

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 19, 2017

Findings Date: July 19, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Lisa Pittman

Project ID #: E-11298-17

Facility: Blue Ridge Surgery Center

FID #: 170067

County: Burke

Applicant(s): Blue Ridge HealthCare Hospitals, Inc.

Blue Ridge HealthCare Surgery Center, LLC

Project: Develop a new ambulatory surgery center by separately licensing four existing operating rooms, two gastrointestinal endoscopy rooms and one procedure room on the Valdese campus.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

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

C

Blue Ridge HealthCare Hospitals, Inc., d/b/a Carolinas HealthCare System Blue Ridge (CHS Blue Ridge) and Blue Ridge HealthCare Surgery Center, LLC (Blue Ridge Surgery Center or BRHCSC or Blue Ridge HealthCare Surgery Center, LLC) are, collectively, the applicants. Blue Ridge HealthCare Systems, Inc. (Blue Ridge) is the parent and sole member of both CHS Blue Ridge and Blue Ridge Surgery Center. CHS Blue Ridge has two hospital campuses in Burke County: CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton.

The applicants propose to develop a new ambulatory surgery center (ASC) to be known as Blue Ridge Surgery Center, by separately licensing four operating rooms (ORs), two gastrointestinal endoscopy rooms (GI/endoscopy rooms) and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location. CHS Blue Ridge would manage the proposed ASC. Blue Ridge Surgery Center would lease the existing space, furniture, furnishings and equipment from CHS Blue Ridge.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2017 SMFP.

Policies

The capital cost of the proposed project is \$1,433,190. There are no policies applicable to this review.

Conclusion

In summary, the applicants demonstrates that the proposal is conforming to all applicable policies in the 2017 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (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.

C

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location.

Patient Origin

On page 62, the 2016 SMFP defines the service area for ORs as "*the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 67].*" Figure 6-1 shows Burke County as a single county OR service area. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, pages 69-70, the applicant provides the projected patient origin for the OR, GI/endoscopy room and procedure room cases during the first two operating years (OY) [CY2019 and CY2020] following completion of the project, as shown in the tables below.

Operating Rooms: Blue Ridge Surgery Center

	OY1 (CY2019)		OY2 (CY2020)	
County	Projected Cases	% of Total Cases	Projected Cases	% of Total Cases
Burke	2,488	56.4%	2,655	57.2%
Caldwell	616	14.0%	637	13.7%
McDowell	487	11.0%	504	10.9%
Catawba	414	9.4%	428	9.2%
Other*	406	9.2%	420	9.0%
Total	4,411	100.0%	4,643	100.0%

*Other includes Alexander, Ashe, Avery, Buncombe, Cabarrus, Carteret, Chatham, Cleveland, Durham, Forsyth, Gaston, Haywood, Henderson, Iredell, Lincoln, Macon, Madison, Mecklenburg, Mitchell, Montgomery, Onslow, Rowan, Rutherford, Sampson, Stanly, Surry, Transylvania, Tyrell, Union, Wake, Watauga, Wilkes and Yancey counties in North Carolina, as well as other states.

GI/endoscopy Rooms: Blue Ridge Surgery Center

	OY1 (CY2019)		OY2 (CY2020)	
County	Projected Cases	% of Total Cases	Projected Cases	% of Total Cases
Burke	1,216	62.1%	1,344	64.3%
Caldwell	317	16.2%	318	15.2%
McDowell	255	13.0%	256	12.3%
Catawba	86	4.4%	87	4.2%
Other*	85	4.3%	85	4.1%
Total	1,959	100.0%	2,090	100.0%

* Other includes Alexander, Ashe, Avery, Buncombe, Cabarrus, Carteret, Cleveland, Edgecombe, Gaston, Granville, Haywood, Iredell, Lincoln, Mecklenburg, Mitchell, Rutherford, Sampson, Stanly, Surry, Watauga and Wilkes counties in North Carolina, as well as other states.

Procedure Room: Blue Ridge Surgery Center

	OY1 (CY2019)		OY2 (CY2020)	
County	Projected Cases	% of Total Cases	Projected Cases	% of Total Cases
Burke	18	52.3%	18	52.3%
Caldwell	8	22.6%	8	22.6%
McDowell	4	10.7%	4	10.7%
Catawba	3	7.5%	3	7.5%
Other*	2	6.9%	2	6.9%
Total	35	100.0%	35	100.0%

* Other includes Alexander, Ashe, Avery, Buncombe, Carteret, Cleveland, Forsyth, Gaston, Iredell, Lincoln, Mecklenburg, Mitchell, Rowan, Rutherford, Wake, Watauga, Wilkes and Yancey counties in North Carolina, as well as other states.

On page 70, the applicants provide the assumptions and methodology used to project patient origin as follows:

“BRHCSC expects the patient origin of Blue Ridge Surgery Center’s baseline projected utilization for surgical and GI endoscopy cases to closely match the historical patient origin or the outpatient cases historical [sic] performed at CHS Blue Ridge-Valdese and CHS-Blue Ridge-Morganton, respectively...”

BRHCSC assumed that all incremental cases associated with the recruitment of EmergeOrtho’s sixth surgeon and Blue Ridge Medical Group’s gastroenterologist would originate in Burke County. All cases resulting from the repatriation of ENT and other outpatient surgical cases are assumed to originate from Burke County by definition as these cases are Burke County residents currently leaving the county for care at a freestanding ASC outside the county...

GI endoscopy patient origin is based on the projected number of cases, not procedures...

BRHCSC projected patient origin of Blue Ridge Surgery Center’s projected procedure room procedures [sic] based on the historical patient origin for these procedures at CHS Blue Ridge-Valdese.”

The applicant adequately identifies the population to be served.

Analysis of Need

In Section II, pages 12-17, Section III, pages 29-66 and 69-70, and Exhibits 14-16, the applicants document the need for the proposal.

Background

The overall project is described in detail in Section II, pages 12-17 and in Section III, page 29.

In summary, CHS Blue Ridge is one hospital system, with one hospital license and two separate hospital campuses in Burke County. One in the city of Valdese and one in the city of Morganton: CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton (aka Grace Hospital). In 2014, CHS Blue Ridge organized CHS Blue Ridge-Valdese to focus solely on outpatient care and CHS Blue Ridge-Morganton to focus solely on inpatient care.

The existing surgical services at CHS Blue Ridge-Valdese, currently operating under CHS Blue Ridge’s hospital license, includes four operating rooms, two GI/endoscopy procedure rooms and one multi-purpose procedure room as well as prep/recovery, PACU, sterile processing and all other essential support services.

The proposed project is to reorganize the described surgical services, which are located on the CHS Blue Ridge-Valdese campus, into a separately licensed ASC in the existing space.

On pages 29-41 the applicants discuss the three factors which they state support the need for the proposal, which are listed and summarized below along with the pages where each factor is discussed in the application:

- *Demand for ASC services* (See application pages 30-33)
- *Need for a multi-specialty ASC in Burke County* (See application pages 33-39)
- *Enhanced Quality, Access and Value* (See application pages 39-41)

In Section III, pages 42-66, and referenced exhibits, the applicants discuss the methodology and assumptions supporting the need calculations for the proposed project.

In Section III, pages 71-72, the applicants discuss the alternatives considered and why the proposal was chosen.

The information provided by the applicants in the pages referenced above is reasonable and adequately supported.

Projected Operating Room Utilization

In Section IV, page 76, the applicants provide the projected utilization for the ORs for the first three OYs (CY2019-CY2021) of the project, as illustrated in the table below:

Operating Rooms: Blue Ridge Surgery Center

	OY 1 (CY 2019)	OY 2 (CY 2020)	OY 3 (CY 2021)
# of ORs	4	4	4
Total Cases	4,411	4,643	4,878
Average OR Cases per OR	1,102.7	1,160.8	1,220
Annual hours based on 1.5 hrs/procedure*	6,616.5	6,964.5	7,317
1872 hrs x # of ORs	7,488	7,488	7,488
Utilization Rate	88.4%	93.0%	97.7%

*In Chapter 6 “Operating Rooms” of the 2017 SMFP there is a section on page 58 which states: “For purposes of the State Medical Facilities Plan, the average operating rooms is anticipated to be staffed nine hours a day, for 260 days per year, and utilized at least 80 percent of the available time. The standard number of hours per operating room per year based on these assumptions is 1,872 hours. (Column K: 9 hours x 260 days x 0.8 – 1,872 hours per operating room per year).” (See pages 57- 58, Step 3, Section f, of the 2017 SMFP)

In Section III, pages 42-66 and referenced exhibits, the applicants provide the assumptions and methodology used to project OR utilization, which are summarized below.

The applicants derived the projected OR cases for OY1, OY2 and OY3 by totaling four sources of Outpatient (OP) cases represented in lines 1-4, as shown in the table below.

Projected OP Cases and OR Need: Blue Ridge Surgery Center

		OY1 (CY2019)	OY2 (CY2020)	OY3 (CY2021)
1	Baseline Outpatient Cases	3,866	3,995	4,129
2	Additional Outpatient Cases form EmergeOrtho	204	306	408
3	Additional Outpatient Cases from ENT Repatriation	268	268	268
4	Additional Outpatient Cases from Non-eye, Non-ENT Repatriation	74	74	74
5	Total Outpatient Cases [Sum of 1+2+3+4]	4,411	4,643	4,878
6	Total Outpatient Surgical Hours (Cases x 1.5 hours)	6,617	6,964	7,317
	OR Need (Outpatient Surgical Hours / 1,872 per SMFP)	3.5	3.7	3.9

Source: Table page 50 of the application.

As shown in the table above, in OY3, the applicants project that 4,878 outpatient surgical cases will be performed in the four ORs at the proposed Blue Ridge Surgery Center, which documents a need for four ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed*
OY 3	----	4,878	7,317	3.9	4.0

*The Burke County Operating Room Service Area has over 10 ORs. Per the OR Performance Standard “in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater.”

The four categories of OP OR cases which the applicants utilize to project OP OR cases for the first three OY’s are summarized below.

1. Baseline Outpatient Cases (See application pages 42-45)

Baseline Outpatient Cases refer to the number of OP OR cases the applicants project will “shift” from CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton to Blue Ridge Surgery Center upon project completion.

To calculate what is referred to as “Baseline Outpatient Cases” the applicants:

1st) Calculated a compound annual growth rate (CAGR) of 3.3% based on the historical OP OR cases for both CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton for the last four CY’s (2013-2016) [page 43];

2nd) Projected OP OR cases at both CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton using the 3.3% CAGR for the CY’s 2017-2021 which includes OY1(CY2019), OY2(CY2020), and OY3(CY2021) [page 43];

3rd) Projected 80% of the projected OP OR cases at CHS Blue Ridge-Morganton would “shift” over to the proposed ASC, Blue Ridge Surgery Center [page 44]

Baseline Outpatient Cases

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
OP OR Cases from CHS Blue Ridge-Valdese	2,122	2,193	2,266
OP OR Cases from CHS Blue Ridge-Valdese	1,744	1,802	1,862
Total “Baseline Outpatient Cases” to Shift to Blue Ridge Surgery Center	3,866	3,995	4,129

*Source: Table on page 44.

2. Additional Outpatient Cases form EmergeOrtho (See application pages 45-46)

CHS Blue Ridge currently has a contractual agreement with a five-physician orthopedic practice to serve Burke County and surrounding areas. The five-physician clinic is part of EmergeOrtho, a state-wide orthopedic practice. EmergeOrtho is recruiting a sixth orthopedic for this clinic. Based on historic data, the applicants project that this sixth

orthopedic surgeon will perform 408 surgical cases at Blue Ridge Surgery Center as of OY1(CY2019). However, to be conservative, the applicants do not project 408 OP OR cases for this sixth orthopedic surgeon until OY3(CY2021). The applicants “ramp-up” over three years based on 50%, 75% and 100% as illustrated in the table below.

Additional Outpatient Cases from EmergeOrtho

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
Additional projected OP Cases from the Sixth EmergeOrtho Orthopedic Surgeon	408	408	408
Ramp Up Percentages	50%	75%	100%
Total Additional OP Cases from the Sixth EmergeOrtho Orthopedic Surgeon	204	306	408

*Source: Table on page 46.

3. Additional Outpatient Cases from ENT Repatriation (See application pages 46-47)

The applicants state that an ENT practice closed in 2012 and one of the physicians associated with the ENT practice and a former member of CHS Blue Ridge’s medical staff left the area. In 2012, prior to his departure, the physician performed 268 outpatient cases annually. As outlined in pages 46-47, the applicants note that for a variety of reasons Burke County residents receiving ENT surgery declined or went out of county to lower cost ASC’s. Exhibit 25 contains a letter for an ENT physician practicing at Blue Ridge ENT & Allergy documenting that doctor’s commitment to perform ENT cases at Blue Ridge Surgery Center. It is noted that these estimates conservatively only address serving Burke County residents, they do not project any residents from outside of Burke County coming into Burke County to Blue Ridge Surgery Center. As shown in the table below the applicants also, conservatively, do not project any increase in OR cases from OY1 to OY3. Based on the above, the applicants project 268 ENT OP OR cases for each of the first three OYs as show in the following table.

Additional Outpatient Cases from ENT Repatriation

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
Additional Outpatient Cases for ENT Repatriation	268	268	268

*Source: Table on page 47.

4. Additional Outpatient Cases from Non-eye, Non-ENT Repatriation (See application pages 48-50)

On pages 48-50, the applicants set forth the analysis for the repatriation of non-eye and non-ENT OP OR cases for Burke County residents who are currently leaving the county for OP surgery either for access or the lower charge structure of an ASC. It is noted that these estimates conservatively only address serving Burke County residents, they do not project any residents from outside of Burke County coming into Burke County to Blue Ridge Surgery Center. As shown in the table below the applicants also, conservatively, do not project any increase in OR cases from OY1 to OY3.

Additional Outpatient Cases from Non-eye, Non-ENT Repatriation

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
Additional Outpatient Cases from Non-eye, Non-ENT Repatriation	74	74	74

*Source: Table on page 50.

On pages 50-55, the applicants offer additional support for the projected OP OR cases for Blue Ridge Surgery Center which is reasonable, credible and supported.

Projected utilization of the existing and proposed ORs is based on reasonable and adequately supported assumptions.

GI/Endoscopy Rooms

In Section IV, page 76, the applicants provide the projected utilization for the GI/endoscopy rooms for the first three OYs (CY2019-CY2021) following completion of the project, as illustrated in the table below:

GI/Endoscopy Rooms: Blue Ridge Surgery Center

	OY 1 (CY 2019)	OY 2 (CY 2020)	OY 3 (CY 2021)
# of GI/Endoscopy Rooms	2	2	2
# of Procedures	3,102	3,316	3,530

In Section III, pages 55-64, the applicants provide the assumptions and methodology used to project utilization of the GI/Endoscopy rooms.

	OY 1 (CY2019)	OY 2 (CY2020)	OY 3 (CY2021)
Procedures in GI/Endoscopy Rooms	3,102	3,316	3,530
# of GI/Endoscopy Rooms	2	2	2
Procedures per Room	1,551	1,658	1,765

As shown in the table above, the applicants project at least 1,600 GI endoscopy procedures per GI endoscopy room in OY2 which exceeds the performance standard of at least 1,500 GI endoscopy procedures per GI endoscopy room for GI/endoscopy rooms promulgated in N.C. Gen. Stat. §131E-182(a) and 10A NCAC 14C .3903(b).

CHS Blue Ridge provides GI/endoscopy services from three locations: CHS Blue Ridge-Valdese; CHS Blue Ridge-Morganton; and Carolina Digestive Health (a separately licensed, free standing GI/endoscopy ASC). The proposed project does not rely on any shift of volume from Carolina Digestive Health. Rather, Blue Ridge Surgery Center’s projected GI/endoscopy utilization is based on: 1) historical utilization from CHS Blue Ridge-Valdese, which are the two GI/endoscopy rooms which will become part of the proposed ASC, Blue Ridge Surgery Center; 2) potential shifts from CHS Blue Ridge- Morganton; and 3) additional new volume created by recruitment of new physicians. (See application page 55.)

The three categories of GI/endoscopy cases/GI/endoscopy cases which the applicants utilize to project GI/endoscopy utilization for the first three OY’s are summarized below.

Shift from CHS Blue Ridge-Valdese to Blue Ridge Surgery Center (See application pages 55-60)

The applicants project the GI/endoscopy cases currently being performed at CHS Blue Ridge-Valdese will “shift” to the Blue Ridge Surgery Center upon project completion.

1st) Calculated a CAGR of 0.6% based on the historical GI/endoscopy cases for CHS Blue Ridge-Valdese for the last four CY’s (2013-2016) [page 56];

2nd) Projected GI/Endoscopy cases at CHS Blue Ridge-Valdese using the 0.6% CAGR for the CY’s 2017-2021 which includes OY1(CY2019), OY2(CY2020), and OY3(CY2021) [pages 56-57];

3rd) Calculated the ratio of GI/endoscopy procedures to GI/endoscopy cases. (page 58)

GI/endoscopy cases projected at Blue Ridge Surgery Center from CHS Blue Ridge-Valdese

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
GI/endoscopy Cases from CHS Blue Ridge-Valdese	1,351	1,360	1,368
GI/endoscopy Procedure to GI/endoscopy Case ratio	1.63	1.63	1.63
GI/endoscopy Procedures from CHS Blue Ridge-Valdese	2,201	2,215	2,228

*Source: Table on page 59.

Shift from CHS Blue Ridge-Morganton to Blue Ridge Surgery Center (See application pages 55-60)

The applicants project the GI/endoscopy cases currently being performed at CHS Blue Ridge-Morganton will “shift” to the Blue Ridge Surgery Center upon project completion.

1st) Calculated a CAGR of -15.0% based on the historical GI/endoscopy cases for CHS Blue Ridge-Morganton for the last four CY’s (2013-2016) [page 56];

2nd) Projected GI/Endoscopy cases at CHS Blue Ridge-Morganton using the 0.0% CAGR for the CY’s 2017-2021 which includes OY1(CY2019), OY2(CY2020), and OY3(CY2021) due to fact that decline in GI/endoscopy cases was directly related to two gastroenterologists leaving [pages 56-57];

3rd) Projected 80% of the projected GI/endoscopy cases at CHS Blue Ridge-Morganton would “shift” over to the proposed ASC, Blue Ridge Surgery Center. [page 57]

4th) Calculated the ratio of GI/endoscopy procedures to GI/endoscopy cases. (page 58)

GI/endoscopy cases projected at Blue Ridge Surgery Center from CHS Blue Ridge-Morganton

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
GI/endoscopy Cases from CHS Blue Ridge-Morganton	452	452	452
Projecting 80% shift to Blue Ridge Surgery Center	.80	.80	.80
Total GI/endoscopy cases to shift from CHS Blue Ridge-Morganton to Blue Ridge Surgery Center	362	362	362
GI/endoscopy Procedure to GI/endoscopy Case ratio	1.38	1.38	1.38
GI/endoscopy Procedures from CHS Blue Ridge-Morganton	501	501	501

*Source: Table on page 59.

Additional new volume created by recruitment of new gastroenterologist. [pages 59-61]

1st) The applicants calculated additional new GI/endoscopy cases, including a ratio of 1.63 GI/endoscopy cases to GI/endoscopy procedures, based on recruitment of a new gastroenterologist including a “ramp up” period over three years as shown in the table below

GI/endoscopy cases projected at Blue Ridge Surgery Center from a new Gastroenterologist

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
GI/endoscopy Cases from new gastroenterologist	492	492	492
GI/endoscopy Procedures from new gastroenterologist	801	801	801
Ramp up percentages	.5	.75	1.0
Additional GI/endoscopy procedures at Blue Ridge Surgery Center from a new gastroenterologist	400	601	801

*Source: Table on page 60.

Summary

GI/endoscopy procedures projected at Blue Ridge Surgery Center

	OY1(CY2019)	OY2(CY2020)	OY2(CY2021)
GI/endoscopy Procedures from CHS Blue Ridge- Valdese	2,201	2,215	2,228
GI/endoscopy Procedures from CHS Blue Ridge-Morganton	501	501	501
GI/Endoscopy Procedures from new gastroenterologist	400	601	801
Total projected GI/endoscopy procedures at Blue Ridge Surgery Center	3,102	3,316	3,530
GI Endoscopy Room Projected Need at Blue Ridge Surgery Center**	2.1	2.2	2.4

*Source: Table on page 61.

**Total GI/endoscopy procedures divided by 1500 per 10A NCAC 14C .3903 Performance Standard. The GI/endoscopy room rules are not applicable in this application. This calculation is provided as a point of reference.

Projected utilization of the GI/Endoscopy Rooms is based on reasonable and adequately supported assumptions.

Utilization Projections for one proposed minor procedure room

In Section III, pages 64-66, the applicant provides the projected utilization, including methodology and assumptions, of the procedure room at the proposed Blue Ridge Surgery Center for the first three OYs.

	OY1 (CY 2019)	OY2 (CY 2020)	OY3 (CY 2021)
Total procedures	35	35	35

Projected procedures equate to approximately 1 procedure every 10 days of the year.

Projected utilization of the procedure room is based on reasonable and adequately supported assumptions.

Based on review of: 1) information provided by the applicants in Section I, pages 12-17, Section III, pages 29-66 and 69-70, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicants response to comments received at the public hearing, the applicants adequately document the need to reorganize the existing surgical services at CHS Blue Ridge-Valdese into a separately licensed ASC in its current location.

Access

On page 83 the applicants state “Blue Ridge Surgery Center will provide services to all persons in need of medical care, regardless of race, color, religion, natural origin, sex, age, disability, or source of payment. Blue Ridge Surgery Center will not discriminate based on age, race, national or ethnic origin, disability, sex, or source of income.”

In Section VI.14, pages 89-90, the applicants project that as of OY2 (CY2020) at Blue Ridge Surgery Center 55.7% of OR patients, 67.9% of GI/Endoscopy Room patients and 79.0% of Procedure Room patients will have all or part of their services paid for by Medicare and/or Medicaid, as indicated in the tables below:

Operating Rooms: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	32.7%
Medicaid	23.0%
Commercial/Managed Care	35.7%
Other*	5.2%
Self Pay	3.3%
Total	100.0%

*Other includes workers’ compensation and unspecified payors.

GI/Endoscopy Rooms: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	51.6%
Medicaid	16.3%
Commercial/Managed Care	27.3%
Other*	3.5%
Self Pay	1.3%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

Procedure Room: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	55.0%
Medicaid	24.0%
Commercial/Managed Care	8.2%
Other*	11.2%
Self Pay	1.7%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

On page 90, the applicants state that CHS Blue Ridge's internal data was used to develop the projected payor mix based on the historical mix for the cases and procedures projected to be performed at Blue Ridge Surgery Center. The historical and projected payor mix are identical with respect to patients who will have all or part of their services paid for by Medicare and/or Medicaid. The applicants adequately demonstrate the extent to which each group will have access to the proposed services. Furthermore, the applicants adequately demonstrate that the proposed project will increase access to OR and GI/Endoscopy room services for residents of Burke County due to cost savings. Currently all ten of CHS Blue Ridge ORs are on the hospital's license. Upon project completion, there will be six ORs on the hospital's license and four ORs at the Blue Ridge Surgery Center operating on an ASC license with patients able to benefit from the cost savings associated with having outpatient surgery at an ASC as opposed to having the same outpatient surgery performed in a hospital-based OR.

The applicants adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identified the population to be served, demonstrated the need that the population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (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.

CA

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room by transferring ownership of the four OR's, two GI/endoscopy rooms and the one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location.

In Section III.8, pages 71-72, the applicants discuss the two alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – The applicants rejected maintaining the status quo because it does not allow the ability to partner with physicians and capitalize on the benefits of physician integration and would prevent the possibility of reduced charges through the establishment of more than one charge structure. Maintaining the status quo is not the most effective alternative to meet the need.
2. Implement the Reorganized Facility at Another Location or as a Newly Built Facility- This alternative was determined to be too costly as the proposed project can be developed at its current location in its existing space with relatively minor renovation costs and avoiding all costs that would arise in moving the services to another location from their current location. This alternative was not cost-effective.

After considering these alternatives to its proposal, the applicants believe the most effective alternative is to develop the ASC as proposed.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that this proposal is their least costly or most effective alternative to meet the identified need for an ASC in Burke County. Therefore, the application is conforming to this criterion subject to the following conditions

- 1. Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Blue Ridge HealthCare Hospitals, Inc., and Blue Ridge HealthCare Surgery Center, LLC shall develop an ambulatory surgery center at CHS Blue Ridge-Valdese licensed for no more than four operating rooms, two gastrointestinal endoscopy rooms and one procedure room to be transferred from CHS Blue Ridge-Valdese.**
 3. **Upon licensure of the ambulatory surgery center, Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC shall take the steps necessary to delicense four operating rooms, two gastrointestinal endoscopy rooms and one procedure room at CHS Blue Ridge-Valdese such that CHS Blue Ridge-Valdese shall no longer be licensed for any operating rooms or gastrointestinal endoscopy rooms.**
 4. **Blue Ridge HealthCare Surgery Center, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
 5. **Procedures performed in the minor procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
 6. **Blue Ridge HealthCare Hospitals, Inc. and Blue Ridge HealthCare Surgery Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (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.

C

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location.

Capital and Working Capital Costs

In Section VIII, pages 100-101, the applicants project the total capital cost of the project will be \$1,433,190, which includes:

Cost of Materials	\$1,162,190
Contingency	\$161,000
Architect & Engineering Fees	\$110,000
Total	\$1,433,190

In Section IX, page 105, the applicants project no working capital costs (start-up and initial operating expenses) as the proposed services at Blue Ridge Surgery Center are currently operated as a hospital-based surgical program at CHS Blue Ridge-Valdese.

Availability of Funds

In Section VIII.3, page 101, the applicants state that the proposed project will be financed through the accumulated reserves of CHS Blue Ridge.

In Exhibit 22, the applicants provide a letter from Robert Fritts, Chief Financial Officer of Blue Ridge and CHS Blue Ridge, which states that that \$1,433,190 and more is available for the proposed project and from the accumulated reserves of Blue Ridge. The letter refers to the audited consolidated balance sheets of Blue Ridge in Exhibit 23 and specifically the line “Board-Designated as Funded Depreciation” which has \$5,250,136 as of December 31, 2015.

Exhibit 22 also contains a copy of a letter from Kathy C. Bailey, the manager of Blue Ridge Surgery Center, which states that Blue Ridge Surgery Center will use the designated funds from Blue Ridge for the capital costs of the proposed project.

The applicant adequately designates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Forms B and C), the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Number of Surgical Cases	4,411	4,643	4,878
Number of GI/endoscopy Procedures	3,102	3,316	3,530
Number of Procedures (Procedure Room)	35	35	35
Total Cases/Procedures	7,549	7,994	8,443
Total Gross Revenues (Charges)	\$32,163,682	\$34,969,131	\$37,940,364
Total Net Revenue	\$9,750,998	\$10,599,600	\$11,498,609
Average Net Revenue per total cases/procedures	\$1,291.69	\$1,325.94	\$1,361.91
Total Operating Expenses (Costs)	\$7,838,938	\$8,302,376	\$8,790,247
Average Operating Expense per total cases/procedures	\$1,038.41	\$1,038.58	\$1,361.91
Net Income	\$1,912,059	\$2,297,224	\$2,708,362

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this 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.

C

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location.

On page 62, the 2016 SMFP defines the service area for ORs as *“the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 67].”* Figure 6-1 shows Burke County as a single county OR service area. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 62 of the 2017 SMFP, there are 11 ORs in Burke County located in three facilities: Surgery Center of Morganton Eye Physicians (2 ORs) and CHS Blue Ridge-Valdese (4 ORs) and CHS Blue Ridge-Morganton (5 ORs). Blue Ridge also has a dedicated C-Section OR which is not included. See table below.

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
Surgery Center of Morganton Eye Physicians	0	2	0	0	2
Blue Ridge*	1	0	9	0	10
Total**	1	2	9	0	12

*CHS Blue Ridge has two campuses under the same hospital license: CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton.

**Does not include CON adjustments for C-Section ORs.

The total number of ORs (12) in Burke County will not increase as a result of this proposal nor will there be a change in the physical location of any of the ORs, only how four of the twelve

OR's are licensed. The four shared ORs located at CHS Blue Ridge-Valdese and which are licensed as part of the hospital, will be licensed separately as part of an ASC, Blue Ridge Surgery Center. The cost to the patient, for the same outpatient surgical procedure, is generally lower if the surgery is performed in an ASC rather than in a hospital-based OR.

The discussions regarding analysis of need, alternatives and competition found in Criteria (3) (4) and (18a), respectively, are incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved ORs in Burke County. Consequently, the application is conforming to this 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.

C

In Section VII.2, page 92, the applicants project staffing at Blue Ridge Surgery Center in the second operating year, as illustrated in the following table:

Position	Number of Full-Time Equivalent (FTE) Positions
Executive Director	1.0
Registered Nurse	21.0
Nursing Aides, Orderlies, or Attendants	0.8
Surgical Technicians	6.4
Anesthesia Technicians	1.0
Materials Specialist	1.0
Sterilization Preparation Technician	1.0
OR Desk Coordinator	1.0
All "non-health professionals" and "technical" personnel*	5.0
Totals	38.2

*Includes staff related to medical records, billing, scheduling (unit secretary), and family coordinator.

As shown in the table above, the applicants project to employ 38.2 FTEs in the second operating year. In Section VII.7, page 96, the applicants describe their experience and process for recruiting and retaining staff. Exhibit 10 contains a letter from Christopher Hanger, MD, which expresses his commitment to serve as Medical Director for the proposed Blue Ridge Surgery Center.

Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed ambulatory surgical services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Blue Ridge Surgery Center is not an existing facility. However, the four ORs, two GI/endoscopy rooms and one procedure room which will constitute Blue Ridge Surgery Center are currently operational and hospital-based in the CHS Blue Ridge-Valdese facility and, upon project completion, will remain on the same property and in the same location. Exhibit 6 contains a letter from Kathy C. Baily, the President and CEO of Blue Ridge which states “*I would like to document that ancillary and support services provided to patients prior to and following surgical procedures, such as laboratory tests, diagnostic imaging, and the pathology are currently available at CHS Blue Ridge-Valdese and will continue to be available to patients of the proposed Blue Ridge Surgery Center.*” See also pages 15-16 of the application. On page 16, the applicants state that “*with the exception of anesthesia and consulting pharmacy services, all ancillary and support services necessary for the project will be provided by the patient’s physician, by CHS Blue Ridge, or by staff listed in Section VII.*” On page 15, the applicants state that Blue Ridge Surgery Center will contract for a consulting pharmacist. Exhibit 7 contains a letter from TeamHealth Anesthesiology which states that TeamHealth Anesthesiology intends to provide contracted anesthesia services to the proposed Blue Ridge Surgery Center. Exhibit 10 contains a letter from the proposed medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system in Section V, pages 78-82. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO.

In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

Blue Ridge Surgery Center is not an existing facility. In Section VI.13, pages 89-90, the applicants provide the payor mix for the surgical program at CHS Blue Ridge Valdese for CY2016, as shown in the following tables:

Operating Rooms: CY2016 CHS Blue Ridge Valdese

Payor	Cases as a % of Total Cases
Medicare	32.7%
Medicaid	23.0%
Commercial/Managed Care	35.7%
Other*	5.2%
Self Pay	3.3%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

GI/Endoscopy Rooms: CY2016 CHS Blue Ridge Valdese

Payor	Cases as a % of Total Cases
Medicare	51.6%
Medicaid	16.3%
Commercial/Managed Care	27.3%
Other*	3.5%
Self Pay	1.3%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

Procedure Room: CY2016 CHS Blue Ridge Valdese

Payor	Cases as a % of Total Cases
Medicare	55.0%
Medicaid	24.0%
Commercial/Managed Care	8.2%
Other*	11.2%
Self Pay	1.7%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Burke						
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 88, the applicants state that "Neither Blue Ridge Surgery Center nor CHS Blue Ridge has any federal obligation to provide uncompensated care." In Section VI.10, page 88, the applicants state that Blue Ridge Surgery Center is not an existing facility and that in the past five years no civil rights access complaints have been filed against CHS Blue Ridge. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, pages 89-90, the applicants provide that as of OY2 (CY2020) 55.7% of OR patients, 67.9% of GI/Endoscopy Room patients and 79.0% of Procedure Room patients will have all or part of their services paid for by Medicare and/or Medicaid, as indicated in the tables below:

Operating Rooms: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	32.7%
Medicaid	23.0%
Commercial/Managed Care	35.7%
Other*	5.2%
Self Pay	3.3%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

GI/Endoscopy Rooms: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	51.6%
Medicaid	16.3%
Commercial/Managed Care	27.3%
Other*	3.5%
Self Pay	1.3%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

Procedure Room: CY2020 Blue Ridge Surgery Center

Payor	Cases as a % of Total Cases
Medicare	55.0%
Medicaid	24.0%
Commercial/Managed Care	8.2%
Other*	11.2%
Self Pay	1.7%
Total	100.0%

*Other includes workers' compensation and unspecified payors.

On page 90, the applicants state that CHS Blue Ridge's internal data was used to develop the projected payor mix based on the historical mix for the cases and procedures projected to be performed at Blue Ridge Surgery Center. On page 83 the applicants state "*Blue Ridge Surgery Center will provide services to all persons in need of medical care, regardless of race, color, religion, natural origin, sex, age, disability, or source of payment. Blue Ridge Surgery Center will not discriminate based on age, race, national or ethnic origin, disability, sex, or source of income.*" The applicant adequately demonstrates the extent to which each group will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, pages 87-88, the applicants describe the range of means by which persons will have access to the proposed facility. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1, pages 78-79, the applicants state that CHS Blue Ridge has extensive relationships with training programs and offers its facilities for health training programs that

are interested in providing educational opportunities for their students and that Blue Ridge Surgery Center, as a facility that will be both managed and staffed by CHS Blue Ridge, will represent a unique opportunity for training nurses, operating room technicians and other clinical professionals. The applicants provide a table of training programs that it has an existing relationship with including Appalachian State University, Caldwell Community College, Catawba Community College and Western Piedmont Community College. On page 79, the applicants state that all of the existing training programs will have access to clinical training at Blue Ridge Surgery Center. Exhibit 17 contains a copy of a clinical training agreement. The information provided in Section V is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (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.

C

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location.

According to Table 6A, on page 62 of the 2017 SMFP, there are 11 ORs in Burke County located in three facilities: Surgery Center of Morganton Eye Physicians (2 ORs) and CHS Blue Ridge-Valdese (4 ORs) and CHS Blue Ridge-Morganton (5 ORs). Blue Ridge also has a dedicated C-Section OR which is not included. See table below.

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
Surgery Center of Morganton Eye Physicians	0	2	0	0	2
Blue Ridge*	1	0	9	0	10
Total**	1	2	9	0	12

*CHS Blue Ridge has two campuses under the same hospital license: CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton.

**Does not include CON adjustments for C-Section ORs.

On page 62, the 2016 SMFP defines the service area for ORs as *“the operating room planning area in which the operating room is located. The operating room planning areas are the single*

and multicounty groupings shown in Figure 6-1 [on page 67].” Figure 6-1 shows Burke County as a single county OR service area. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

The total number of ORs (12) in Burke County will not increase as a result of this proposal nor will there be a change in the physical location of any of the ORs, only how four of the twelve OR's are licensed. The four shared ORs located at CHS Blue Ridge-Valdese and which are licensed as part of the hospital, will be licensed separately as part of an ASC, Blue Ridge Surgery Center. The cost to the patient, for the same outpatient surgical procedure, is generally lower if the surgery is performed in an ASC rather than in a hospital-based OR.

In Section III.V.7, page 82, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicants adequately demonstrate that they will provide access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

CHS Blue Ridge and Blue Ridge Surgery Center propose to develop a separately licensed ambulatory surgery center with four ORs, two GI/endoscopy rooms and one procedure room on the Valdese campus. The proposed project does not involve the construction of a new

facility or movement to a new location. The four OR's, two GI/endoscopy rooms and the one procedure room will still be on the same property and in the same location. In Section I, pages 4-11, the applicants state Blue Ridge is the parent and sole member of CHS Blue Ridge and Blue Ridge Surgery Center. CHS Blue Ridge is managed by CHS. CHS Blue Ridge will manage the proposed ASC, Blue Ridge Surgery Center.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision, Blue Ridge and CHS have not been found to be out of compliance with any Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) *In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.*

-C- In Section II, page 24, the applicants state that the ORs at the proposed Blue Ridge Surgery Center facility are considered to be available for use five days per week and 52 weeks a year.

(b) *A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

- (1) *demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: $\{[(\text{Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of facility's projected outpatient cases times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$ minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and*
- (2) *The number of rooms needed is determined as follows:*
 - (A) *in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*
 - (B) *in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*
 - (C) *in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-C- The proposed project is in the Burke County Operating Room Service Area which has more than ten ORs. CHS Blue Ridge has two campuses in Burke County: CHS Blue Ridge-Valdese and CHS Blue Ridge-Morganton. The two campuses are on the same hospital license and while reported in the same license renewal application (LRA) the two campuses are distinguished within the LRA.

In Section II, page 21 and Section IV, page 76 the applicants project the four ORs being relicensed from CHS Blue Ridge (Valdese Campus) to the proposed Blue Ridge Surgery Center facility will perform 4,878 outpatient surgical cases in the third year of operation which demonstrates a need for 4 ORs at the facility [4,878 cases x 1.5 hours per case = 7,317 hours; 7,317 hours/ 1,872 hours = 3.9 or 4 operating rooms needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

(c) *A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:*

(1) *demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and*

(2) *The number of rooms needed is determined as follows:*

(A) *in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*

(B) *in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*

(C) *in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-NA- The applicants are not proposing to increase the number of ORs in the Burke County Operating Room Service Area.

(d) *An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The applicants are not proposing to develop an additional dedicated C-Section OR.

e) *An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

- (1) *provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and*
- (2) *demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.*

-NA- The applicants are not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

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

-C- In Section III, pages 29-66 and 69-70, and Exhibits 14-16, the applicants document the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.