in light of the facts that:

- The unadjusted OR tally in the proposed 2019 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 thirteen ambulatory ORs.
- The standard OR methodology does not accurately reflect the OR supply and demand for Buncombe County because the inventory includes two dedicated C-section rooms - apparently underutilized and cannot be used for other purposes.
- Three of the thirteen IP 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 51.
- 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 in a way which is consistent with the Charlotte, Triad and Triangle service areas 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, 2016, 2017, 2018 and 2019 (proposed) NC SMFPs. The SHCC does reference and update but does not reconsider or advance the single specialty, ambulatory surgical facility demonstration project in the proposed 2019 plan. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (proposed)) respectively.)
- In previous year's petition denials the SHCC offered that it would assess the operational and economic effectiveness of the three originally approved, single specialty, demonstration projects after their five years of operation as part of the basis from which to consider additional demonstration projects.

In previous years the NC SMFP 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.

EO | BRD submitted similar petitions since 2009 (not 2016, 2017), all of which the SHCC denied. We believe that since our last petition submittal (in July 2015 on the proposed 2016 NC SMFP), the environment has changed to further enhance many of EO | BRD’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 other’s comments regarding our earlier petitions.

Importantly, recent local/regional developments regards ASCs include Surgery Partners’, Asheville located, Orthopaedic Surgery Center will become a multi-specialty surgery center (structured under the name Asheville SurgCare) after receiving CON approval to add two, newly available, operating rooms to its current CON. Projected to be operational in 2020, Asheville SurgCare will move from a single specialty ASC to a multispecialty ASC.

On May 15, 2018, EO | BRD filed its CON application for a single specialty, orthopedic ambulatory orthopedic surgery center in Buncombe County. As mentioned above we filed the application subsequent to the SHCC’s determining a need for two operating rooms (ORs) in Buncombe County and detailing that in the 2018 NC SFMP. On October 28, 2018, we learned that the CON division denied our application. The CON division awarded the CON for the two ORs to Surgery Partners to its Orthopedic Surgery Center of Asheville (OSCA) which will be renamed Asheville SurgCare (ASC). EO | BRD is appealing the decision.

Portions of our CON application and its exhibits are attached in Appendices 1 and 2, as well as our justification for our submitting this petition demonstrating the changing environment.

## II. RATIONALE FOR THE REQUESTED SPECIAL NEED DETERMINATIONS

The proposed 2019 NC SMFP does not include a single specialty, ambulatory surgery demonstration project for Buncombe County. EO | BRD 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 2019 NC SMFP. 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, access and cost.

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. 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 the different and multiple 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 many other national orthopedic associations, EO | BRD physicians know a number of orthopedic surgeons who have, for some time now, been successfully performing OP lower extremity joint replacement procedures in ASCs for select patients.
- Appears the SHCC does not consider Buncombe County in a way which is consistent with the Charlotte, Triad and Triangle service areas 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, 2016, 2017, 2018 and 2019 (proposed) NC SMFPs. The SHCC does update but does not reconsider or advance the single specialty, ambulatory surgical facility demonstration project in the proposed 2019 NC SMFP. (Attached see Table 6C (2010 and 2012) and Table 6D (2011, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (proposed)) respectively.)

### Numerous Communities to Include Buncombe County 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-one 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. Accepting the status quo does not maximize the needs of patients seeking easily accessible, quality, cost effective 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 and the NC SMFP 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 – which are used for both patient types. This is determined not by patients’/surgeons’ choice - instead due to the prevalence of IP and shared operating rooms that represent 74.5 percent of the total unadjusted inventory in Buncombe County. See below from the proposed 2019 NC SMFP.

Existing Unadjusted OR Inventory	Inpatient	Shared	Ambulatory	Total
Buncombe-Madison-	8	30	13	51
Yancey Total OR Inventory	15.7%	58.8%	25.5%	100%

This in light of the fact that almost 72% of the surgeries performed in Buncombe County were outpatient cases. (See the table below.)



Buncombe County OR Cases in the Proposed 2019 Plan	Cases	Percentage
Inpatient	11,384	28.4%
Outpatient	28,740	71.6%
Total	40,124	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, access, reduce cost 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. That is file a CON application to the SHCC for formal consideration, review and approval by CON reviewers.

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.

Now somewhat new to orthopedics is the increasing number of orthopedic surgeons who are performing total joint surgeries for patients in the ASC setting. Physician patient selection remains an integral part in bringing/offering this option to patients.

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). In our introduction we only presented a few of the dozens of references we could present discussing the economic effectiveness and quality of care non-HOPD ASCs provide.

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.

***(See pages 90 – 99 in the accompanying BROSC May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section K – Criterion (12), Questions 1 - 7.)***

### Access

EO | BRD physicians have an excellent, 3+ decades-long history of treating patients representing the entire spectrum of individual economic circumstance. EO | BRD physicians routinely provide care for persons covered by government payer insurance and persons dependent on charity care. Most recent payer mix information substantiates EO | BRD's commitment to all patients, regardless of ability to pay. Very consistently during the last several years more than 55% of EO | BRD's patients have been government payer or charity care patients. EO | BRD physicians are dedicated to the care of government payer and charity care patients.

Additionally, EO | BRD physicians have demonstrated their commitment to enhance access for the medically underserved. EO | BRD 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. EO | BRD physicians provide Project Access patients all of their care to include office visits, diagnostic imaging, needed surgery(ies) and rehabilitation(s) free.

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 – which we represent in our accompanying 2018 ASC CON.

***(See pages 23 – 49 in the accompanying BROSC May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section C – Criterion (3), Questions 4, 5, 6, and 8. Also see pages 88 – 89 Appendix 1, where EO | BRD addressed Section J – Criterion (9), Questions 1-2. Also see pages 100 – 105 Appendix 1, where EO | BRD addressed Section L – Criterion (13), Questions 1 – 5. Also see pages 108 – 112 Appendix 1, where EO | BRD addressed Section N – Criterion (18a), Questions 1 – 4.)***

### **III. REQUESTED CHANGE**

The petitioners' requested change to the proposed 2019 NC SMFP 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 single specialty ambulatory surgery facility. As stated above EO | BRD physicians believe such an opportunity will enhance opportunities to establish a new single specialty orthopedic ambulatory surgery facility to improve quality, access and cost 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 in these higher costs settings. Patients will have little choice but to continue paying high hospital rates 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 be 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% for some time. 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.

Rather than try to change the present OR methodology, the petitioners propose the SHCC's support in the proposed 2019 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. EmergeOrtho | Blue Ridge Division 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.

***(See pages 61 – 68 in the accompanying BROSC May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section E – Criterion (4), Questions 1 – 2.)***

#### **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 74.5 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 promotes more cost effective service, equal quality lower charges and lower costs as compared to the majority of the operating rooms in the inventory.

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.

***(See pages 77 – 79 in the accompanying BROSC May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section G – Criterion (6), Questions 1 - 3. Also see page 87 Appendix 1, where EO | BRD addressed Section I – Criterion (7), Question 2.)***

**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**

EmergeOrtho | Blue Ridge Division physicians understand the need to meet the specific criteria, the criteria basic principle and the rationale.

EO | BRD physicians have worked in and helped foster systems which incorporated the implementation of systems to measure and report quality. These efforts promote identification and correction of quality of care issues and overall improvement in the quality of care provided. EO | BRD, Blue ridge Bone & Joint implemented electronic medical records more than eighteen years ago into its daily practice operations. EO | BRD 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. EO | BRD 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.

EO | BRD 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. EO | BRD physicians have, and will, promote(d) equitable access to indigent patients. At this point EO | BRD 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 EO | BRD were to be awarded a CON, EO | BRD 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 74.5 percent in Buncombe County. EO | BRD physicians would be the owners of the proposed demonstration project - a single specialty, two operating room, ambulatory surgical facility.

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

***(See pages 113 – 115 in the accompanying BROSC May 15, 2018 CON application in Appendix 1, where EO | BRD addressed Section O – Criterion (20), Questions 1 - 3. Also***

*see pages 118 - 125 Appendix 1, where EO | BRD addressed Section Q – Utilization Methodology and Assumptions, Questions 1 - 4.)*

#### **VIII. 2016 SHCC DENIAL**

Appendix 3 contains the 2016 SHCC Denial to EO | BRD's 2016 petition. We believe we understand the SHCC's Analysis/Implications section.

That said we understand the original criteria established by the work group. We do understand as well that Buncombe County does not meet one of the criterion – number of ambulatory and shared ORs. Buncombe County will soon have 45 ORs once the Asheville SurgCare center becomes operational and we respectfully ask the SHCC's Single Specialty Ambulatory Surgery Demonstration Project Work Group (Work Group) to reconsider the criterion lowering this criterion. As the Work Group has seen from the numerous documents offered from EO | BRD's 2018 CON application a proposed ASC would be located in Buncombe County.

Also we do understand that the Table D (and other iterations of the table in subsequent NC SMFPs) do represent an update on the demonstration project – and appreciate that update.

Additionally we do appreciate the SHCC's intention of evaluating the demonstration projects after 5 years of operations. As noted earlier that time frame seems to have been met.

We presented substantial additional information regarding hospital versus ambulatory surgery center quality, access to the broad range of patients and cost comparisons in the opening of our introduction, and in our 2018 CON application.

#### **IX. CONCLUSION**

EO | BRD appreciates the SHCC's consideration of its request to include in the proposed 2019 NC SMFP 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.**

<b>OPERATING ROOM SERVICE AREA</b>	<b>OPERATING ROOM NEED DETERMINATION*</b>	<b>CERTIFICATE OF NEED APPLICATION DUE DATE**</b>	<b>CERTIFICATE OF NEED BEGINNING REVIEW DATE</b>
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**

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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
<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.</p>		

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

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

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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**

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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**

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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**

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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 – 2016 SMFP**

<b>Operating Room Service Area</b>	<b>Provider</b>	<b>ORs</b>
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.

**Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project – 2017 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 2017 State Medical Facilities Plan, page 92.

**Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project – 2018 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>		

Beginning with the Year 5 report for Triangle Orthopaedics Surgery Center and the Year 4 report for Mallard Creek Surgery Center, the calculation of revenue attributable to self-pay and Medicaid (third criterion from Table 6D in the 2010 State Medical Facilities Plan) shall be as follows: The percentage of the facility's total earned revenue that is attributed to self-pay and Medicaid revenue shall be at least seven percent, which shall be calculated as follows: the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue earned from self-pay and Medicaid cases, divided by the total earned revenues for all surgical cases performed in the facility for procedures for which there is a Medicare allowable fee as of the end of the reporting period.

From the proposed NC 2018 State Medical Facilities Plan, page 94.

**Table 6D: Inventory for Single Specialty Ambulatory Surgery Demonstration Project – Proposed 2019 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 2019 State Medical Facilities Plan, page 104.