Comments in Opposition to
Project ID # B-011514-18 – Orthopaedic Surgery Center of Asheville
Project ID # B-011515-18 – Blue Ridge Outpatient Surgery Center

Comments Submitted by Summit Health Partners, LLC ("SHP")

Pursuant to NCGS § 131E-185, SHP submits the following comments in opposition to the Orthopaedic Surgery Center of Asheville ("OSCA") and Blue Ridge Outpatient Surgery Center ("Blue Ridge") CON applications.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

Policy GEN-3 applies to each application in this review.

> A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for the resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.

OSCA

OSCA fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, OSCA did not adequately demonstrate that its proposal will maximize healthcare value, and therefore does not satisfy Policy GEN-3. As a result, OSCA is nonconforming with Criterion (1).

Blue Ridge

Blue Ridge fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, Blue Ridge did not adequately demonstrate that its proposal will maximize healthcare value, and therefore does not satisfy Policy GEN-3. As a result, Blue Ridge is nonconforming with Criterion (1).

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

OSCA

It is evident from OSCA's application that issues with its existing facility are a major reason why it filed its application. OSCA includes the following table on pages 26 through 28 of its application and identifies "the existing building constraints that detract from the overall facility function." OSCA has determined that the only reasonable alternative is to submit a competitive CON application to relocate the existing ambulatory surgical facility and expand it by two operating rooms. However, all of "the existing building constraints that detract from the overall facility function" can be accomplished without a competitive CON application. The following table illustrates this:

| Issue Identified in Application | Summary of Existing OSCA Facility Constraints | Solution |
|---|---|---|
| Parking and Site | Limited | Relocate facility with non-competitive CON application |
| Facility Age, Size and Condition | Small and old | Relocate facility with non-competitive CON application |
| Waiting Area<br>Consult Room | Small<br>No consult rooms | Expand in relocated facility with non-competitive CON application |
| Registration | Limited | Expand in relocated facility with non-competitive CON application |
| Pre-Op and Post-Op | Limited | Expand in relocated facility with non-competitive CON application |
| Surgical Operating Rooms | Three small 360 SF ORs | Build larger ORs in relocated facility with non-competitive CON application |
| Procedure Rooms | No procedure rooms | Add procedure rooms to relocated facility with non-competitive CON application |
| Post Anesthesia Care Unit | Limited | Expand in relocated facility with non-competitive CON application |
| Sterile Processing | Limited | Expand in relocated facility with non-competitive CON application |
| Equipment Storage | Very limited | Expand in relocated facility with non-competitive CON application |
| Offices | Very limited | Expand in relocated facility with non-competitive CON application |
| Staff Lockers | Very compact | Expand in relocated facility with non-competitive CON application |
| Materials Management | Limited to 600 SF | Expand in relocated facility with non-competitive CON application |
| Building Systems | Frequent maintenance and lack of insulation | Relocate facility with non-competitive CON application |

As the table illustrates, none of the existing OSCA facility constraints requires the submission of a competitive CON application to add two operating rooms. It should also be noted that OSCA states that it has no procedure rooms in the table on page 27 of the application, but in the table on page 92, OSCA identifies 309 cases performed in "Procedure Rooms" in the last full fiscal year.

Adding two more operating rooms will not necessarily solve issues like physicians who are frustrated due to the lack of larger modern operating rooms; staff burnout; costly facility repairs and maintenance; and scheduling bottlenecks as described on application pages 25 and 38 of the OSCA application. In particular, issues like staff burnout must be addressed at the root; otherwise, the problems may only increase because the staff will be burdened with even more work to do with two more operating rooms. Moreover, the existence of these issues does not mean that two more operating are needed. OSCA has failed to demonstrate a clear connection between these stated problems and the need for more operating rooms. The two issues are not necessarily correlated and should not be "merged" into OSCA's premise of "we have certain facility problems, therefore we need two more operating rooms." Many of these problems could be solved by relocating the existing ambulatory surgical facility, building larger operating rooms, and adding procedure rooms.

The identified service area for the operating room need determination is Buncombe, Madison, and Yancey Counties. The table on page 21 of the application identifies the patient origin OSCA projects in Years 1 through 3 for the ORs. An identical patient origin table for the procedure rooms appears on page 22. OSCA projects to serve only 55.1 percent [ ((3,139 + 273 + 172) / 6,505) x 100 ] of patients from the identify service area of Buncombe, Madison, and Yancey Counties. With slightly more than half its patients projected to come from the identified service area, OSCA's proposed project does not truly meet the needs of the service area.

Furthermore, on page 23 of the application OSCA states,

> The patient origin percentages for the proposed Asheville SurgCare are projected to be same as the historical percentages for OSCA because many of the participating physicians are the same for both facilities and the new location is only five miles south of the current.

However, the physician letters included as Exhibit C.4 tell a different story. Although some of the participating physicians are OSCA credentialed, their surgical cases represented in the letters are NOT the majority of surgical cases projected by OSCA. The following table highlights the letters included in Exhibit C.4.

| Physician | Specialty | Cases | Existing OSCA Physician |
|---|---|---|---|
| Elder | Orthopaedics | 150 | Yes |
| Abrams | Orthopaedics | 150 | Yes |
| Minkin | Orthopaedics | 218 | Yes |
| Thornburg | Orthopaedics | 509 | Yes |
| West | Orthopaedics | 392 | Yes |
| Dement | Orthopaedics | 100 | Yes |
| Barnett | Orthopaedics | 25 | Yes |
| Lechner | Orthopaedics | 566 | Yes |
| Moody | Orthopaedics | 100 | Yes |
| Groh | Orthopaedics | 294 | Yes |
| Przynosh | Podiatry | 40 | Yes |
| Sheedy | Podiatry | 40 | Yes |
| Milich | Podiatry | 40 | Yes |
| Lawrence | Podiatry | 33 | Yes |
| Marne | Podiatry | 30 | Yes |
| Waldman | Podiatry | 30 | Yes |
| Total Cases from Existing OSCA Physicians | | 2,707 | |
| Looking Glass | Ophthalmology | 1,500 | No |
| Bakish | Pain Management | 200 | No |
| McDonough | Plastics | 115 | No |
| Halvorson | Plastics | 30 | No |
| Mashall | Plastics | 480 | No |
| Bare | Urology | 134 | No |
| Burriss | Urology | 173 | No |
| Hooper | Urology | 56 | No |
| Cargill | Urology | 123 | No |
| Brien | Urology | 101 | No |
| Total Cases from New OSCA Physicians | | 2,912 | |
| Total Cases | | 5,619 | |

The letters show that existing OSCA physicians propose to perform 2,707 surgical cases, while the new OSCA physicians propose to perform 2,912 surgical cases. Thus, more cases are proposed to be performed by new OSCA physicians than by existing physicians of which "many of the participating

physicians are the same for both facilities." Because 51.8 percent [ (2,912 / 5,619) x 100 ] of surgical cases identified in physician letters are from new OSCA physicians, the utilization of historical patient origin to project future patient origin is unreasonable. It should also be noted that the surgical case volume identified by new OSCA physicians was miscalculated on page 109 of the application.

Further, as discussed below in Criterion (7), not all the current OSCA physicians appear to support the project. This raises significant issues about the validity of OSCA's projections.

Accordingly, the OSCA application is nonconforming with Criterion (3).

### Blue Ridge

Blue Ridge is proposing an orthopedic only ambulatory surgical facility in a county that already has an orthopedic only ambulatory surgical facility, i.e., OSCA. Approval of the Blue Ridge application would therefore mean that Buncombe County would have two orthopedic only ambulatory surgical facilities, which is not needed. Approval of the Blue Ridge application would also maintain the status quo in Buncombe County, which currently has no freestanding multispecialty ambulatory surgical facility. Blue Ridge fails to adequately identify the need that this population has for the services proposed. Specifically, Blue Ridge asserts on page 40 of the application:

> Given that orthopaedic surgery is the most common outpatient surgical specialty in the service area, an orthopaedic ASC would be an effective alternative to increase access to ambulatory surgical services.

The table on page 40 of the application illustrates that in FY2017, 3,250 outpatient orthopedic surgical cases were performed at Orthopaedic Surgery Center of Asheville while 3,609 outpatient orthopedic surgical cases were performed at Mission Hospital. This indicates that 47.4 percent [ (3,250 / 6,859) x 100 ] of the outpatient orthopedic surgical cases performed in the service area had access to non-hospital based outpatient surgical charges. The table also illustrates that in FY2017, 2,378 outpatient ophthalmology surgical cases were performed at Asheville Eye Surgery Center, which indicates that 45.7 percent [ (2,378 / 5,201) x 100 ] of the outpatient ophthalmology surgical cases performed in the service area had access to non-hospital based outpatient surgical charges.

However, the table also indicates that 11 of the remaining 12 outpatient surgical specialties DO NOT have access to non-hospital based outpatient surgical charges; podiatry cases are also performed at Orthopaedic Surgery Center of Asheville. This means that 16,193 outpatient surgical cases or 56.3 percent [ (16,193 / 28,740) x 100 ] of outpatient surgical cases performed in the service area do not have access to non-hospital based outpatient surgical charges, which is 4.5 times [ 16,193 / 3,609 ] more outpatient surgical cases as compared to the remaining orthopaedic surgical cases performed at Mission Hospital. Thus, the majority of outpatient surgical cases performed in the service area do not have access to lower cost freestanding ambulatory surgical facility pricing. Clearly, the need that the Buncombe/Madison/Yancey OR Service Area has is for a multispecialty ambulatory surgical facility that can serve the greatest number of surgical conditions. Introducing a second orthopaedic ambulatory surgical facility in the service area would be unreasonable and unnecessary.

The total service area population is projected to be 322,704 by 2023. See page 34 of the SHP application. By comparison, Wake County's population 2016 population was estimated by NCOSBM at 1,026,748. See https://files.nc.gov/ncosbm/demog/muniestbycounty_2016.html. Wake County, with more than three times the projected population of the Buncombe/Madison/Yancey OR Service Area, can support two orthopaedic only ambulatory surgical facilities (Triangle Orthopaedics Surgery Center and Raleigh Orthopaedic Surgery Center). Wake County, unlike the Buncombe/Madison/Yancey OR Service Area, also has a diverse range of ambulatory surgical facilities. The Buncombe/Madison/Yancey OR Service Area simply does not have the population or the demand to support a second orthopaedic only ambulatory surgical facility. There is nothing in the Blue Ridge application to demonstrate that the Buncombe/Madison/Yancey OR Service Area has special characteristics to warrant a second orthopaedic only ambulatory surgical facility, to the exclusion of having its first multispecialty ambulatory surgical facility.

According to Table 6A, page 63 of the 2018 SMFP, there are thirteen ambulatory operating rooms in the Buncombe/Madison/Yancey OR Service Area. The award of two operating rooms to any one of the applicants in this review will increase the number of ambulatory operating rooms in the service area to fifteen. If the Blue Ridge application is approved 5 of these ambulatory operating rooms would be orthopaedic only. Thus, one-third of the ambulatory operating room capacity in the service area would be orthopaedic only. There is no need for one-third of the ambulatory operating room capacity in the service area to be orthopaedic only.

The problem with the Blue Ridge application is exacerbated when one considers just the ORs in the freestanding (i.e., non-hospital based) ambulatory surgical facilities in the Buncombe/Madison/Yancey OR Service Area. There are only 4 such operating rooms currently (OSCA has 3 and Asheville Eye has 2). See Table 6A, page 63 of the 2018 SMFP. The award of two operating rooms to any one of the applicants in this review increases the number of operating rooms in freestanding ambulatory surgical facilities to six. If Blue Ridge's application is approved, that means five out of six, or 83% of the operating rooms in freestanding ambulatory surgical facilities in the service area, would be orthopaedic only. This is unreasonable, unnecessary and does a disservice to the many other surgical patients in the service area who have needs other than orthopaedic surgery.

Since the State Medical Facilities Plan began regulating the development of operating rooms, there has never been a need determination for operating rooms in the Buncombe/Madison/Yancey OR Service Area. The likelihood that another operating room need determination for the Buncombe/Madison/Yancey OR Service Area will be identified in the State Medical Facilities Plan anytime in the near future supports the need to establish non-hospital based operating rooms that will benefit the most residents of the service area. Another single specialty, orthopaedic ambulatory surgical facility would only benefit EmergeOrtho patients, who already have access to non-hospital based operating rooms at OSCA.

The identified service area for the operating room need determination is Buncombe, Madison, and Yancey Counties. The table on page 21 of the application identifies its patient origin Blue Ridge projects in Years 1 through 3. Blue Ridge projects to serve only 41.1 percent [ ((1,459 + 105 + 81) / 4,007) x 100 ] of patients from the identify service area of Buncombe, Madison, and Yancey Counties.

The Blue Ridge projected utilization is unreasonable based on the data provided in the application. On page 122 of the application, Blue Ridge states,

> Please note the letters of support from BROSC physician members serve as documentation to support BROSC's methodology for projecting surgical cases to be performed in the proposed ASC. The specific methodology and assumptions for projecting surgical cases at BROSC are described in Steps 1 - 3 and are conservative in comparison to physician estimates provided in their letters of support.

However, this statement is not consistent with what Blue Ridge provides in the application.

> In consideration of the quantitative and qualitative benefits of the proposed project for local patients, BROSC reasonably projects that 60 percent of projected ambulatory surgical cases will be performed in the proposed ASC during project year one, 70 percent during project year two, and 75 percent during project year three. In estimating the projected percentages, BROSC considered the historical facility locations where ambulatory surgery cases were performed for the surgeons who will utilize BROSC and the likely preferences of those surgeons.

However, Blue Ridge fails to explain how "historical facility location" and "likely preferences" result in surgical cases shifting to the ambulatory surgical facility by 60 percent in Year 1, 70 percent in Year 2, and 75 percent in Year 3.

Additionally, in Year 3, Blue Ridge projects to perform 4,007 orthopaedic surgical cases in the two operating rooms. Blue Ridge uses the 2018 SMFP methodology's case time of 68.6 minutes per case to estimate 4,581 surgical hours in Year 3. Based on operating 250 days per year, Blue Ridge will have to operate its operating rooms for 9.2 [ (4,581 / 2) / 250 ] hours per day not including pre-operative and post-operative recovery time.

Furthermore, the service area's other orthopaedic only ambulatory surgical facility, OSCA, had an actual orthopaedic case time of 105 minutes per case. Utilizing this case time and 250 operating days would result in Blue Ridge having to operate its operating rooms for 14.0 [ (((4,007 x 105) / 60) / 2) / 250 ] hours per day not including pre-operative and post-operative recovery time. Blue Ridge's utilization projections are unreasonable and unachievable in only two operating rooms.

On page 19 of the application, Blue Ridge states,

> BROSC [Blue Ridge] will have an open Medical Staff whereby physicians may apply for surgical privileges at the ASC; thus, it is possible that BROSC may offer additional surgical specialties in the future. BROSC acknowledges that the conversion of a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program constitutes a "new institutional health service" per§ 131E-176(16)(r). Therefore,

any prospective additions and/ or changes to the surgical specialties offered at BROSC would be requested in a certificate of need application and developed pursuant to approval from the Healthcare Planning and Certificate of Need Section.

As this statement indicates, only EmergeOrtho surgeons will have surgical privileges at the facility and only EmergeOrtho surgeons will perform surgical cases at the facility. This is confirmed by the surgeon letters of support which are exclusively from EmergeOrtho physicians. Blue Ridge could have added any two other surgical specialties from either gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, or oral surgery with minimal surgical cases and have been prepared for future use as a multispecialty ambulatory surgical program. Blue Ridge chose to restrict access to only EmergeOrtho orthopaedic patients.

Additionally, on page 124 of its application, Blue Ridge states that it applied a 5.0 percent growth rate for the pain management cases performed in the procedure rooms. There is no explanation for this growth rate. The only information given is Dr. Hankley's historical procedures in CY 2017. Dr. Hankley's letter of support states that he anticipates performing 1,500 procedures at BROSC in Year 1. This number does not match Blue Ridge's projections that 60.0 percent of Dr. Hankley's cases will be performed at BROSC at Year 1. This inconsistency therefore calls the projections and the pro formas into question. If the number in Dr. Hankley's letter is correct, that means that more pain management procedures will be performed, which means more expense. It appears the pro formas are driven by the lower number provided on page 124.

Lastly, the projected volume of portable x-ray procedures (page 125) is also questionable. On page 125 of the application, Blue Ridge states that approximately 10 percent of the cases utilize a portable x-ray unit (C-arm). The application also states that the C-arm will be used in conjunction with pain management procedures, but no further details are provided. On page 121 of the application, Blue Ridge states 3,038 surgical cases will be performed at BROSC in Year 1. Using the 10.0 percent estimate provided on page 125, this equates to 304 portable x-ray procedures in Year 1. Yet for reasons it does not explain, Blue Ridge projects 1,346 portable x-ray procedures in Year 1. The Agency is being asked to assume, without any basis for doing so, that 1,042 C-arm procedures will be used in pain management cases in Year 1, which is exactly the number of pain management cases projected to be performed at BROSC, according to

the chart at the top of page 125 of the application (notwithstanding Dr. Hankley's letter to the contrary). Thus, the Agency is being asked to assume, without any basis for doing so, that every pain management procedure requires the C-arm. Dr. Hankley's letter says nothing about the C-arm so it is impossible for the Agency to validate the applicant's assumption.

Even though procedure rooms and C-arms are not specifically regulated under the CON Law, the applicant still must provide reasonable and adequately supported assumptions, which Blue Ridge failed to do.

Accordingly, the Blue Ridge application should be found nonconforming with Criterion (3).

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

OSCA

OSCA fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, OSCA did not adequately demonstrate that the least costly or most effective alternative has been proposed, and therefore its application does not satisfy Criterion (4).

Blue Ridge

Blue Ridge fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, Blue Ridge did not adequately demonstrate that the least costly or most effective alternative has been proposed, and therefore its application does not satisfy Criterion (4).

In addition, as Blue Ridge states on page 61 of the application,

> In 2017, EO/BRD physicians performed 4,600 ambulatory surgery cases. Approximately 85 percent of these cases were performed in hospital-based ORs. Therefore, there is a tremendous opportunity to reduce the cost of ambulatory surgery for EO/BRD patients.

As Blue Ridge clearly states, their application is only intended to benefit their patients, not the vast majority of non-orthopaedic outpatient surgical patients in the service area.

As previously stated ,16,193 outpatient surgical cases or 56.3 percent [ (16,193 / 28,740) x 100 ] of outpatient surgical cases performed in the service area do not have access to non-hospital based outpatient surgical charges, which is 4.5 times [ 16,193 / 3,609 ] more outpatient surgical cases as compared to the remaining orthopaedic surgical cases performed at Mission Hospital. Introducing a second orthopaedic ambulatory surgical facility in the service area would be unreasonable, as both Wake County and Mecklenburg County with over 3 times the population have two or fewer orthopaedic only ambulatory surgical facilities per service area.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

OSCA

OSCA fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, OSCA did not adequately demonstrate the immediate and long-term financial feasibility of the proposal, and therefore does not satisfy Criterion (5).

Additionally, there is a discrepancy between the table on page 65 of the application and the funding letter. On page 65, the source of capital financing is identified as Orthopaedic Surgery Center of Asheville LP. However, in Exhibit F.2 on page 142 of the application, Surgery Partners, Inc. is identified as the person incurring the obligation for the capital expenditure. Specifically, the last sentence of the 3rd paragraph states,

> Surgery Partners is committed to fund the Asheville SurgCare CON project capital costs amount of $9,238,973.

Accordingly, the OSCA application is nonconforming with Criterion (5).

Blue Ridge

Blue Ridge fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, Blue Ridge did not adequately demonstrate the immediate and long-term financial feasibility of the proposal, and therefore does not satisfy Criterion (5).

In addition, on page 5 of the application, two applicants are identified, Blue Ridge Outpatient Surgery Center, LLC and BRBJ Asheville.2, LLC. Form F.1a Capital Cost in Section Q identifies the same two applicants and their associated project capital costs. Finally, on page 70 of the application, the same two applicants are identified with their associated Sources of Capital Cost Financing.

However, Blue Ridge fails to provide Forms F.2, F.3, F.4, and F.5 for BRBJ Asheville.2, LLC to demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal. Specifically, the table on page 70 of the application, as well as the First Citizens Bank funding letter in Exhibit 17, indicates that BRBJ Asheville.2, LLC will use a bank loan to fund 100.0 percent of the project costs of $9,498,425 over 20 years (240 months) at 4.79 percent interest rate. As the following amortization table shows, based on these three loan factors; amount, period, and interest rate, BRBJ Asheville.2, LLC's monthly loan payment is $61,598 and its annual loan payments equals $739,065.

| | | | |
|---|---|---|---|
| Loan Amount | $ | 9,498,425 |
| Int. Rate/YR | | 4.79% |
| Act. Mortgage | | $61,589 |

| | | Balance | Monthly Payment | Interest | Principle | Annual Payment |
|---|---|---|---|---|---|---|
| Month | 1 | $9,498,425 | $61,589 | $37,915 | $23,674 | |
| Month | 2 | $9,474,751 | $61,589 | $37,820 | $23,769 | |
| Month | 3 | $9,450,982 | $61,589 | $37,725 | $23,864 | |
| Month | 4 | $9,427,118 | $61,589 | $37,630 | $23,959 | |
| Month | 5 | $9,403,160 | $61,589 | $37,534 | $24,054 | |
| Month | 6 | $9,379,105 | $61,589 | $37,438 | $24,150 | |
| Month | 7 | $9,354,955 | $61,589 | $37,342 | $24,247 | |
| Month | 8 | $9,330,708 | $61,589 | $37,245 | $24,344 | |
| Month | 9 | $9,306,364 | $61,589 | $37,148 | $24,441 | |
| Month | 10 | $9,281,923 | $61,589 | $37,050 | $24,538 | |
| Month | 11 | $9,257,385 | $61,589 | $36,952 | $24,636 | |
| Month | 12 | $9,232,748 | $61,589 | $36,854 | $24,735 | $739,065 |
| Month | 13 | $9,208,014 | $61,589 | $36,755 | $24,833 | |
| Month | 14 | $9,183,180 | $61,589 | $36,656 | $24,933 | |
| Month | 15 | $9,158,248 | $61,589 | $36,557 | $25,032 | |
| Month | 16 | $9,133,216 | $61,589 | $36,457 | $25,132 | |
| Month | 17 | $9,108,084 | $61,589 | $36,356 | $25,232 | |
| Month | 18 | $9,082,851 | $61,589 | $36,256 | $25,333 | |
| Month | 19 | $9,057,518 | $61,589 | $36,155 | $25,434 | |
| Month | 20 | $9,032,084 | $61,589 | $36,053 | $25,536 | |
| Month | 21 | $9,006,548 | $61,589 | $35,951 | $25,638 | |
| Month | 22 | $8,980,911 | $61,589 | $35,849 | $25,740 | |
| Month | 23 | $8,955,171 | $61,589 | $35,746 | $25,843 | |
| Month | 24 | $8,929,328 | $61,589 | $35,643 | $25,946 | $739,065 |
| Month | 25 | $8,903,382 | $61,589 | $35,539 | $26,049 | |
| Month | 26 | $8,877,333 | $61,589 | $35,435 | $26,153 | |
| Month | 27 | $8,851,180 | $61,589 | $35,331 | $26,258 | |
| Month | 28 | $8,824,922 | $61,589 | $35,226 | $26,363 | |
| Month | 29 | $8,798,559 | $61,589 | $35,121 | $26,468 | |
| Month | 30 | $8,772,091 | $61,589 | $35,015 | $26,573 | |
| Month | 31 | $8,745,518 | $61,589 | $34,909 | $26,680 | |
| Month | 32 | $8,718,838 | $61,589 | $34,803 | $26,786 | |
| Month | 33 | $8,692,052 | $61,589 | $34,696 | $26,893 | |
| Month | 34 | $8,665,159 | $61,589 | $34,588 | $27,000 | |
| Month | 35 | $8,638,159 | $61,589 | $34,481 | $27,108 | |
| Month | 36 | $8,611,051 | $61,589 | $34,372 | $27,216 | $739,065 |

However, Blue Ridge only proposes a facility rental rate payment of $34.00 per square foot per year, which based on 15,726 square feet, is equal to $534,684 per year or $44,557 per month. Blue Ridge identifies the $534,684 rental payment in its Form F.3. This rental rate would indicate that the applicant, BRBJ Asheville.2, LLC, cannot in either the short-term or the long-term fund its mortgage

payment to First Citizens Bank. BRBJ Asheville.2, LLC has an annual shortfall of $204,381 [ $739,065 - $534,684 ] in Year 1, $193,687 [ $739,065 - $545,378 ] in Year 2, and $182,780 [ $739,065 - $556,285 ] in Year 3. In order for the rental payment to adequately fund BRBJ Asheville.2, LLC's mortgage payment, the rental rate per square footage would have to increase from $34.00 per square foot to $47.00 [ $739,065 / 15,726 ] per square foot in Year 1.

Accordingly, the Blue Ridge application is nonconforming with Criterion (5).

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

OSCA

OSCA fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, OSCA did not adequately demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities, and therefore does not satisfy Criterion (6).

Blue Ridge

Blue Ridge fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Additionally, the table on page 40 of the application illustrates that in FY2017, 3,250 outpatient orthopedic surgical cases were performed at Orthopaedic Surgery Center of Asheville while 3,609 outpatient orthopedic surgical cases were performed at Mission Memorial Hospital. This indicates that 47.4 percent [ (3,250 / 6,859) x 100 ] of the outpatient orthopedic surgical cases performed in the service area had access to non-hospital based outpatient surgical charges. Blue Ridge does not explain why developing a second orthopaedic only ambulatory surgical facility that will only benefit EmergeOrtho patients and only orthopaedic patients, is not an unnecessary duplication of services when OSCA, which is less than 10 miles from the proposed Blue Ridge facility, already provides orthopedic ambulatory surgery services to the service area.

Consequently, Blue Ridge did not adequately demonstrate that its proposal will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Its application is nonconforming with Criterion (6).

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

OSCA

Surgeon support is critical to the OSCA project. Of the 31 identified credentialed physicians at OSCA on page 77 of the application, only 16 or slightly more than 50.0 percent of the current physicians provided support letters to OSCA for their proposed project.[1] See Exhibit C.4. If current OSCA surgeons do not support the OSCA project, this raises questions about the sufficiency of health manpower. Since OSCA did not demonstrate the availability of resource, including health manpower, its application should be found nonconforming with Criterion (7).

[1] One current OSCA-credentialed physician, Dr. West, submitted two letters. No letters of support were included from the following OSCA-credentialed physicians listed on page 77 of the OSCA application: Boykin, Cammarata, DePaolo, Eddings, Jarrett, Mangone, Massey, Maxwell, Melinski, Napoli, Riley, Rogers, Saenger, and Ward. Dr. DePaolo submitted a letter of support for himself and his partner, Dr. Abby Maxwell, for the SHP project. See page 240 of the SHP application. Most of the other OSCA-credentialed physicians who did not provide letters of support for OSCA are supporting the Blue Ridge application since they are EmergeOrtho shareholders or employees.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and
d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

OSCA

In the table on page 92 of the application, OSCA identifies that currently 6.1 percent of its surgical cases are Medicaid patients. While the table on page 95 indicates that OSCA will serve more Medicaid patients than it currently does in Year 2, the percentage of Medicaid patients is actually projected to decline to 5.0 percent in Year 2 of the project. See pages 93 and 95 of the OSCA application. With a declining Medicaid payor mix, OSCA should be found nonconforming with Criterion (13c).

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

OSCA

OSCA fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Consequently, OSCA did not adequately demonstrate that its proposal will enhance competition, and therefore does not satisfy Criterion (18a).

Additionally, competition in the service area is not enhanced by awarding two operating rooms to OSCA, a current ambulatory surgical facility provider in Buncombe County. As stated earlier, OSCA has a viable alternative to its identified facility constraints. It can submit a non-competitive CON application to relocate its existing ambulatory surgical facility, expand the size of its existing operating rooms, add procedure rooms, and convert to a multispecialty ambulatory surgical facility.

Blue Ridge

Blue Ridge fails to adequately demonstrate the need for the proposed project. See Criterion (3) for discussion. Adding another orthopedic only ambulatory surgical facility in the service area does not enhance competition except in the limited sphere of orthopedic surgery. As discussed in Criterion (3), the negative effects of concentrating scarce outpatient operating rooms and ambulatory surgical facility in the orthopaedic specialty are significant. If the Blue Ridge application is approved, 83% of the freestanding ambulatory surgical facility operating rooms in the service area would be orthopaedic only. Except for ophthalmology and orthopaedic surgeries, patients who want or need to have their outpatient surgery performed in Buncombe County would be forced to have their surgeries at Mission Hospital at higher prices. The Blue Ridge application does nothing to enhance competition more broadly because it does not provide access to a wide range of surgical specialties. Therefore, higher hospital based pricing will remain the norm for the majority of outpatient surgical procedures in the

Buncombe/Madison/Yancey OR Service Area. Consequently, Blue Ridge did not adequately demonstrate that its proposal will enhance competition, and therefore does not satisfy Criterion (18a).

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2018 SMFP, no more than two operating rooms may be approved for the Buncombe, Madison, and Yancey Service Area in this review. Because each application proposes to develop two operating rooms in the Buncombe, Madison, and Yancey OR Service Area, all three applications cannot be approved. For the reasons set forth below and in the remainder of the comments, the application submitted by SHP should be approved and all other applications should be disapproved.

The factors below were taken from the Agency Findings in the 2017 New Hanover County OR Review, which were issued on May 4, 2018. The New Hanover findings are the most current competitive operating room findings available.

## Conformity with Applicable Statutory and Regulatory Review Criteria

Since OSCA and Blue Ridge are not conforming to all applicable statutory and regulatory review criteria as discussed in these comments. Therefore, the applications of OSCA and Blue Ridge are not approvable.

The SHP application is conforming to all applicable statutory and regulatory review criteria. Therefore, its application is approvable.

## Geographic Accessibility

The 2018 SMFP identifies a need for two additional operating rooms in the Buncombe/Madison/Yancey OR Service Area. All applications propose to develop two new operating rooms in Buncombe County. SHP and Blue Ridge propose to develop their facilities in Arden, and OSCA proposes to develop its facility in Asheville, about 4 miles from the proposed locations of the SHP and Blue Ridge proposals. Accordingly, the three applications are comparable with respect to this factor

## Physician Support

OSCA provides physician letters representing 28 physicians of which only twelve of those physicians are not already OSCA physicians; Blue Ridge provides physician letters representing 17 physicians in one specialty; and SHP provides physician letters representing 36 physicians. SHP provides the greatest number of physician support letters of the three applications, and is the most effective alternative.

## Patient Access to Alternative Providers

In Buncombe/Madison/Yancey County OR Service Area, there are only three facilities with ORs: Mission Hospital, OSCA, and Asheville Eye Surgery Center. Neither Mission Hospital nor Asheville Eye Surgery Center is an applicant in this review.

OSCA is an existing provider of surgical services in an ASF in Buncombe County. If OSCA's application is approved, OSCA would be the only provider of operating rooms in an ambulatory surgical facility that provides surgical specialties other than ophthalmology in the Buncombe/Madison/Yancey OR Service Area.

If Blue Ridge's application is approved, Blue Ridge would develop the third single specialty ambulatory surgical facility and the second orthopaedic only ambulatory surgical facility in the Buncombe/Madison/Yancey OR Service Area. For the reasons previously stated, the service area does not need and cannot support another orthopaedic only ambulatory surgical facility.

SHP and its members, Park Ridge Health and Compass Surgical Partners, do not currently provide surgical services in the Buncombe/Madison/Yancey OR Service Area. Approval of SHP would introduce an alternative provider of operating room services and introduce the only multispecialty ASF in Buncombe/Madison/Yancey OR Service Area.

Therefore, with regard to providing patients in the Buncombe/Madison/Yancey OR Service Area with access to an alternative provider of outpatient operating room services, SHP is the most effective alternative.

## Patient Access to Low Cost Outpatient Surgical Services

OSCA is an existing ambulatory surgical facility offering outpatient operating room surgical services.

Blue Ridge is a proposed ambulatory surgical facility which would offer outpatient operating room surgical services.

SHP is a proposed ambulatory surgical facility which would offer outpatient operating room surgical services.

All three applications are or will be an ambulatory surgical facility offering outpatient operating room surgical services. Accordingly, all three applications are equally effective alternatives.

## Patient Access to Multiple Surgical Specialties

OSCA is a single specialty, orthopaedic, ambulatory surgical facility that proposes a multispecialty ambulatory surgical facility providing ophthalmology, orthopedic surgery, plastic surgery, podiatry and urology services, which equals five specialties.

Blue Ridge projects only orthopaedic cases, which equals one specialty.

SHP proposes a multispecialty facility providing gynecology, ophthalmology, orthopedic surgery, otolaryngology, podiatry services, hand, pain management, and surgical retina which equals eight specialties.

SHP is the most effective alternative and Blue Ridge is the least effective in providing Buncombe/Madison/Yancey County OR Service Area with access to more multiple surgical specialties.

## Access by Underserved Groups

### Charity Care

The following table shows projected Charity Care to be provided in the second operating year in terms of projected dollars. A second comparison is added showing charity care as a percent of gross patient revenue.

| | Charity Care | Percent of Gross Patient Revenue |
|---|---|---|
| SHP | $1,287,263 | 4.85% |
| OSCA | $286,906 | 0.50% |
| Blue Ridge | $213,465 | 0.81% |

As the table indicates, SHP is the most effective in both the amount of charity care provided and the amount of charity care provided as a percentage of gross patient revenue.

### Medicare/Medicaid

The following table shows projected total number of cases to be provided to Medicare/Medicaid recipients in the third operating year, based on the information provided in the pro forma financial statements.

| | Total Cases | Total Medicare Cases | Total Medicaid Cases | Total Medicare/ Medicaid Cases | Medicare/Medicaid Cases as a Percent of Total Cases |
|---|---|---|---|---|---|
| SHP | 7,477 | 3,381 | 531 | 3,912 | 52.3% |
| OSCA | 7,187 | 3,324 | 356 | 3,680 | 51.2% |
| Blue Ridge | 5,443 | 2,183 | 294 | 2,477 | 45.5% |

As shown in the in the table, SHP projects the highest percentage of cases to Medicare/Medicaid recipients. Accordingly, SHP is the most effective alternative with regard to access by underserved groups.

### Average Net Revenue per Case

The following table shows the projected net revenue per case in the third year of operation based on the information provided in the pro forma financial statements.

| | Project Year 3 | | |
|---|---|---|---|
| | # of Cases | Net Patient Revenue | Average Net Patient Revenue per Case |
| SHP | 7,477 | $12,409,783 | $1,659 |
| OSCA | 7,187 | $15,143,000 | $2,107 |
| Blue Ridge | 5,443 | $8,911,119 | $1,637 |

As shown in the table, in Project Year 3, SHP is within $22 of the lowest average net revenue per case.

### Average Operating Expense per Case

The following table shows the projected average operating cost per case in the third year of operation based on the information provided in the pro forma financial statements.

| | Project Year 3 | | |
|---|---|---|---|
| | # of Cases | Total Operating Expense | Operating Expense per Case |
| SHP | 7,477 | $8,327,099 | $1,114 |
| OSCA | 7,187 | $11,707,298 | $1,629 |
| Blue Ridge | 5,443 | $7,294,576 | $1,340 |

As shown in the table, in Project Year 3, SHP has the lowest average operating cost per case. SHP is the most effective alternative with respect to average operating expense per case.

In addition to the factors used in the recent New Hanover OR Review, SHP requests that the CON Section consider using the following additional factors in the 2018 Buncombe/Madison/Yancey OR Review.

### Access for Residents of the OR Service Area

The following table shows projected total number of cases to be provided to residents of the Buncombe/Madison/Yancey OR Service Area in the third operating year.

| | Total Cases | Buncombe Cases | Madison Cases | Yancey Cases | Total OR Service Area Cases | Total OR Service Area Cases as a Percent of Total Cases |
|---|---|---|---|---|---|---|
| SHP | 7,477 | 4,577 | 416 | 311 | 5,304 | 70.9% |
| OSCA | 7,187 | 3,468 | 302 | 190 | 3,960 | 55.4% |
| Blue Ridge | 5,443 | 1,981 | 142 | 109 | 2,232 | 41.0% |

As shown in the in the table, SHP projects the highest percentage of cases to originate from the Buncombe/Madison/Yancey OR Service Area. Accordingly, SHP is the most effective alternative with respect to this factor.

### Timetable to Operation

The following table shows the projected date of operation for the project ambulatory surgical facilities.

| | Date of Operation |
|---|---|
| SHP | 01 / 01 / 2020 |
| OSCA | 01 / 01 / 2021 |
| Blue Ridge | 01 / 01 / 2020 |

As shown in the in the table, OSCA is the least effective alternative with respect to this factor.

SUMMARY

The following is a summary of the reasons the proposal submitted by SHP is the most effective alternative in this review:

- SHP has the most physician support letters.
- SHP would introduce an alternative provider of surgical services and introduce the only multispecialty ambulatory surgical facility for surgical services in Buncombe/Madison/Yancey OR Service Area
- SHP is the most effective alternative in providing residents of the Buncombe/Madison/Yancey County OR Service Area with access to more surgical specialties.
- SHP provides the most charity care and the highest percentage of charity care compared to gross patient revenue.
- SHP projects the most Medicare surgical cases, the most Medicaid surgical cases, and the highest percentage of surgical cases to Medicare/Medicaid recipients.
- SHP has the lowest average operating cost per case.
- SHP has the highest number and percent of surgical cases from the Buncombe/Madison/Yancey County OR Service Area.

The following table:

1) Compares the proposal submitted by SHP with the proposals submitted by the other applicants; and

2) Illustrates the reasons the SHP application should be determined to be a more effective alternative than the proposals submitted by the other applicants.

| Comparative Factor | SHP | OSCA | Blue Ridge |
|---|---|---|---|
| Conformity with Rules and Criterion | Most Effective | Least Effective | Least Effective |
| Geographic Accessibility | Equally Effective | Equally Effective | Equally Effective |
| Physician Support | Most Effective (36) | Least Effective (28) | Least Effective (17) |
| Patient Access to Alternative Providers | Most Effective | Least Effective | Effective |
| Patient Access to Low Cost Outpatient Surgical Services | Equally Effective | Equally Effective | Equally Effective |
| Patient Access to Surgical Specialties | Most Effective (8) | Effective (5) | Least Effective (1) |
| Access by Underserved Groups | Most Effective (4.85%/52.3%) | Least Effective (0.50%/51.2%) | Least Effective (0.81%/45.5%) |
| Average Net Revenue per Case | Effective ($1,659) | Least Effective ($2,107) | Most Effective ($1,637) |
| Average Operating Expense per Case | Most Effective ($1,114) | Least Effective ($1,629) | Least Effective ($1,340) |
| Access by Operating Room Service Area | Most Effective (70.9%) | Least Effective (55.4%) | Least Effective (41.0%) |
| Timetable to Operation | Effective (01/01/2020) | Least Effective (01/01/2021) | Effective (01/01/2020) |