Competitive Comments Regarding Buncombe County
2018 Operating Room Need Determination
Submitted by Orthopaedic Surgery Center of Asheville

The following comments are submitted in accordance with N.C.G.S. §131E-185(a1)(1) regarding the representations in the project applications, including a comparative analysis and discussion, as to whether the applications comply with the Certificate of Need (CON) review criteria. Three applications were submitted in response to the need determination in the 2018 State Medical Facilities Plan:

Western Carolina Surgery Center, Project ID No. B-11520-18 ("WCSC")
Blue Ridge Outpatient Surgery Center, Project ID No. B-11515-18 ("BROSC")
Asheville SurgCare, Project ID No. B-11514-18 ("SurgCare")

Comparative Comments

The SurgCare application is the superior proposal based on multiple factors:

- Most effective for geographic accessibility
- Only application that demonstrates conformity to CON Criteria
- Largest number of physician letters documenting intent to perform procedures
- Largest medical staff
- Largest number of surgical specialties to utilize the operating rooms
- Highest RN staffing levels based on hours per patient and FTEs per room
- Highest staffing expense as percentage of total expenses
- Highest Medicare percentage and highest combined Medicare and Medicaid percentage
- Only application to demonstrate financial feasibility based on reasonable assumptions

The tables on the following pages provide the comparative data that was obtained from the applications.

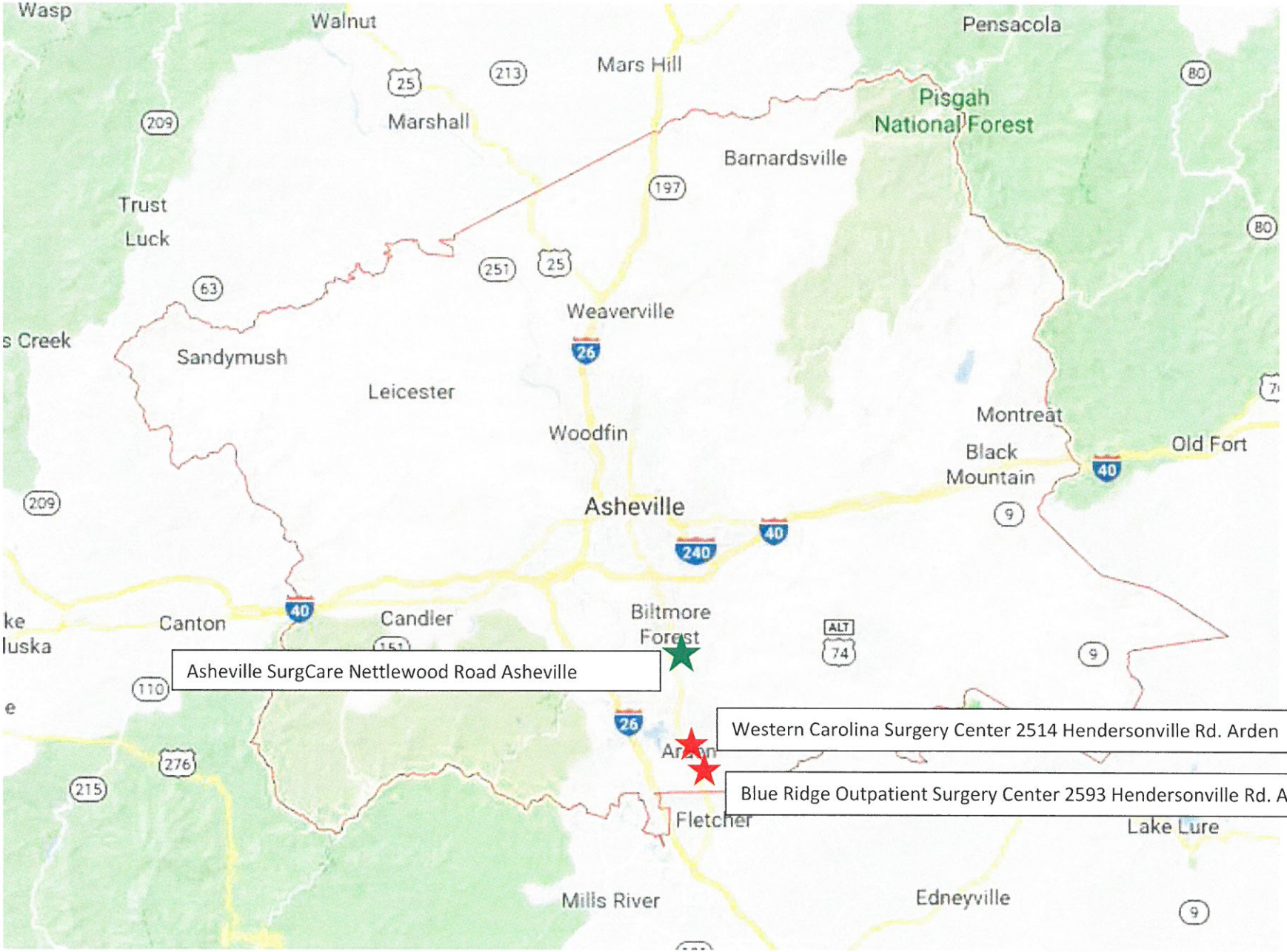
	Western Carolina Surgery Center	Blue Ridge Outpatient Surgery Center, LLC	Asheville SurgCare
	B-11520-18	B-11515-18	G-11514-18
Project Descriptions	Develop a new ASF with two ORs and three procedure rooms	Develop a new ASF with two ORs and two procedure roooms	Develop a new ASF with five ORs and two procedure rooms
Address and Locations	2514 Hendersonville Rd. Arden	2593 Hendersonville Rd. Arden	Nettlewood Drive Asheville
Geographic Location	South Buncombe Near the Border With Henderson County	South Buncombe Near the Border With Henderson County	South Central Buncombe - 5 Miles south of Current OSCA
Conformity to CON Criteria and Performance Standard	Nonconforming to Criteria 1, 3, 4, 5, 6, 7, 13c, 18a, and 10A NCAC 14C 2103	Nonconforming to Criteria 1, 3, 4, 5, 6, 13c, 18a and 10A NCAC 14C.2103	Conforming to all Criteria and the Performance Standards
Patient Access to Alternative Provider	New Provider / New Multi-Specialty ASF	New Provider / New Single Specialty ASF	Existing Provider / New Multi-Specialty ASF
Physician Support and Projected Number of Physicians on Medical Staff	29 signed support letters indicating intent to obtain privileges and 29 physicians on medical staff	17 signed support letters indicating intent to obtain privileges and 17 physicians on medical staff	34 signed support letters and projected 45 physicians on medical staff
Total Specialties Projected	Gynecology, Orthopaedics Podiatry, Otolaryngology, Ophthalmology, Pain Management	Orthopaedics, Pain Management	Orthopedics, Podiatry, Ophthalmology, Plastic Surgery, Urology, Pain Management (Spine Implants)
Surgical Specialties Performed in ORS	Gynecology, Orthopaedics, Podiatry, Otolaryngology	Orthopaedics	Orthopedics, Podiatry, Ophthalmology, Plastic Surgery, Urology, Pain Management (Spine Implants)

	Western Carolina Surgery Center	Blue Ridge Outpatient Surgery Center, LLC	Asheville SurgCare
	B-11520-18	B-11515-18	G-11514-18
YR 2 Total RN Staff	12.5	11.6	25
Ratio of Total RN FTEs per OR and PR	12.5 / 5 = 2.5	11.6 / 4 = 2.9	25 / 7 = 3.57
Staffing Expenses as Percentage of Total Expenses (Year 2)	1,735,776 8,268,478 **21.0%**	1,767,555 6,596,522 **26.8%**	3,186,064 11,212,691 **28.4%**
Access by Underserved Groups (OR Cases)	OR Cases Medicare 40.0% Medicaid 9.8% Combined 49.8%	OR Cases Medicare 37.50% Medicaid 5.79% Combined 43.29%	OR Cases Medicare 46.24% Medicaid 4.95% Combined 51.19%
Projected Average Gross Revenue Per OR Case	Incorrectly Reports Combined Revenue for OR and Procedure Room for ENT	OR Cases YR 1 $6,251 YR 2 $6,251 YR 3 $6,251	OR Cases YR 1 $8,434 YR 2 $8,692 YR 3 $8,953
Projected Average Net Revenue Per OR Case	Incorrectly Reports Combined Revenue for OR and Procedure Room for ENT	OR Cases YR $2,221 YR 2 $2,221 YR 3 $2,221	OR Cases YR 1 $2,111 YR 2 $2,174 YR 3 $2,234
Projected Average Cost per OR and Procedure Room Combined	OR and PR Volume YR 1 $1,229 YR 2 $1,106 YR 3 $1,114	OR and PR Volume YR 1 $1,408 YR 2 $1,342 YR 3 $1,340	OR and PR Volume YR 1 $1,559 YR 2 $1,598 YR 3 $1,629

Geographic Accessibility

All three of the applicants propose to develop ambulatory surgical facilities in Buncombe, the most populous county in the Buncombe/Madison/Yancey Service area.
However, the proposed sites for WCSC and BROSC are in extreme southern Buncombe County, distant from both Madison and Yancey Counties and the majority of senior and low-income persons in the service area who reside in Asheville. The SurgCare location in Asheville is five miles south of the current location of Orthopaedic Surgery Center and is in reasonable proximity to the Madison and Yancey County populations and the low-income population of Buncombe County.

The following maps show the locations of the proposed ambulatory surgical facilities and the census tracts in Buncombe County with the highest poverty levels. The SurgCare location in south Asheville is the more effective location for geographic accessibility for low income persons in Asheville. Also, the SurgCare site is closer to the intersection of Interstate 40 with Highway 26 to provide superior access for residents in eastern and western Buncombe County.


Asheville SurgCare Nettlewood Road Asheville
Western Carolina Surgery Center 2514 Hendersonville Rd. Arden
Blue Ridge Outpatient Surgery Center 2593 Hendersonville Rd. Arden
Wasp
Walnut
Pensacola
Mars Hill
Marshall
Pisgah National Forest
Barnardsville
Trust
Luck
Weaverville
Sandymush
Leicester
Woodfin
Montreat
Black Mountain
Old Fort
Asheville
Canton
Candler
Biltmore Forest
Fletcher
Lake Lure
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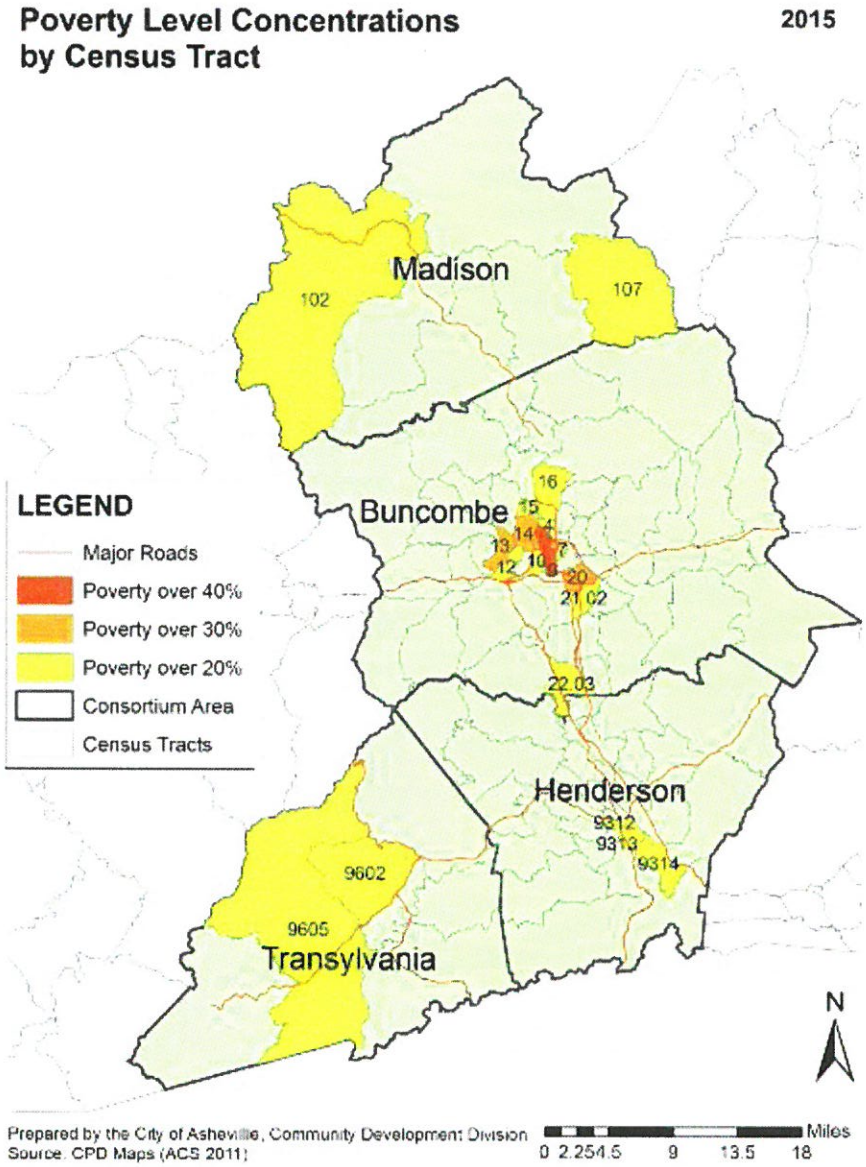

Poverty Level

	Asheville SurgCare Nettlewood Road, Asheville	Western Carolina Surgery Center 2514 Hendersonville Rd, Arden	Blue Ridge Surgery Center 2593 Hendersonville Rd, Arden
Travel Distance to Border of Buncombe / Henderson County Line (Google Maps)	5.4 Miles from Buncombe / Henderson County Line	0.9 miles from Buncombe / Henderson County Line	0.4 miles from Buncombe / Henderson County Line

As seen in the table above, the WCSC and BROSC locations are in close proximity to the southern border of Buncombe County which makes the locations the furthest possible from the populations of Madison and Yancey Counties. The SurgCare location in southern Asheville is a more effective location for geographic access.

Conformity to CON Review Criteria

The WCSC and BROSC applications are nonconforming to multiple CON Criteria and the Performance Standard causing their proposals to be unapprovable. The SurgCare application conforms to the Criteria and Performance Standards and is the most effective application.

Patient Access to New ASC Provider

All three applications propose to develop new ambulatory surgical facilities that will offer patients a new alternative provider scope of services and location. While the SurgCare application involves the relocation of operating rooms from an existing ASC facility, the application demonstrates that the existing building is outdated and has significant limitations. Thus, the proposed new SurgCare replacement facility is equally effective as the WCSC and BROSC proposals regarding patient access to a new ASC.

Medical Staff Support

The SurgCare application includes support from 34 physicians indicating their intent to utilize the facility and documents that the medical staff will total 45 physicians. WCSC includes support from 29 physicians indicating their intent to utilize the facility and documents that the medical staff will total 29 physicians. BROSC includes support from 17 physicians indicating their intent to utilize the facility and documents that the medical staff will total 17 physicians. Therefore, the SurgCare application is the most effective proposal with regard to the medical staff support.

Surgical Specialties Performed in Operating Rooms

The number of surgical specialists that will perform cases in the operating rooms is a relevant comparative factor because the need determination is for operating rooms and not procedure rooms. WCSC states that its operating rooms will be utilized to perform gynecology, orthopedics, podiatry and otolaryngology procedures for a total of four specialties. BROSC states that its operating rooms will be utilized for only orthopedic surgery. SurgCare documents that its operating rooms will be utilized for orthopedic, podiatry, ophthalmology, plastic surgery, urology and pain management (spine implant surgery) for a total of six specialties. Thus, the SurgCare application is the most effective proposal for surgical specialties performed in operating rooms.

Total RNs per OR and Procedure Room (Combined) in Year 2

The Association for Operating Room Nurses Position Statement on Perioperative Safe Staffing and On-Call Practices states, **"Staffing for the perioperative setting is dynamic in nature and depends on clinical judgment, critical thinking, and the administrative skills of the perioperative registered nurse (RN) administrator. Patients undergoing operative and other invasive procedures require perioperative nursing care provided by a perioperative RN, regardless of the setting."**

The Patient Safety Primer published by Agency for Healthcare Research and Quality, (https://innovations.ahrq.gov/qualitytools/patient-safety-primers) documents that nurses have a critically important role in ensuring patient safety by monitoring patients for clinical deterioration, detecting errors and near misses, understanding care processes and weaknesses inherent in some systems, and performing countless other tasks to ensure patients receive high-quality care.

The following tables provide the comparative RN staffing for Years 1 and 2 for each of the proposed project to analyze how each of the applicants propose to add incremental staff in relationship to the projected facility utilization.

	Year 1	Year 2	% Increase
WCSC OR + PR Patients	5,628	7,477	32.85%
WCSC RN FTEs	10.5	12.5	19.05%
WCSC RN Hrs per Patient	3.9	3.5	-10.39%
BROSC OR + PR Patients	4,080	4,917	20.51%
BROSC RNs	10.1	11.6	14.85%
BROSC RN Hrs per Patient	5.1	4.9	-4.70%
SurgCareOR + RR Patients	6,849	7,016	2.44%
SurgCareRNs	24	25	4.17%
SurgCare RN Hrs per Patient	7.3	7.4	1.69%

The WCSC application projects that utilization will increase by 32.85 percent but only projects to increase the RN staff by 19.05% from 10.5 Full Time Equivalents ("FTEs") in Year 1 to 12.5 FTEs in Year 2. Consequently, the projected WRSC total hours per patient will decrease in Year 2. BROSC projects that utilization will increase by 20.51 percent but only projects to increase the RN staff by 14.85% from 10.1 FTEs in Year 1 to 11.6 FTEs in Year 2. Consequently, the projected BROSC total hours per patient will decrease in Year 2. In contrast to these applications, SurgCare projects that utilization will increase by 2.44 percent and the RN staff will increase from 24 to 25 FTEs for a 4.17 percent increase. With regard to RN staffing, the SurgCare application is the most effective proposal because the FTE increase in Year 2 is higher than the projected volume increase and the RN hours per patient far exceed those for the other applicants.

The following table provides the RN staffing for Year 2, the combined numbers of ORs and procedure rooms for each applicant and the RN FTE ratio per room.

	YR 2 FTE RNs	# Rooms	Ratio
WCSC OR + PR	12.5	5	2.50
BROSC OR + PR	11.6	4	2.90
Surgcare OR + PR	25	7	3.57

It is alarming that both WCSC and BROSC budget low RN hours per patient and low RN coverage per room. The WCSC and the BROSC applications are not effective proposals regarding RN staffing levels because both fail to add RN staff in Year 2 in proportion to their projected increases in total facility utilization. SurgCare proposal provides superior RN staffing levels based on the total RN FTEs divided by the combined number of ORs and procedure rooms.

Salary and Benefits Expense as Percentage of Total Expenses

Comparing the ambulatory surgery centers' budgeted expenses for overall facility staffing is useful to look at the adequacy of the healthcare resources that are used to provide the service. Generally the facility with the higher total salaries and benefits as a percentage of total expenses is the more effective proposal.

	YR 2 Total Salaries and Benefits	YR 2 Total Expenses	Salaries and Benefits % of Total Expenses
WCSC	1,735,776	8,268,478	20.99%
BROSC	1,767,555	6,596,522	26.80%
SurgCare	3,186,064	11,212,691	28.41%

As seen in the above table, the SurgCare proposal budgets 28.41 percent for salary and benefits as compared to 26.8 percent for BRSC and 20.9 percent for WCSC. Therefore, the SurgCare application is the most effective application for this factor.

Access by Underserved Groups

Access by to the operating rooms by underserved groups is an important factor to evaluate competing proposals; the more effective applicant projects to serve the higher percentages of Medicare and Medicaid patients.

	WCSC		BROSC		SurgCare	
Access by Underserved Groups (OR Cases)	**OR Cases**		**OR Cases**		**OR Cases**	
	Medicare	40.0%	Medicare	37.50%	Medicare	46.24%
	Medicaid	9.8%	Medicaid	5.79%	Medicaid	4.95%
	Combined	49.8%	Combined	43.29%	Combined	51.19%

It does not make sense to compare the number of patients per OR because WSCS is categorized as Group 5 and has an assigned average case time of 45 minutes while the BROSC and SurgCare proposals are assigned to Group 6 that are assigned 68.6 minutes average case time. Thus, the facility with the lower case time would have shorter duration cases and could potentially serve more patients per operating room.

Also it is illogical to make comparisons based on percentages or numbers of patient served in the proposed procedure rooms because procedure rooms are not the regulated healthcare services that is the subject of this analysis.

BROSC proposes to serve the lowest percent of Medicare patients and the lowest combined percentage of Medicare and Medicaid; thus, this is not an effective proposal. WCSC projects the second lowest percentage of Medicare patients and the highest percentage of Medicaid. However, the WCSC payor percentages are not based on reasonable assumptions given that the otolaryngology payor percentages are not provided separately for the operating rooms and procedure rooms. Consequently, the WCSC application is not effective. The SurgCare application projects to serve the highest percentage of Medicare patients and the highest combined Medicare and Medicaid percentage. Thus, the SurgCare application is comparatively superior regarding this factor.

Financial Comparisons

Differences in the scope of services and the SMFP Group assignment (Group 5 vs Group 6) for these three proposals could make it difficult to make conclusive comparisons of projected revenues and expenses. However, neither the WCSC application nor the BROSC applications are based on reasonable utilization projections causing both proposals to lack financial feasibility. The SurgCare application is based on historical data, reasonable assumptions and utilization projections that demonstrate financial feasibility. Therefore, the SurgCare application is comparatively superior.

Comments Specific to Western Carolina Surgery Center Project ID No. B-11520-18. Develop a New Ambulatory Surgical Facility with Two Operating Rooms and Three Procedure Rooms

The Western Carolina Surgery Center (WCSC) project application is nonconforming to CON Review Criteria based on the multiple deficiencies in the project application.

- The WCSC utilization projections are not reasonable because the applicant does not adequately explain the patient selection criteria (or other factors) to determine the projected operating room cases versus the utilization for the procedure rooms.
- Physician support letters that include projected volumes for "outpatient surgical procedures" are unclear if these procedures meet the certificate of need definition of a surgical case to be performed in an operating room.
- Patient origin data are unreliable because no supporting data or documentation is provided and the applicant fails to describe the hundreds of patients who are expected to originate from the undefined "Other."
- The application fails to adequately describe why the patient origin percentages for the operating rooms are significantly different for the procedure rooms.
- The proposed location in Arden, in extreme southern Buncombe County, is distant and not easily accessible from the majority of low income and elderly persons in the service area who reside in Asheville.
- Financial projections are unreliable due to overstated volumes, erroneous payor mix assumptions, and the unreasonable assumption that salaries will have 0% annual inflation for the first three years of operation.
- The projected RN staffing for the proposed project is dangerously insufficient with only 2.5 RNs per OR and PR combined in Year 2.
- The ENT payor percentages are flawed because these are not reported separately for the operating rooms and procedure rooms.

These deficiencies cause the application to be nonconforming to the following criteria:

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

POLICY GEN-3: BASIC PRINCIPLES states:

"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 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."

The WCSC application fails to conform to Criterion 1 and Policy GEN-3 because the patient origin projections are unreasonable and the projected patient surgery volumes are overstated. This application is not an effective proposal for promoting equitable access because the location is the most distant possible from the majority of the low income and senior population in Asheville.

Criterion 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."*

The WCSC application does not demonstrate the need the population has for the proposed project because:

- There is no data or documentation to support the patient origin projections that are provided on page 29 of the WCSC application. It is unclear if the data exists and if it is for actual OR cases and procedures performed in licensed facilities or physician offices or both. Unsupported numbers are not credible.
- The proposed facility location in unincorporated Arden is distant and inconvenient for the low income and senior patients who mostly live in and near Asheville.
- The physician support letters include projected volumes for "outpatient surgical procedures" that are vague and misleading because they do not explain if these "procedures" are actual surgical cases that require an operating room. In contrast, the physician support letters in the Asheville SurgCare application specifically include projections for the numbers of "ambulatory surgery cases."
- The tables on pages 78 and 79 of the application don't provide any assumptions for allocating the combined projection for "outpatient surgical procedures" for the ENT operating cases and procedure room volumes.
- Carolina Ophthalmology has an existing in-house operating suite in its existing office in Hendersonville to perform minor procedures. Thus it appears that the ophthalmology procedure volumes on page 65 represent a shift of utilization from the physician office-based procedure room to the proposed licensed ASC which will increase healthcare costs.
- Asheville, Heald, Neck, and Ear Surgeons have an in-office surgery suite where office-based procedures are performed. Thus it appears that the ENT procedure volumes on page 65 represent a potential shift of utilization from the physician office-based procedure room to the proposed licensed ASC which will increase healthcare costs.
- Based on a review of all 2018 License Renewal applications, the projected procedure room utilization at WCSC is overstated because it far exceeds the actual utilization of any similarly-sized ambulatory surgical facility in North Carolina..
- According to the 2018 SMFP, Park Ridge Health has a surplus of 1.39 operating rooms and the proposed WCSC is likely to shift large numbers of surgery cases

away from the hospital. However, the WCSC application does not explain how the project will impact OR utilization at Park Ridge Health.

Criterion 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."*

WCSC fails to comply to Criterion 4 because the application proposes to develop additional operating rooms in a facility that is not an effective alternative:

1) The utilization projections are overstated and unreasonable as discussed in the Criterion 3 comments.
2) As discussed in the Criterion 5 comments the revenue projections are unreliable because ENT surgery cases and procedure room volumes are combined in a way that distorts the potential CON analysis of the proposed operating rooms.
3) The application fails to demonstrate that the proposed building and land lease arrangement involving Carolina Ophthalmology Properties III, LLC is the least costly alternative.

Criterion 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."*

The WCSC application fails to comply with Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions and the physician support letters are deficient resulting in overstated and unreliable volumes.

Revenue projections are unreliable because in Form F.5 the applicant has merged the ENT OR Case projections with ENT procedure room utilization which makes it impossible to determine if the projected combined ENT charges are based on reasonable

assumptions. The other surgical specialties have separate revenue calculations for the projected OR cases and the procedure room volumes.

WCSC fails to explain the reasonableness to project no salary increases for the first three years of operation. According to data from the Bureau of Labor Statistics, nursing salaries increased on average about 1.3% per year from 2008 to the middle of 2014; since then the rate has gone up 2.6% per year through 2017.

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

The WCSC proposal fails to comply with Criterion 6 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed, resulting in overstated volumes.

Criterion 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."*

The WCSC application is nonconforming to Criterion 7 due to the understaffed registered nurse positions plus the erroneous assumption that healthcare salaries are not increasing.

The following table shows the Registered Nurse (RN) FTE staffing levels for the proposed facility:

	Year 1	Year 2	% Increase
WCSC OR + PR Patients	5,628	7,477	32.85%
WCSC RN FTEs	10.5	12.5	19.05%

While the total numbers of patients served in Year 2 are projected to increase 32.85 percent, the RN staffing is only increase by 19.05 percent. Compounding the problem is that the applicant projects no salary increases for any of the positions.

Even if WCSC is able to recruit staff in its second year of operation its projected level of RN staff positions is still far lower than competing proposals.

	YR 2 FTE RNs	# Rooms	Ratio
WCSC OR + PR	12.5	5	2.50
BROSC OR + PR	11.6	4	2.90
ASC OR + PR	25	7	3.57

The WCSC fails to explain how it's extremely sparse staffing for these RN positions can provide sufficient patient care coverage for the huge volume of patients that are projected to be expedited through this facility.

According to the VMG Health 2016 Intellimarker Multi-Specialty ASC Study, the national average is 7 nurse hours per case. In Year 2, the facility projects to serve 7,477 patients. With 12.5 projected FTEs the facility will provide 26,000 annual RN total paid hours. Consequently, the facility projects 3.5 RN hrs. per patient served at the facility. Even if the 2.0 FTEs for LPNs are included, WCSC is only projecting 4.0 nursing hours per case.

The following table shows the comparisons for the ratio of RNs per Combined OR and Procedure Rooms for each applicant.

	YR 2 FTE RNs	# Rooms	Ratio
WCSC OR + PR	12.5	5	2.50
BROSC OR + PR	11.6	4	2.90
ASC OR + PR	25	7	3.57

As seen in the next comparative analysis, the proposed WCSC staffing is substandard overall because it has the lowest total salaries and benefits as a percentage of total expenses.

	YR 2 Total Salaries and Benefits	YR 2 Total Expenses	Salaries % of Total
WCSC	1,735,776	8,268,478	20.99%
BROSC	1,767,555	6,596,522	26.80%
Asheville SurgCare	3,186,064	11,212,691	28.41%

The WCSC application fails to demonstrate that the projected RN staffing levels are based on reasonable assumptions based on its projected number of ORs and procedure rooms and its overall projected patient volume.

Criterion 13c *"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:*

(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."

The WCSC application fails to comply to Criterion 13c because the proposed project near the border of Buncombe and Henderson will not provide adequate access for senior and low-income persons, including Medicare and Medicaid patients. The largest number of low income persons in Buncombe County is in the census tracts near Asheville.

Criterion 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."*

The operational and financial projections in the WCSC application are unreasonable as discussed in the Criteria 3 and 5 comments.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

WCSC documents the assumptions and provides data supporting the methodology used for its operating room projections. However, the applicant's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the BROSC application is not conforming with this rule.

Comments Specific to Blue Ridge Outpatient Surgery Center Project ID No. B-11518-18. Develop a new ambulatory surgical facility with two Operating Rooms and two Procedure Rooms.

The Blue Ridge Outpatient Surgery Center (BROSC) project application is nonconforming to CON Review Criteria based on the multiple deficiencies in the project application.

- The proposed project is based on overstated volume projections that far exceed the actual utilization of Triangle Orthopaedic Surgery Center, the single-specialty orthopedic ambulatory surgical facility with two operating rooms that the BROSC project is supposedly modeled after.
- Patient origin data is flawed because it purportedly is based on BROSC's participating surgeon' ambulatory surgery cases that are expected to be "shifted" from Park Ridge Hospital in Henderson, Mission Hospitals and Orthopaedic Surgery Center in Asheville. The application never quantifies the numbers of patients that will supposedly be redirected way from each of these facilities.
- The application omits the projected patient origin for the procedure rooms even though this information is specifically requested in the application form.
- The proposed location in Arden, in extreme southern Buncombe County, is distant and not easily accessible from the majority of low income persons in the service area who reside in Asheville. Elderly patients may also have difficulty with travel and would prefer to stay close to home.
- Financial projections are unreliable due to overstated and unreasonable utilization projections.
- The proposed BROSC is not adequately justified and represents unnecessary duplication of the existing operating rooms at Orthopaedic Surgery Center of Asheville.
- The payor mix calculations for the proposed project are incorrect.
- BROSC wrongly assumes that its physicians can compel patients to utilize its proposed facility without any acknowledgement of the patients' freedom to choose competing facilities that are more accessible.

These deficiencies cause the application to be nonconforming to the following criteria:

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

POLICY GEN-3: BASIC PRINCIPLES states:

"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 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."

The BROSC application fails to conform to Criterion 1 and Policy GEN-3 because the patient origin projections are unreasonable and the projected patient surgery volumes are overstated. This application is not an effective proposal for promoting equitable access because the location is the most distant possible from the majority of low income population in Asheville.

Criterion 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."*

There are multiple reasons why the BROSC application fails to comply to Criterion 3 including: 1) incomplete and unreasonable patient origin projections; 2) erroneous growth assumptions; 3) unreasonable assumptions regarding the expected "shift" of cases to the Center; 4) overstated numbers of cases per surgeon, and 5) failure to consider travel distances and weather factors.

Incomplete and unreasonable patient origin data make this application unapprovable. The projected patient origin for the surgery cases is mistakenly based on historical data for the orthopedic surgery case performed by Blue Ridge / Emerge Ortho surgeons at Mission Hospital, Park Ridge Hospital and Orthopaedic Surgery Center of Asheville. Patients definitely get to choose both their surgeon and their facility. The BROSC application fails to explain why patients from Henderson, Haywood, Transylvania, Polk, McDowell and Madison Counties, that represent 47.8 percent of the total projected cases, would chose to drive further and pass by the existing facilities that already provide orthopedic surgery. This is especially true for orthopedic patients who have had previous surgery at Orthopaedic Surgery Center of Asheville and have no potential cost savings to travel to the BROSC in Arden, NC. The existing Orthopaedic Surgery Center of Asheville, where five of the Blue Ridge Emerge Ortho physicians currently have privileges is more geographically accessible for the vast majority patients from Buncombe, Madison, Haywood, McDowell and Yancey Counties due to the configuration of the highway system.

Erroneous growth assumptions are found in Step 3 of the methodology that wrongly assume that the 17 participating physicians will continually perform increasing numbers of ambulatory surgery cases every year going forward with no plan to recruit additional physicians.

	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022
BROSC User Physicians	4672					
BROSC Projections		4799	4929	5026	5201	5342
Participating Physicians	17	17	17	17	17	17
OR Cases per Physician	275	282	290	296	306	314

The continued growth in the average numbers of cases per physician is unreasonable because these physicians have not documented their intent to spend more time performing surgery and less time traveling about to the various offices in Henderson and Buncombe Counties plus the proposed BROSC. Thus, their travel times will have to increase in future years to provide care at the proposed BROSC, which has fewer operating rooms as compared to all of the existing facilities that provide ambulatory orthopaedic surgery. So, their productivity will surely decline. Furthermore, population growth is not a reasonable basis for projected growth because the number of participating physicians is finite, and these physicians already have access to multiple facilities where orthopedic ambulatory surgery is provided. BROSC fails to document that the participating physicians are unable to schedule ambulatory surgery cases at any of their present facilities.

Step 3 of the methodology in Section Q (pages 120 and 121) unreasonably assumes that the expected "shift" of ambulatory cases will occur based on the arbitrary 60%, 70% and 80% assumptions. From what facilities are these thousands of ambulatory surgery cases going to be shifted? Does the methodology assume that of 60%, 70% and 80% are going to be shifted from just Park Ridge Hospital or do these same percentages apply to the ambulatory cases performed at Mission Hospitals and OSCA? Without knowing the numbers of cases to be diverted from these facilities, the BROSC application fails to demonstrate that the "shift" assumptions are reasonable.

This methodology should fool no one. These percentages are based solely on the alleged "expected physician preferences" with no regard to the patient's right to choose between alternate facilities. The proposed location in Arden may be convenient for a subset of BRBJ physicians who are routed to their office practices in Arden, Asheville, and Hendersonville, but this location is geographically distant for most of the population of Buncombe County as well as the counties to the east, west and north. Since BROSC will have only two operating rooms and will be in the geographically remote and unincorporated community of Arden, the vast majority of patients will likely prefer to utilize other existing facilities. It makes no sense for patients to bypass the existing facilities,

including OSCA, that has more surgical capacity, existing accreditation, Medicare and Medicaid certification and agreements with insurers.

The projected numbers of BROSC ambulatory surgery cases are overstated and unreliable based on the comparison to actual utilization data for Triangle Orthopaedic Ambulatory Surgery Center (TOASC) and other single-specialty orthopedic surgery centers. The following table provides the BROSC projections as compared to actual OR cases and numbers of participating surgeons at the existing single-specialty orthopaedic surgery centers.

BROSC Projections (2 ORS Single Specialty)

	CY2020	CY2021	5342
BROSC OR Cases	**3,038**	**3,641**	**4,007**
Participating Physicians	**17**	**17**	**17**
OR Cases per Physician	**179**	**214**	**236**

Triangle Orthopaedic Surgery Center (2 ORS Single Specialty)

	FY2017
Actual Cases	2,437
Participating Physicians	21
OR Cases per Physician	**116**

University Surgery Center / Mallard Creek (2 ORS Single Specialty)

	FY2017
Actual Cases	2,227
Participating Physicians	18
OR Cases per Physician	**124**

Orthopaedic Surgery Center of Raleigh (4 Ors Single Specialty)

	FY2017
Actual Cases	4,384
Participating Physicians	22
OR Cases per Physician	**199**

The annual ambulatory surgery cases for these existing ambulatory surgical facilities are based on the 2018 license renewal applications and the numbers of participating physicians are obtained each facility's website. The projected numbers of BROSC cases far exceed the Triangle Orthopaedic Surgery Center in terms of total cases and OR cases per physician. In fact, BROSC projects OR cases for Years 2 and 3 that exceeds the OR cases per physician for all orthopedic surgery centers in North Carolina. It is unreasonable for BROSC to project surgery volumes in Year 1 that far exceed the existing single specialty centers with two operating rooms (TOSC and University) in service areas with much larger populations and have been licensed and operational for more than three years.

The BROSC utilization projections ignore the travel distance from Asheville and the frequency of winter weather conditions that create traffic hazards. Because the proposed location is only 0.4 miles from the Buncombe and Henderson County line, the facility will be approximately 10 miles distant from the majority of the population in Asheville, which is the twelfth largest municipality in North Carolina. According to the North Carolina Climate Office *(www.nc-climate.ncsu.edu/)*, Buncombe County averages six winter weather events per year that make driving hazardous. Snow, sleet and freezing rain can cause driving to be treacherous for multiple days due to refreezing. Since Arden is a small unincorporated community at the very edge of Buncombe County it is not a frequent destination for most people. Hence, it is improbable that surgery patients will agree to be "shifted" by their physicians to BROSC, especially in the winter months.

The utilization projections for the procedure rooms are based on a single physiatrist, Dr. Daniel Hankley. The application erroneously assumes that Dr. Hankley can continually increase his utilization by 5 percent annually and that thousands of patients are eager to travel to the proposed facility in Arden. Further, the application fails to demonstrate the patient origin for the proposed procedure rooms. From the Blue Ridge Bone and Joint (BRBJ) website, it appears that Dr. Hankley is based in the Arden office where he has access to a procedure room at the physician office location. The BROSC application fails to document a medical need for the office-based non-surgical pain management

procedures to be performed at the proposed facility. Shifting office-based procedures to a licensed ambulatory surgery facility increases costs and charges to patients and the healthcare system.

Additionally, the application does not adequately explain why only 17 of the 22 BRBJ physicians have documented their intent to obtain privileges at the proposed center. While it is understandable that some specialists are focused on non-procedural sports medicine, other orthopedic surgeons are likely approaching retirement. Yet the BROSC application omits a physician recruitment plan that might have propped up its overly aggressive utilization projections.

Criterion 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."*

The BROSC application fails to comply to Criterion 4 because the application proposes to develop additional ambulatory surgery operating room capacity that is not an effective alternative:

4) The utilization projections are overstated and unreasonable as discussed in the Criterion 3 comments.
5) As discussed in the Criterion 5 comments the capital costs are also unreliable and financial projections are not based on reasonable assumptions, causing the project to not be a cost-effective alternative.
6) The proposed project is not an effective alternative because it is unnecessary and duplicative as discussed in Criterion 6.

Criterion 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."*

The BROSC application fails to comply with Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed resulting in overstated volumes. The capital costs and projected building rent are unreasonable because:

1) The project capital cost includes the purchase price of the land in the amount of $1,913,043 which is only sufficient for the primary site and is inadequate for the secondary site with a purchase cost of $2,750,000.
2) The application fails to document that the building rent of $34 per square feet is based on reasonable assumptions because the cost of the proposed site ranges from $650,000 to $2,750,000; the applicant failed to adequately document how it arrived at $34 per square feet.
3) As seen in the applicant's Exhibit 16 the letters from WGLA Engineering Services PLLC, explain that the site development costs do not include "stream and wetland delineation, surveying, geotechnical boring, surveying, permitting."

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

The BROSC proposal fails to comply with Criterion 6 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed, resulting in overstated volumes. Assumptions regarding the expected shift of cases from existing facilities are not adequately explained.

What the BROSC application proposes will unnecessarily duplicate what already exists at OSCA. The application fails to demonstrate the need the population has for the proposed BROSC with two orthopedic single-specialty ORs in addition to the three existing single-specialty orthopedic ambulatory operating rooms at OSCA. Five physicians with Blue Ridge Bone and Joint currently have medical staff privileges at OSCA. The application does not adequately explain why patients from the Asheville area

would want to drive to the proposed facility at the very border of Buncombe County when BRBJ physicians already have the option to perform ambulatory surgery at the existing, more centrally located OSCA.

Criterion 13c *"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:*

(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."

The BRSC application fails to comply to Criterion 13c because the proposed project, near the border of Buncombe and Henderson, will not provide adequate access to low income persons, including Medicare and Medicaid patients, and the elderly. The largest number of low income persons in Buncombe County is in the census tracts near Asheville. BROSC projects to serve an unacceptably low percentage of Medicare patients at its proposed facility based on its incorrect analysis. The applicant projected its payor percentages based on an inaccurate comparison of payor percentages for existing facilities in Buncombe. The correct payor data for Orthopaedic Surgery Center of Asheville was provided to the Acute Care Licensure and Certification Section in February 2018 as documented in Exhibit C.1 of the SurgCare application.

Criterion 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."

The operational and financial projections in the BROSC application are unreasonable as discussed in the Criteria 3 and 5 comments. The application proposes to duplicate single-specialty ambulatory surgery orthopedic operating rooms based on a methodology that involves "shifting" surgical patients from other facilities with no supporting data. The premise of the participating physicians having the unilateral ability to shift patients from facility A to facility B is anticompetitive and disregards patients' rights to choose where they want to obtain surgery. Therefore, the application fails to demonstrate that the project will provide any enhanced competition in the service area. Consequently, the BROSC application does not demonstrate conformity to Criterion 18a.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

BROSC documents the assumptions and provides data supporting the methodology used for its operating room projections. However, the applicant's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the BROSC application is not conforming with this rule.