July 2, 2018

Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments on Buncombe County OR CON Applications

Dear Ms. Faenza:

Enclosed please find comments prepared by Blue Ridge Outpatient Surgery Center, LLC regarding the competing CON applications to develop two new operating rooms in Buncombe County to meet the need identified in the *2018 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of all the applications.

If you have any questions about the information presented here, please feel free to contact me at 828.281.7129. I look forward to seeing you at the public hearing.

Sincerely,

Stefan Magura

Stefan Magura
Chief Executive Officer
EmergeOrtho | Blue Ridge Division

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
BUNCOMBE COUNTY OPERATING ROOMS

Submitted by Blue Ridge Outpatient Surgery Center, LLC
July 2, 2018

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2018 State Medical Facilities Plan (SMFP)* for two new operating rooms (ORs) in the Buncombe/Madison/Yancey multi-county service area. In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes comments relating to the representations made by the competing applicants, and a discussion about whether the material in their applications complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the competing proposals represents the most effective alternative for development of two new ORs in the service area.

Specifically, the Healthcare Planning and Certificate of Need Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

(1) Enhances market competition for surgical services and provides local patients with a new alternative source for outpatient surgery in Buncombe County;
(2) Maximizes healthcare value in the delivery of health care services and represents a cost-effective alternative for development of the need-determined ORs, with competitive charges and costs;
(3) Demonstrates that projected surgical utilization is based on reasonable and adequately supported assumptions;
(4) Projects to develop the need-determined operating rooms in a timely manner; and
(5) Demonstrates conformity with applicable review criteria and standards.

The Agency typically performs a comparative analysis when evaluating all applications in a competitive batch review. The purpose of the comparative analysis is to identify the proposal that would bring the greatest overall benefit to the community. The table on the following page summarizes 16 objective metrics that the Agency should use for comparing the three applications in this OR batch review.

Buncombe County OR Batch Review
Applicant Comparative Analysis

Metrics			
Comparative	**Blue Ridge Outpatient Surgery Center (BROSC)**	**Summit Health Partners, LLC Western Carolina Surgery Center**	**Orthopaedic Surgery Center of Asheville, LP**
Enhance Market Competition	Yes	Yes	No
Conformity with Review Criteria	Yes	No	No
Physician Owned	Yes (100%)	No	Minority Interest
Improve Geographic Access	Yes	Yes	Yes
Access to Surgical Specialties	Single Specialty	Multi-specialty	Multi-specialty
Operational Date	1/1/2020	1/1/2020	1/1/2021
PY3 Gross Revenue/Case	$6,250	$5,793	$8,953
PY3 Net Revenue/Case	$2,221	$2,791	$2,239
PY3 Operating Cost/Case	$1,820	$2,644	$1,800
Self-Pay/Charity Care %	0.75%	10.30%	3.20%
Medicare %	37.50%	45.20%	46.20%
PY3 Medicare Cases	1,503	1,424	3,005
Medicaid %	5.79%	7.10%	5.00%
PY3 Medicaid Cases	232	224	325
RN Salary	$85,190	$74,928	$65,876
Surgical Tech Salary	$49,310	$36,592	$47,772

The table on the following page summarizes the relative effectiveness (1 being most effective and 3 being least effective) for each applicant in each of the comparative metrics.

Buncombe County OR Batch Review
Applicant Comparative Analysis

Rankings			
Comparative	**Blue Ridge Outpatient Surgery Center (BROSC)**	**Summit Health Partners, LLC Western Carolina Surgery Center**	**Orthopaedic Surgery Center of Asheville, LP**
Enhance Market Competition	1	1	3
Conformity with Review Criteria	1	2	2
Physician Owned	1	3	2
Improve Geographic Access	1	1	1
Access to Surgical Specialties	1	1	1
Operational Date	1	1	3
PY3 Gross Revenue/Case	2	1	3
PY3 Net Revenue/Case	1	3	2
PY3 Operating Cost/Case	2	3	1
Self-Pay/Charity Care %	3	1	2
Medicare %	3	2	1
PY3 Medicare Cases	2	3	1
Medicaid %	2	1	3
PY3 Medicaid Cases	2	3	1
RN Salary	1	2	3
Surgical Tech Salary	1	3	2
Average	**1.56**	**1.94**	**1.94**
Total	**25**	**31**	**31**

The applicant with the best ranking (lowest average/total) is the most effective alternative. Based on this comparative analysis, which shows BROSC ranks most favorably on the overall head-to-head comparisons, and considering that the BROSC application conforms to the Review Criteria and best achieves the Basic Principles of the 2018 SMFP (Policy GEN-3), BROSC is the most effective alternative for development of the two need-determined operating rooms.

Comparative Analysis

Conformity with Review Criteria

Without establishing conformity with all applicable statutory and regulatory review criteria, an application cannot be approved. For the reasons discussed below, WCSC is non-conforming with Criteria 5, 12, 13c, 18a, and 20. Further, OSCA is non-conforming with Criteria 1, 3, 4, 5, 6, 8, 12, 13c, and 18a. Thus, the only approvable application in this competitive batch review is BROSC. WCSC and OSCA are not effective alternatives with regard to conformity with review criteria.

Enhance Market Competition/Patient Access to Alternative Providers

Aside from Conformity with Review Criteria, this is the most important comparative factor in this batch review. The need determination for two additional operating rooms in the service area represents a rare opportunity to establish a new licensed healthcare facility. Buncombe County is the 7th most populous county in North Carolina, yet has only three licensed facilities with operating rooms (one hospital and two ASCs). Further, currently just 4 of 51 ORs in Buncombe County are located in a non-hospital setting. So, it makes sense that all three applicants propose to develop the new operating rooms in a dedicated outpatient setting. However, one of the applicants, Orthopaedic Surgery Center of Asheville (OSCA), is an existing ASC in Asheville and is simply proposing to relocate its facility and add two new ORs. Therefore, the proposal by OSCA will not introduce a new entrant into the healthcare licensed facility marketplace in Buncombe County. Approval of the OSCA application would result in a missed opportunity to increase competition and expand local access to care with a fourth licensed facility.

Geographic Accessibility

The 2018 SMFP identifies a need for two additional ORs in the Buncombe/Madison/ Yancey multi-county service area. All three applications propose to develop a new ASC in the southern portion of Buncombe County (within five miles of each other), where there are not currently any existing operating rooms. Therefore, with regard to geographic accessibility, the three proposed projects are comparable.

Physician Ownership Structure & Participation

As shown in the following table, the three applicants each propose a different ownership structure for their ASC projects.

Proposed Physician Ownership Structure

Comparative	Blue Ridge Outpatient Surgery Center (BROSC)	Summit Health Partners, LLC Western Carolina Surgery Center	Orthopaedic Surgery Center of Asheville, LP
Physician Owned	Yes (100%)	No	Yes (Minority Interest)

By operating in ASCs in which they are majority owners, physicians gain increased control over their surgical practices. Majority physician ownership of ASCs enables appropriate professional control over the clinical environment and over the quality of care delivered to patients. Surgery is a complex and specialized service, so it makes sense for the surgeons themselves to be able to assert greater control over surgery, including having greater authority in scheduling surgeries and in purchasing equipment. Surgeons, as owners and operators of the clinics where patients are already seen, are able to coordinate and schedule surgical procedures more conveniently, assemble teams of specially trained and highly skilled staff, ensure that the equipment and supplies being used are best suited to their techniques, and design facilities tailored to their specialties and to the specific needs of their patients.

Majority physician ownership also helps reduce frustrating wait times for patients and allows for maximum specialization and patient–doctor interaction. Majority physician-owned ASCs:

- Provide responsive, non-bureaucratic environments tailored to each individual patient's needs, and
- Enable physicians to personally guide innovative strategies for governance, leadership, and most importantly, quality improvement.

Western Carolina Surgery Center (WCSC) is the least effective alternative in terms of physician ownership because there are no physician members in WCSC. The only members of WCSC are Fletcher Hospital, Inc. and Compass Surgical Partners, LLC (see application page 11).

OSCA is the existing surgery center in Asheville and is majority-owned and managed by Surgery Partners, Inc. (54 percent ownership). Individual physicians collectively hold 46 percent ownership of the partnership. Physicians will continue to have only a minority ownership interest in OSCA; there is no indication for additional physician investment.

BROSC's proposal would introduce a new provider in the surgical marketplace in Buncombe County, one that will be 100 percent physician-owned and operated. BROSC's physician members are physician partners of the Blue Ridge Division of EmergeOrtho (EO|BRD) (formerly Blue Ridge Bone and Joint), a regional referral center for comprehensive orthopaedic care. Therefore, with regard to improving accessibility and enhancing market competition in Buncombe County, BROSC is the most effective alternative.

Maximize Healthcare Value

Average Charges, Reimbursement and Cost per Case

An essential issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of outpatient surgical services. In the current healthcare marketplace, where cost of care is a major concern with payors and consumers, the projected average charges, average reimbursement and average cost per surgical case are all important measures of healthcare value. In this OR batch review, BROSC projects competitive charges and costs, with the second lowest gross charges, the lowest average reimbursement per surgical case, and the second lowest average costs of the competing proposals. BROSC is the only applicant to rank either first or second in each metric. Please see the following tables which compare the charge and cost data for the third project year (consistent with the 2017 New Hanover OR batch review).

Projected Average Charge per Surgical Case*

Project Year	BROSC	WCSC	OSCA
3	$6,250	$5,793	$8,953

Source: CON Applications
*Reflects only technical charges. For surgical cases only, not non-surgical procedures.

Projected Average Reimbursement per Surgical Case*

Project Year	BROSC	WCSC	OSCA
3	$2,221	$2,791	$2,239

Source: CON Applications
*Reflects only technical charges. For surgical cases only, not non-surgical procedures.

Projected Average Cost per Case*

Project Year	BROSC	WCSC	OSCA
3	$1,820	$2,644	$1,800

Source: CON Applications
*Reflects total project expenses for all surgical cases and non-surgical procedures.

As has been pointed out, OSCA is an existing facility, so approval of the OSCA application does nothing to further the objective of expanding access to cost-effective surgical care. Additionally, OSCA's charges are significantly higher compared to BROSC. Orthopedic and podiatry cases comprise 60 percent of total surgical cases at OSCA during project year three [(3,756 + 126) ÷ 6,505]. Thus, it is reasonable to compare BROSC and OSCA with respect to charges and cost. BROSC is a more cost-effective alternative than OSCA.

It should be noted that facilities operated by Surgery Partners have a history of comparatively higher charges in CON batch reviews. In the 2016 New Hanover OR Review, Wilmington SurgCare (CON Project I.D. #O-11272-16) – operated by Surgery Partners – projected average charges of $10,789 per case in Year 3. In that Review, Cape Fear Surgical Center SurgCare (CON Project I.D. # O-11275-16) projected average charges of $6,893 per case and Surgery Center of Wilmington (CON Project I.D. #O-11277-16) projected average charges of $8,729 per case in Year 3. Surgery Partners was the highest average charge per case in the 2016 New Hanover OR batch review. Thus, it is no surprise that OSCA, which is majority owned by Surgery Partners, projects the highest average charge per case in this competitive OR batch review. OSCA's proposal is not cost-effective with respect to charges.

Comparing the WCSC and the BROSC applications is the most meaningful comparison with regard to maximizing healthcare value, and as shown in the above tables, BROSC proposes substantially lower net revenue/case and lower operating cost per case. It is important to consider that orthopaedic surgical cases are typically more complex, and

thus costlier than many other specialties. So, BROSC's projection of comparatively low costs and charges per surgical case is particularly noteworthy.

This comparative analysis demonstrates BROSC's commitment to competitive pricing and greater cost-effectiveness. Clearly, BROSC effectively satisfies the value requirement of Policy GEN-3 and is the comparatively superior application because it combines cost effectiveness with enhanced competition via the addition of a new market entrant in Buncombe County.

Quality in Delivery of Services

Clinical Staff Salaries

In recruitment and retention of high quality clinical personnel, salaries are a significant factor. All applicants provided salary information in Form H. As shown on the table below, as a new market entrant, BROSC demonstrates that its proposed salaries for RNs and Surgical Technicians are the most competitive, with a corresponding positive impact on quality of care.

RN & Surgical Tech Salaries, YR 2

	BROSC	WCSC	OSCA
Registered Nurse	$85,310	$74,928	$65,876
Surgical Tech	$49,310	$36,592	$47,772

Source: CON Applications

Access to Care

The 2018 SMFP determined a need for two additional operating rooms in the Buncombe/Madison/Yancey service area; therefore, the timeliness of the proposals is an important comparative consideration. As shown on the table below, BROSC and WCSC both project to develop the two operating room one year earlier than OSCA.

Thus, the OSCA application is not the most effective alternative in terms of offering timely access to services for local residents.

Projected Operational Date

BROSC	WCSC	OSCA
1/1/2020	1/1/2020	1/1/2021

Source: CON Applications

Access to Surgical Specialty Services

In prior CON Reviews, the Agency has used "Patient Access to Surgical Specialties" as a comparative metric. Generally, in a service area with limited access to non-hospital-based ambulatory surgical services, the application proposing to provide access to "***the broader range of different specialty surgical services***" in a freestanding ambulatory setting would appear the more effective alternative on this comparative factor. (Brunswick County 2016 OR Review).

In this Review, a meaningful comparison of the applicants on which one provides access to "***the broader range of different specialty surgical services***" is not possible simply by comparing a list of named specialty areas. For instance, the WCSC application names three specialty areas that will be offered in the proposed operating rooms: orthopedics, gynecology, and ENT. For information purposes, podiatry is not included as an individual specialty area per 10A NCAC 14C .2101(15) and hand is a subspecialty of orthopedic surgery per the American Board of Surgical Specialties. With respect to OB/GYN, the WCSC project is supported by only a single OB/GYN practice estimating only 30 surgical procedures annually (2.5 surgeries per month), or only 1 percent of projected surgical cases (30 ÷ 3,150). Therefore, the extent to which the WCSC application provides a broader range of different specialty surgical services is minimal.

Surgeries classified as "orthopaedic" typically represent a significant percentage of all surgeries performed on an outpatient basis. A comparison of projects that offer "orthopaedics" is not as simple as identifying the applicants that list "orthopaedics" as a specialty area. WCSC's application is supported by just one hand surgeon, two orthopaedic surgeons, a pain management physician, and a podiatric medicine and

surgery group. As compared to WCSC, the physicians supporting BROSC can offer patients a ***broader range of different specialty surgical services***.

Physicians supporting BROSC will be able to offer "specialty surgical services" ranging from arthroscopy of the hip, knee, shoulder, and wrist to minimally invasive joint replacement and spine surgery, among others. As posted on the Emerge Ortho |Blue Ridge Division website, the scope of treatments/surgeries offered by the physicians supporting the BROSC ASC will enable patient access to care for a host of conditions, including shoulder and spine related conditions, as well as:

Ankle and related injuries and conditions

- Achilles tendonitis
- Ankle arthritis
- Ankle deformities
- Alignment problems
- Bone spur
- Damaged cartilage
- Fractures
- Heel pain
- Lateral (outside) ligament damage
- Posterior impingement of the ankle
- Tendon injuries and conditions

Back and related injuries and conditions

- Spinal Stenosis
- Compression fractures
- Degenerative disc disease
- Fractured vertebrae
- Herniated discs
- Nerve issues
- Osteoporosis
- Degenerative spondylolisthesis
- Scoliosis
- Lumbar spondylosis/arthritis

Elbow and related injuries and conditions

- Bone spur
- Bursitis in the elbow
- Cubital tunnel syndrome
- Dislocated elbow
- Fractures
- Injuries to the tendons

- Lateral epicondylitis (tennis elbow)
- Ligament injuries
- Medial epicondylitis (golfer's elbow)
- Osteoarthritis
- Ulnar nerve compression

Foot and related injuries and conditions

- Clubfoot
- Forefoot conditions (hammertoes, bunions)
- Fractures
- Plantar fasciitis
- Metatarsal joint issues
- Muscle sprains or strains
- Tendonitis

Hand and related injuries and conditions

- Arthritis
- Carpal tunnel syndrome
- De Quervain's disease
- Dupuytren's contracture
- Flexor tendon damage
- Fractures
- Nerve injuries
- Rheumatoid arthritis
- Swan-neck deformity
- Trigger finger or thumb (digital tendon entrapment)

Hip and related injuries and conditions

- Broken hip or fractures
- Bursitis
- Cartilage degeneration
- Compressed nerves
- Deformity
- Flexor damage
- Impingement (femoral acetabular)
- Osteoarthritis
- Osteoporosis

Pain Management

- Complex regional pain syndrome
- Low back pain
- Muscle pain

- Other spine and musculoskeletal conditions
- Sciatica
- Shingles
- Sports-related injuries

Joints and related injuries and conditions

- Arthritis
- Artificial joint clicks or grinds
- Artificial joint failure
- Artificial joint has reached the end of its lifespan
- Cartilage degeneration
- Deformities
- Fractures
- Joint instability
- Osteoarthritis

Knee and related injuries and conditions

- A loose bone trapped within the joint
- ACL (anterior cruciate ligament) and MCL (medial collateral ligament) tears
- Dislocation
- Loose bone trapped within joint
- Osteoarthritis
- Patellar fracture (broken kneecap)
- Sports injury
- Sprained knee
- Tendonitis (medically referred to as tendinitis)
- Torn meniscus

Neck and related injuries and conditions

- Bone spurs
- Cervical kyphosis
- Cervical spinal stenosis
- Herniated discs
- Misuse or misalignment conditions
- Osteoarthritis
- Pinched nerves
- Soft tissue damage (sprains or strains)
- Spondylosis
- Whiplash

Sports-related pain

- Adductor (groin) tendonitis
- Anterior cruciate ligament (ACL) injuries
- Cartilage damage
- Concussion
- Hamstring injuries
- Knee or shoulder dislocation
- Meniscus tear
- Patella (knee) tendonitis
- Swimmer's shoulder
- Tennis elbow

Wrist and related injuries and conditions

- Arthritis
- Carpal tunnel syndrome
- De Quervain's contracture
- Dupuytren's disease
- Gout
- Hyperextension
- Ligament and tendon injuries
- Osteoarthritis
- Rheumatoid arthritis
- Sprains
- Tendonitis
- Trigger finger and/or thumb
- Wrist fractures

Specific comments regarding the Western Carolina Surgery Center application/CON Project I.D. #B-11520-18

General Comments

Given the limited available block time for a 2-OR ASC, it is unlikely that the specialties identified on page 26 of WCSC's application can effectively be made accessible to the prospective physicians and patients in a meaningful way. Indeed, WCSC projects to perform only 30 GYN surgical cases annually (2.5 surgeries per month), or only 1 percent of projected surgical cases (30 ÷ 3,150). Therefore, the extent to which the WCSC application provides access to a range of different specialty surgical services is minimal.

Furthermore, OR turnover time between cases of different specialties is likely to be longer compared to OR turnover time between cases of the same specialty because of the different equipment and set up that may be needed for the various types of specialties proposed. Offering different surgical specialties in two ORs results in a less-efficient ASC with less available capacity compared to a single-specialty ASC. Thus, the WCSC proposal is not the most effective alternative in this competitive batch review.

Comments specific to Criterion 5

The WCSC project capital cost table on Form F.1a does not show any financing costs associated with the projected loan. Typically loan financing equals at least 1 percent of the loan amount. In this case, assuming a loan of approximately $7.4M as shown on page 68, one would expect to see financing costs of approximately $74,000. Therefore, the WCSC project appears to be underfunded, and is therefore non-conforming to Criterion 5.

It is also notable that WCSC projects a difference of only $147 in average net revenue per case versus average cost per case during project year three (e.g., $2,791 average net revenue per case - $2,644 average cost per case = $147). Therefore, it is questionable that the WCSC proposal represents a financially realistic endeavor. In recent CON batch reviews, conditions have been imposed on approved applicants to maintain the charges represented in their CON applications; therefore, any unexpected increase in costs could have a devastating impact on the financial viability of WCSC's project.

Comments specific to Criterion 12

In his April 30, 2018 letter (page 280 of WCSC exhibit book), Mr. Hardaway from Massachusetts states that the WCSC project involves developing "*the ambulatory surgical facility in an existing building at 2514 Hendersonville Road*" and describes the project as "*the upfit of a medical office building*," a 12,000 square foot project.

As of April 30, it appears Mr. Hardaway has an incorrect understanding of the project as there is no existing building at 2514 Hendersonville Road. His April 30 letter indicates a budget for "*upfit for the 12,000 square foot project*." No mention is made in the April 30 letter of an undeveloped two-story 24,000 square foot building.

Yet, on May 8, 2017 (page 324 of WCSC exhibit book), Mr. Hardaway from Massachusetts states that the WCSC project "*involves the renovations and upfit of a medical office building*" which he then indicates will be two 12,000 square foot floors for a total of 24,000 square foot project.

Mr. Hardaway's floor plan at Tab 17 (page 316 of WCSC exhibit book) is for a 11,530 SF area. The floor plan does not make it clear whether the assumption was that the ASC would be one floor of a two-story building or a stand-alone one-story building. Reference is indicated to "Basement Elec" but it is not clear which floor the ASC will occupy. Additionally, WCSC's reference on page 92 to "isolation rooms" is not reflected in the line drawings on page 316. Furthermore, the architect letter in Exhibit F.1 and the bank funding letter in Exhibit F.2 project based on a facility square footage of 12,000. The applicant does not explain the difference between the two differing figures.

The line drawings provided by the applicant (page 316 of WCSC exhibit book) depict 11,530 square feet of space for the surgery center, which is inconsistent with the narrative description of 12,000 square feet in the application. This calls into question whether or not the cost, design and means of construction represent the most reasonable alternative. See FMC Dialysis Services Neuse River, Project I.D. No. K-11396-17, p. 19.

Building in Western North Carolina is well known to involve specific challenges due to the mountainous terrain. Notably, per page 90, site preparation and construction costs for the MOB are not included in the WCSC Application.

BROSC spent considerable time investigating and researching the feasibility and cost of constructing its proposed ASC in Arden which indicates that the project is highly likely to have anticipated and addressed the realities of Western North Carolina site preparation and construction. It is not clear that the Cost Estimates and plans for WCSC were prepared with a recognition of all relevant issues or by an individual with a full or clear understanding of the WCSC project proposal.

Finally, the line drawing shows that the proposed operating rooms will be sized at just 400 SF. This is small by contemporary standards of practice, and especially for a facility that purports that it will offer orthopaedic surgery. With the necessary instrumentation and equipment, it is likely that orthopaedic surgeons will balk at performing cases in such small operating rooms.

In summary, for the reasons previously described, WCSC is not able to demonstrate that the cost, design and means of construction represent the most reasonable alternative and that the project will not unduly increase the cost of providing services and is non-conforming to Criterion 12.

Comments specific to Criterion 13c

The WCSC payor mix projection for self-pay/indigent/charity care patients is neither reasonable nor comparable. As shown in Section L.3 of the application, WCSC projects a self-pay payor mix of 10.3 percent. It is difficult to see from where this figure was derived, as in Form F.5 (Gross Revenue Worksheets) WCSC portrays a self-pay mix of 2.5 percent for each surgical specialty. Therefore, WCSC did not reasonably identify the medically underserved groups and the extent to which they will utilize the proposed service and is non-conforming to Criterion 13c.

It is also important to note that, as a direct point of comparison, as shown on the Form F.5 (page 135), WCSC projects no Medicaid access for the orthopaedic/hand/podiatry specialty in its ASC. Orthopaedics is the single largest volume specialty for outpatient surgery in the service area. By comparison, BROSC projects a 5.79 percent Medicaid mix for orthopaedic cases.

Comments specific to Criterion 18a

Because the WCSC application is non-conforming with Criteria 5 and 13c, it should also be found non-conforming with Criterion 18a. WCSC did not

adequately demonstrate the financial feasibility of the proposal and did not reasonably identify the medically underserved groups and the extent to which they will utilize the proposed service. Thus, the proposed WCSC project will not have a positive impact on competition.

WCSC did not reasonably demonstrate how any enhanced competition will have a positive impact upon the cost-effectiveness to the services proposed. In fact, the WCSC application is the least cost-effective option of the three applicants. Specifically, as shown in the table on the following page, WCSC projects higher reimbursement and operating cost per case than BROSC.

Comparison of Projected Reimbursement and Costs

Third Operating Year	BROSC	WCSC
Per Case:		
Net Revenue	**$2,221**	$2,791
Cost	**$1,820**	$2,644

Source: CON applications

Comments specific to Criterion 20

Question O.3. (b) states, "*Document that the facilities identified in response to Section O, Question 3(a) have provided quality care during the 18 months immediately preceding submission of the application (18-month look-back period)*."

On page 115, WCSC refers to Exhibit O.3 (Tab 23) for documentation which it contends is responsive to the aforementioned question. However, Exhibit O.3 only includes a letter from Park Ridge Health documenting the provision of quality care during the 18-month look-back period (p.376). Exhibit O.3 does not include documentation from Compass Surgical Partners regarding the provision of quality care at Capital City Surgery Center or Holly Springs Surgery Center.

It is the applicant's burden to provide the documentation needed to demonstrate conformity to Criterion 20. The documentation must be included in the application as submitted. Absent any documentation regarding the provision of quality care at Capital City Surgery Center or Holly Springs Surgery Center, WCSC did not meet its burden. Consequently, the application is nonconforming to Criterion 20.

Specific comments regarding the Orthopaedic Surgery Center of Asheville application/CON Project I.D. #B-11514-18

General Comments

OSCA is an existing ASC. Addition of two ORs at OSCA is not the most effective alternative in terms of community benefit or competition. Buncombe County is the 7th most populous county in North Carolina, yet has only three licensed facilities with operating rooms (one hospital and two ASCs). Further, currently just 4 of 51 ORs in Buncombe County are located in a non-hospital setting. OSCA is simply proposing to relocate their facility and add two new ORs. Therefore, the proposal by OSCA will not introduce a new entrant into the healthcare licensed facility marketplace in Buncombe County. Approval of the OSCA application would result in a missed opportunity to increase competition and expand access to care with a fourth licensed facility.

Comments specific to Criterion 1

OSCA does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, OSCA does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

Per page 9 of its application, OSCA will not own the building where the proposed ASC will be located. The building owner is Ryan Companies US Inc. The building owner is not identified as an applicant in Section A. However, OSCA's written statement in response to GEN-4 (page 15 of application) clearly encompasses steps that the unrelated non-applicant builder will undertake (for example, building insulation, HVAC, and energy efficient windows). To the extent that OSCA will lease space in which the proposed ASC will be developed and the building owner is not an applicant for the project, the ability of the applicant to develop the building in a manner consistent with Policy GEN-4 is questionable.

Comments specific to Criterion 3

OSCA describes in Section C and Form C that "*continued growth of orthopedic and podiatry OR cases and nonsurgical pain procedures at Orthopedic Surgery Center of Asheville is projected based on 2.44 percent annual growth. Orthopedic and podiatry cases and pain management procedures are projected to shift to the new Asheville SurgCare facility in 2021 with continued 2.44 percent annual growth.*" (see application pages 40 and 107). However, OSCA failed to describe why the 2.44 percent growth rate for orthopedic and podiatry cases is reasonable.

A review of OSCA's recent surgical utilization (shown on the following table) indicates the projected growth rate of 2.44 percent (for orthopedic and podiatry cases) is not supported.

Orthopedic Surgery Center of Asheville
Orthopedic & Podiatry Surgery Cases, FY2013-FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
OP Surgical Cases	3,162	3,201	3,138	3,016	3,359
% Change		*1.2%*	*-2.0%*	*-3.9%*	*11.4%*
Surgical Specialists*	23	22	19	26	25

*Excluding anesthesiologists
Source: OSCA annual license renewal applications (2014-2018)

The 4-year compound annual growth rate (CAGR) for orthopedic and podiatry cases at OSCA is 1.5 percent. The 3-year CAGR is 1.6 percent. OSCA's recent surgical growth trends do not support the applicant's assumption that orthopedic and podiatry surgical cases will increase 2.44 percent during each of the next six years, i.e. 2018-2023. The one-year increase of 11.4 percent from FY2016 to FY2017 is not sufficient to support the reasonableness of OSCA's projected utilization because the facility previously experienced two consecutive years of negative growth. OSCA failed to describe the reasons for the two years of decreasing volume and why it is reasonable to assume the trend will cease.

Orthopedic and podiatry cases comprise 60 percent of total surgical cases at OSCA during project year three [(3,756 + 126) ÷ 6,505]. Absent any information in OSCA's application regarding to support the reasonableness of the described growth rate, OSCA's projected OR utilization is not reasonable and adequately supported. Consequently, the application is nonconforming to criterion 3.

The existing OSCA facility in Asheville provides only orthopedic and podiatry surgical cases. Instead of projecting to remain single-specialty for orthopedics, OSCA has proposed to add ophthalmology, plastic and urology cases. By proposing to add cases in other specialties, OSCA identifies its proposed Center as "multi-specialty" in the CON Comparative Analysis.

Asheville already has an eye surgery center. Beyond a physician support letter, the OSCA Application presents no methodology to project need in relation to its projected volume of eye cases. In other words, the need for increased "access" to an ASC for eye cases is not established in in the OSCA Application.

The eye doctors who propose to support OSCA in its new location presently practice at Pardee Hospital and Transylvania Community Hospital in Henderson and Transylvania Counties, south of Buncombe County. These eye doctors propose to perform 1,450 cases out of the 6,199 cases in Project Year 1. These cases represent about 23 percent of the cases to be performed at the new OSCA. Yet, the patient origin for OSCA is projected to mirror the historical OSCA patient origin for orthopedic and podiatry cases from its most recent LRA. It is unlikely that the patient origin will remain the same when over 23 percent of the cases will be eye cases shifted from an ophthalmology group with offices in Brevard and Henderson that historically performs surgery cases at Pardee Hospital and Transylvania Community Hospital.

Comments specific to Criterion 4

As described previously, OSCA does not demonstrate that projected surgical utilization is based on reasonable and adequately supported assumptions. Therefore, the application is not conforming to Criterion 4.

Also, to the extent it argues that the existing building is small/inadequate (see pages 25-30 of OSCA application), OSCA can simply submit a CON application to replace and relocate its facility. OSCA failed to discuss this alternative in Section E. If there are such significant facility constraints present in the existing facility, OSCA failed to discuss why it has never contemplated replacing and relocating the facility in the past. Furthermore, in this CON batch review, OSCA could be approved to relocate its facility without adding ORs. The Agency has made similar decisions in competitive OR batch reviews, i.e., the approval issued by the CON Section to Cape Fear Surgical and NHRMC (CON Project I.D. O-11275-16) in the 2016 New Hanover Review. Doing so would effectively address

any concerns about building age, size constraints, etc. at OSCA while still introducing a new competitor (i.e., BROSC) in the service area.

OSCA projects a later date for bringing the two operating rooms online than BROSC. OSCA's proposed date of January 1, 2021 is one year later than the other applicants. Given the 2018 SMFP's determination that two additional operating rooms are needed locally in 2020, the OSCA application is not the most effective alternative in terms of offering timely access to services for Buncombe County residents.

Moreover, OSCA does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the need because it is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Comments specific to Criterion 5

As described previously, OSCA does not demonstrate that projected surgical utilization is based on reasonable and adequately supported assumptions. Because OSCA does not reasonably project utilization of its facility, it does not demonstrate the financial feasibility of the proposal. Therefore, the application is not conforming to Criterion 5.

The Form F.3 assumptions state that utilities project to increase 3 percent annually. However, in Form F.3 OSCA projects the utilities to increase at 2 percent annually.

The Form F.3 projected expenses for medical supplies, other supplies, and equipment maintenance do not match to the accompanying assumptions.

The equipment budget in Exhibit F.1 consists of a brief summary table of four lines to portray the estimated $3.8 million equipment budget. This table does not reflect any itemization of equipment or instrumentation for the proposed multi-specialty ASC. The application thus lacks the details and specificity necessary for the Agency to determine the reasonableness of the project capital cost projections. Thus, the Agency also will be unable to ascertain that the applicant demonstrated the availability of funds for the capital and operating needs.

The facility lease agreement in Exhibit M.3 indicates an operating expense of $8.50/square foot, plus a separate property management fee of 4 percent of the

annual building rent. However, the proforma financial statements do not reflect these substantive expenses in Form F.3.

All these financial inconsistencies and inadequacies indicate that OSCA did not demonstrate the financial feasibility of the proposal based upon reasonable projections of the costs and charges for providing health services and is therefore non-conforming to Criterion 5.

Comments specific to Criterion 6

OSCA did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in Buncombe County. Specifically, OSCA did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the ORs that OSCA already owns in Buncombe County. See discussion regarding projected utilization in Criterion 3. Therefore, the OSCA application is non-conforming to Review Criterion 6.

Comments specific to Criterion 8

In Section I.1 OSCA indicates that it will have pathology services provided by Pathologist Medical Laboratory. However, the application does not provide any documentation by PML to provide such ancillary service. Therefore, OSCA failed to demonstrate the provision of necessary ancillary and support services and is non-conforming to Criterion 8.

Comments specific to Criterion 12

Section K.1 of the OSCA application and the architect letter in Exhibit F.1 both specify a total facility square footage of 23,312. However, Exhibit M.3 and the proforma financials project based on a facility square footage of 22,683. The applicant does not explain the difference between the two differing figures. Therefore, OSCA is not able to demonstrate that the cost, design and means of construction represent the most reasonable alternative and that the project will not unduly increase the cost of providing services and is non-conforming to Criterion 12. See FMC Dialysis Services Neuse River, Project I.D. No. K-11396-17, p. 19.

Comments specific to Criterion 13c

As stated on page 94 of its application, OSCA projects the payor mix for non-surgical procedures to be exactly the same as the projected surgical case payor mix. The applicant does not provide any explanation for why this makes sense or is a reasonable assumption.

The OSCA payor mix projection for self-pay/indigent/charity care patients is neither reasonable nor comparable. As shown in Section L.1 of the application, OSCA shows that during FFY17 its self-pay/charity care payor mix was 0.46 percent. Yet in Section L.3 the projected payor mix for the renamed Asheville SurgCare is 3.2 percent (2.7 percent self-pay and 0.5 percent charity care). This represents a nearly 600 percent projected increase in access for indigent patients. During the last fiscal year, OSCA provided no charity care access (e.g. zero charity care cases), yet now, after three decades in business, the OSCA owners claim a desire to establish a relationship with local community health clinics to enable access for low income and charity care patients. One might easily regard this as a cynical effort to curry favor with DHSR for the OSCA CON application in this batch review by projecting charity care cases. Asheville SurgCare did not reasonably identify the extent to which medically underserved groups will utilize the proposed service and is thus non-conforming to Criterion 13c.

It is also important to note that the Asheville SurgCare self-pay projection of 2.7 percent is heavily influenced by the proposed plastic surgery service. As shown on page 95 of its application, Asheville SurgCare projects 20.5 percent of plastic surgery cases to be self-pay. Based on a review of the websites for the three plastic surgeons who included letters of support for OSCA, these plastic surgery cases are likely to be purely cosmetic cases, and thus are elective surgeries that are paid for out-of-pocket. Therefore, a comparison of the projected amount of self-pay cases between Asheville SurgCare and BROSC is of no value, because the case mix is completely different.

Comments specific to Criterion 14

In Exhibit M.2, OSCA includes a copy of a letter to Asheville-Buncombe Technical Community College regarding establishing a clinical training agreement. OSCA has been a licensed ASC for approximately 35 years, and yet apparently has not established an agreement with a clinical training program. It would seem that this long history provides abundant evidence that the applicant has not demonstrated a willingness to accommodate the clinical needs of health

professional training programs in the area, and its application is thus non-conforming to Criterion 14.

Comments specific to Criterion 18a

Because the OSCA application is non-conforming with Criteria (3), (4), (5), (6), and (13c), it should also be found non-conforming with Criterion (18a). OSCA did not adequately demonstrate the need the population projected to be served has for the proposed project and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in Buncombe County. OSCA did not adequately demonstrate the financial feasibility of the proposal, nor did OSCA reasonably project access for medically underserved groups. Thus, the proposed OSCA project will not have a positive impact on competition.

CONCLUSION

For the foregoing reasons, both competing applications should be disapproved. They fail to satisfy multiple CON criteria and are also comparatively inferior to the Blue Ridge Outpatient Surgery Center application. The BROSC application should be approved because it satisfies all the applicable CON criteria and is comparatively superior to the competing applications.