

Competitive Comments on 2020 Forsyth County Operating Room Applications

submitted by

MC Kernersville, LLC and The Moses H. Cone Memorial Hospital

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), MC Kernersville, LLC and The Moses H. Cone Memorial Hospital, hereafter referred to as Triad Surgery Center (G-11516-18), submit the following comments related to competing applications to develop additional operating rooms in Forsyth County. Triad Surgery Center's comments include *"discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards."* See N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's ease in reviewing the comments, Triad Surgery Center has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following projects:

G-11910-20, Novant Health Medical Park Hospital (Novant Health or NHMPH)

G-11916-20, North Carolina Baptist Hospital (NC Baptist)

GENERAL COMMENTS

All three applications propose to develop operating rooms in Forsyth County. Triad Surgery Center believes it has presented the most compelling application to develop operating rooms. In addition to the many reasons included in its application, the following factors show that Triad Surgery Center is the most effective applicant for the operating rooms:

- Geographic Accessibility
- Accountable Care Organization Participation
- Development of a New Provider in Forsyth County
- Opportunity to Meet Multiple Needs

Each of these factors is discussed in turn below.

Geographic Accessibility

Triad Surgery Center proposes to develop a freestanding ASF in Kernersville. Both Novant Health and NC Baptist propose to develop operating rooms in Winston-Salem. As demonstrated in Triad Surgery Center's application, the Kernersville region has the greatest need within Forsyth County for additional operating room capacity. An analysis of geographic access to operating rooms in Forsyth County by region, included in Section C.4 of Triad Surgery Center's application, indicates that the Kernersville region has the lowest number of operating rooms per 10,000 population.

The Kernersville region is the second largest region in the county and has a significant medical community including Cone Health MedCenter Kernersville, as well as healthcare resources that are part of other area healthcare systems. Of note, the Clemmons population is less than two-thirds of Kernersville's, yet Clemmons has more than two and half times the operating room capacity per 10,000 population

compared to Kernersville. The Clemmons population also has convenient access to Davie Medical Center, part of the NC Baptist system, located less than two miles from the Davie-Forsyth County border. Davie Medical Center is licensed for two shared operating rooms. Kernersville residents do not have similar access as no Guilford County operating rooms are located within a three-mile radius of the Forsyth-Guilford County line.

In addition, Triad Surgery Center examined the need for operating rooms by region based on the population distribution of Forsyth County. The 2020 SMFP has determined that Forsyth County has a total need for two additional operating rooms beyond its existing/approved inventory of 103 operating rooms for a total of 105 rooms. As demonstrated in Section C.4 of Triad Surgery Center's application, if Forsyth County's total need of 105 operating rooms were distributed among the three regions based on 2019 population and compared to the location of the existing/approved 103 operating rooms, the Kernersville region has the largest operating room deficit in the county at more than 11 operating rooms.

For these reasons, Triad Surgery Center's proposal to develop operating rooms in Kernersville is the most effective alternative.

Accountable Care Organization Participation

Cone Health has a proven commitment to providing high quality, low cost healthcare to its patients, in particular through its accountable care organization (ACO) participation. Triad HealthCare Network (THN) is a physician-led clinically integrated ACO, sponsored by Cone Health and located in the Piedmont Triad area. THN manages and coordinates care for nearly 200,000 covered lives in Alamance, Guilford, Rockingham, Randolph, and part of Forsyth counties through contracts with Medicare, HealthTeam Advantage, Humana, United HealthCare, UMR, and Cigna. THN supports better integration and clinical coordination, the importance of improving measurable healthcare outcomes, and the adoption of evidence-based best practices and cutting-edge technology that can reduce variability in the care it delivers. THN believes that by working together, its network can provide the right care, at the right place, at the right time. As of January 1, 2016, THN was one of 44 ACOs in the nation selected to participate in CMS's Next Generation ACO Program. Over its first three performance years as part of the Next Generation ACO Program, THN saved over \$29.9 million in healthcare costs and had an average savings rate of 3.77 percent. In its third performance year, 2018, it ranked number 13 out of 44 ACOs in savings at \$6.2 million, number 13 in savings at 2.39 percent, and number 15 in quality at 94.89 percent. THN has demonstrated a reputation for providing high quality of care to its patients. THN has earned various rankings and accolades that demonstrate its ability to provide ongoing quality care.

Triad Surgery Center believes that the proposed project will further enable THN to achieve its goal of providing high quality, low cost, coordinated healthcare. While THN has been successful in meeting ACO objectives, it cannot control facility-driven costs or quality when procedures are performed in other facilities. The proposed project will allow Cone Health and its THN partners to refer their patients to a site of care under their control, which is carefully managed to provide the highest quality care at the lowest cost. Patients will benefit directly because of the focus on lower costs, and they will also benefit indirectly through lower costs to the payors, which in turn results in lower costs to the healthcare system, which means less of a burden on taxpayers in the case of CMS and less of one on employers and employees in the case of commercial insurers. As such, the proposed project will expand the scope of high quality, low cost healthcare services available to the community, and competition will be enhanced in Forsyth County and surrounding areas.

Development of a New Provider

Triad Surgery Center's proposed project will enable the development of a new provider and an additional freestanding ASF in Forsyth County, enhancing competition for surgical services. There are currently four existing providers of operating rooms in Forsyth County, and Cone Health is not among them. Moreover, each of the four providers already operates one or more freestanding ASFs in the county:

- Novant Health (Two freestanding ASFs: Novant Health Kernersville Outpatient Surgery and Novant Health Clemmons Outpatient Surgery)
- NC Baptist (Joint venture freestanding ASF with Surgical Care Affiliates: Clemmons Baptist-SCA ASF)
- Surgical Care Affiliates (Joint venture freestanding ASF with NC Baptist: Clemmons Baptist-SCA ASF)
- Piedmont Ear, Nose & Throat Associates (one freestanding ASF: Piedmont Outpatient Surgery Center)

As such, approval of Triad Surgery Center's application will allow the development of a new, low cost, high quality provider in Forsyth County.

In addition, as discussed below, Triad Surgery Center believes that it is the only applicant that has demonstrated conformity with the statutory and regulatory review criteria. The following sections provide detailed comments on each application as well as a comparative analysis.

APPLICATION-SPECIFIC COMMENTS

North Carolina Baptist Hospital (NC Baptist)

NC Baptist's application to develop two additional operating rooms at its main campus in Winston-Salem should not be approved as proposed. Triad Surgery Center identified the following issues, which contribute to NC Baptist's non-conformity:

Failure to demonstrate the need for the proposed project

NC Baptist fails to demonstrate the need of the population for the proposed project. The discussion of need in the application centers largely around the fact that utilization at NC Baptist generated the need for additional operating rooms in Forsyth County. While this statement may be relevant for certain services in some service areas, given the dynamics of the Forsyth County market, the continuing shift of inpatient cases to outpatient, and the desire of patients and payors for a lower cost setting, it is not likely that the status quo suggested by NC Baptist will remain; rather, the growing surgical volume will shift to lower cost providers and settings, such as the proposed Triad Surgery Center ASF. As this shift occurs, the need for additional capacity at NC Baptist will wane. As shown on page 34 of NH Baptist's application, excerpted below, its outpatient surgical cases have declined 5.8 percent from FY 2015 to 2020, or 1.5 percent annually, as cases have shifted to lower cost settings.

NCBH Annual Statistics

	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
IP DOC	220,088	224,214	223,776	232,345	226,388	235,127
ED visits	108,945	109,796	104,730	100,576	100,680	90,331
IP Surgical Cases	14,214	14,534	14,392	14,460	14,271	15,141
OP Surgical Cases	19,549	19,925	20,000	19,786	18,753	18,422

Sources: 2016-2020 NCBH hospital license renewal applications, NCBH internal data.

Source: NC Baptist Application, page 34.

Additionally, NC Baptist's inpatient surgical cases remained almost unchanged (~14,200 to 14,500 annually) between FY 2015 and 2019. NC Baptist's inpatient surgical cases appear to have grown in FY 2020, which is based on partial year data, July 2019 to March 2020, annualized for 12 months. As a result, NC Baptist's historical FY 2015 to 2020 compound annual growth rate of 1.27 percent for inpatient surgical cases, which it uses to project future cases, is based almost entirely on one year of growth in the most recent year derived from actual FY 2019 to annualized FY 2020. Notably, NC Baptist's ED visits declined by over 10 percent from FY 2019 to 2020, which may also impact surgical utilization trends.

Notably, NC Baptist fails to include its actual FY 2020 data anywhere in its application and does not provide it as specifically requested in Section C.7 – Form C Utilization. Section C.7(b) states *“Interim-Provide projected annual utilization data for each full fiscal year from the last full fiscal year prior to submission of the application until the project is complete. One year of annualized data may be necessary to complete the form as requested and is permissible. If it is necessary to include one year of annualized utilization data, specify the number of months for which actual utilization data is available, provide the total actual utilization data for those months and describe the method used to annualize the partial year of actual*

utilization data” (emphasis added). However, NC Baptist’s application fails to include the total actual utilization data for any of the months of FY 2020 including those months that it annualized.

The application also fails to demonstrate that additional capacity is actually needed at NC Baptist, despite the reference to how the need determination was generated. In April 2013, NC Baptist was awarded a CON to develop seven additional operating rooms pursuant to Project ID #G-8460-10, none of which have yet been developed. Based on its application, these seven additional operating rooms are not scheduled to be developed until July 2024, more than 11 years after receiving the CON. Pursuant to the *2018 SMFP* Forsyth County operating room need determination, NC Baptist was approved to develop four additional operating rooms, which also will not be developed until July 2024 according to its application. In its current application, NC Baptist is proposing a development schedule that will develop its two additional operating rooms in July 2024, and that is before any unscheduled delays occur as they have with other recent operating room projects. Given the growth in surgical cases in the service area, though not at NC Baptist, it would be detrimental to the patient population to award the two operating rooms to NC Baptist.

Based on the above issues, Triad Surgery Center believes that NC Baptist should be found non-conforming with Criteria 3 and 6.

Novant Health Medical Park Hospital (Novant Health)

Novant Health's application to develop two additional operating rooms at Novant Health Medical Park Hospital in Winston-Salem should not be approved as proposed. Triad Surgery Center identified the following specific issues, each of which contributes to Novant Health's non-conformity:

- (1) Failure to use proper case times and standard hours per operating room per year**
- (2) Failure to demonstrate projected growth rates are reasonable and supported**

Each of the issues listed above is discussed in turn below. Please note that relative to each issue, Triad Surgery Center has identified the statutory review criteria and specific regulatory criteria and standards related to the non-conformity.

Failure to Use Proper Case Times and Standard Hours per Operating Room per Year

Novant Health's application includes numerous erroneous assumptions that do not comply with the requirements for projecting operating room need based on the *SMFP* OR Methodology including case time and standard hours per operating room per year. As such, the application cannot be approved as explained in detail below.

Section C.6.(d)(iii) of the OR/GI Endo Room Certificate of Need Application form states:

- (iii) For each facility identified in response to Question 6(d)(i), provide the facility's group assignment, standard hours per OR per year and final case times as reported in Chapter 6 of the SMFP in effect at the time the review begins by completing the following table. Use the facility's final case times as reported in Chapter 6 of the SMFP to project estimated surgical hours in Form C.**

In its response and its projections for estimated surgical hours in Form C, Novant Health failed to provide and utilize the proper case times and standard hours per operating room per year as reported in the *2020 SMFP* for Novant Health facilities in Forsyth County. Instead, Novant Health deliberately and erroneously substitutes its assumed standard hours per operating room per year and case times.

Similarly, the applicable performance standard for operating rooms at 10A NCAC 14C .2103 states:

- (a) An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.***

The Definitions at 10A NCAC 14C .2101(2) state "For purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated by reference including subsequent amendments and editions" (emphasis added). As such, Novant Health must demonstrate the need for the proposed operating rooms consistent with the *2020 SMFP* based on its submission date. However, Novant Health failed to utilize the proper case times and standard hours per operating room per year as reported in the

2020 SMFP for Novant Health facilities in Forsyth County. Instead, Novant Health erroneously substitutes its assumed standard hours per operating room per year and case times.

As a result of its failure to use the proper case times and standard hours per operating room per year, Novant Health overstates its operating room need. Further, Novant Health failed to correctly state the number of existing operating rooms at Novant Health Kernersville Medical Center (NHKMC); its calculations assume that facility has only two existing operating rooms rather than the four rooms that it actually operates. As shown below, Novant Health has a projected surplus of 6.75 operating rooms in its third year of operation (not a deficit of 3.17 rooms as stated on pages 48 and 57) based on proper case times and standard hours per operating room per year and corrected inventory.

Please note that the “Surgical Hours” and “# of ORs Needed” sections of Novant Health Form C Utilization tables are entirely miscalculated and cannot be derived from the projected surgical cases and assumed case times, which are improper as noted above. As an example, NHMPH’s Form C Utilization reports 1,187,929 “Total Surgical Hours” and 677 “Total Surgical Hours / Standard Hours per OR per Year” in 2025; based on Novant Health’s improper assumptions, the accurate calculations are YY “Total Surgical Hours” and ZZ “Total Surgical Hours / Standard Hours per OR per Year.” As such, the analysis below relies on the data presented in the tables on pages 45 to 48 of the Novant Health application.

Based on improper case times and standard hours per operating room per year, as well as its inaccurate number of operating rooms at NHKMC, Novant Health’s application purports its system will have a deficit of 3.17 operating rooms in 2025, as shown below based on pages 45 to 48 of its application. Triad Surgery Center has highlighted the improper Novant Health assumptions in orange below.

Inaccurate Novant Health OR Deficit/Surplus As Submitted

<i>Facility*</i>	<i>CY 2025 Cases</i>	<i>Case Time (Hours)</i>	<i>Total Surgical Hours</i>	<i>Standard Hours per OR per Year</i>	<i>OR Demand</i>	<i>Existing/Approved /Proposed ORs</i>	<i>OR Need</i>
NHMPH	10,693		20,160	1,755	11.5	12	0.46
Inpatient	846	3.57	3,017				
Outpatient	9,847	1.75	17,232				
NHFMC	14,018		34,993	1,755	19.9	20	0.10
Inpatient	7,470	2.77	20,693				
Outpatient	6,548	2.18	14,274				
NHKMC	3,523		6,861	1,500	4.6	2	(2.57)
Inpatient	1,259	2.15	2,706				
Outpatient	2,264	1.84	4,166				
NHCMC	3,773		8,879	1,755	5.1	5	(0.06)
Inpatient	1,976	2.54	5,020				
Outpatient	1,797	2.14	3,845				
NHCOS	1,836	1.19	2,178	1,312	1.7	2	0.34
NHKOS	2,137	1.04	2,226	1,312	1.7	2	0.30
NHHOS	8,980	0.84	7,528	1,312	5.7	4	(1.74)
Total	44,959		82,765		50.2	47	(3.17)

*Novant Health Medical Park Hospital (NHMPH), Novant Health Forsyth Medical Center (NHFCM), Novant Health Kernersville Medical Center (NHKMC), Novant Health Clemmons Medical Center (NHCMC), Novant Health Clemmons Outpatient Surgery (NHCOS), Novant Health Kernersville Outpatient Surgery (NHKOS), and Novant Health Hawthorne Outpatient Surgery (NHHOS).

Note: Triad Surgery Center was not able to recalculate several total surgical hours and OR Need statistics in the table above based on Novant Health’s stated assumptions. However, the differences did not appear to be material and may have been due to computer rounding.

As shown clearly in the excerpt below from Table 6A in the 2020 SMFP, operating rooms that are licensed as part of NHFCM, which includes the operating rooms at NHFCM, NHKMC, NHCMC, and NHHOS have 1,950 Standard Hours per OR per Year.

A	B	C	D	E	F	G	H	I	J	K	L	M
Service Area	License	Facility	Inpatient ORs	Ambulatory ORs	Shared ORs	Excluded C-Section ORs	Excluded Trauma/Burn ORs	CON Adjustments	CONs for Excluded C-Section ORs	Total Surgical Hours for Grouping	Group	Standard Hours per OR per Year
Durham	H0015	Duke University Hospital**	7	9	49	0	-1	0	0	129,703.2	1	1,950
Durham	H0233	Duke Regional Hospital	2	0	13	-2	0	0	0	22,819.3	3	1,755
<i>Duke University Health System Total</i>			<i>9</i>	<i>17</i>	<i>62</i>	<i>-2</i>	<i>-1</i>	<i>0</i>	<i>0</i>			
Durham	H0075	North Carolina Specialty Hospital	0	0	4	0	0	0	0	8,974.1	4	1,500
Durham		2018 SMFP Need Determination	0	0	0	0	0	0	4	0.0		
Durham Total			9	17	66	-2	-1	4	0			
Edgecombe	H0258	Vidant Edgecombe Hospital	1	0	5	-1	0	0	0	2,926.9	4	1,500
Edgecombe Total			1	0	5	-1	0	0	0			
Forsyth		Novant Health Clemmons Outpatient Surgery	0	0	0	0	0	2	0	0.0		
Forsyth	AS0149	Novant Health Kernersville Outpatient Surgery	0	2	0	0	0	0	0	181.3	5	1,312
Forsyth	H0209	Novant Health Forsyth Medical Center	5	6	24	-2	0	0	0	55,599.2	2	1,950
Forsyth	H0229	Novant Health Medical Park Hospital	0	0	10	0	0	0	0	18,177.4	3	1,755
<i>Novant Health Total</i>			<i>5</i>	<i>8</i>	<i>34</i>	<i>-2</i>	<i>0</i>	<i>2</i>	<i>0</i>			

Similarly, as shown clearly in the excerpt below from Table 6B from the 2020 SMFP, operating rooms that are licensed as part of NHFCM, which includes the operating rooms at NHFCM, NHKMC, NHCMC, and NHHOS demonstrate an inpatient case time of 157.2 minutes or 2.62 hours and an outpatient case time of 82.0 minutes or 1.37 hours. NHMPH demonstrates an inpatient case time of 217.0 minutes or 3.62 hours and an outpatient case time of 102.0 minutes or 1.70 hours. NHKOS demonstrates an outpatient case time of 44.0 minutes or 0.73 hours. Finally, NHCOS does not have a stated case time as it is a new facility and thus must use 71.2 minutes or 1.19 hours, the average final case time for Group 6 facilities, which is the Group Novant Health assumes in its Form C Utilization worksheet.

A	B	C	D	E	F	G	H	I	J	K	L	M	N
Service Area	License	Facility	Inpatient Cases	Final Inpatient Case Time	Ambulatory Cases	Final Ambulatory Case Time	Total Adjusted Estimated Surgical Hours	Growth Factor	Projected Surgical Hours for 2022	Projected Surgical ORs Required in 2022	Adjusted Planning Inventory	Projected OR Deficit/Surplus (Surplus shows as a "+")	Service Area Need
Duplin	H0166	Vidant Duplin Hospital	440	80.0	1,458	64.6	2,157	-1.28	2,157	1.44	3	-1.56	
Duplin Total													0
Durham		Arrington Ambulatory Surgical Center	0	0.0	0	0.0	0		0	0.00	4	-4.00	
Durham	AS0041	James E. Davis Ambulatory Surgical Center†††	0	0.0	5,877	54.0	5,293	5.96	5,609	4.27	4	0.27	
Durham	H0015	Duke University Hospital**	18,300	257.4	22,215	138.3	129,703	5.96	137,432	70.48	64	6.48	
Durham	H0233	Duke Regional Hospital^/†††	4,061	210.0	3,581	132.9	22,147	5.96	23,467	13.37	13	0.37	
<i>Duke University Health System Total</i>										88.12	85	3.12	
Durham	H0075	North Carolina Specialty Hospital^/†††	1,521	137.7	3,344	89.4	8,474	5.96	8,979	5.99	4	1.99	
Durham		2018 SMFP Need Determination	0	0.0	0	0.0	0		0	0.00	4	-4.00	
Durham Total													0
Edgecombe	H0258	Vidant Edgecombe Hospital†/†††	559	107.8	1,844	62.6	2,927	-1.15	2,927	1.95	5	-3.05	
Edgecombe Total													0
Forsyth		Novant Health Clemmons Outpatient Surgery	0	0.0	0	0.0	0		0	0.00	2	-2.00	
Forsyth	AS0149	Novant Health Kernersville Outpatient Surgery	0	0.0	247	44.0	181	4.05	189	0.14	2	-1.86	
Forsyth	H0209	Novant Health Forsyth Medical Center†	10,821	157.2	19,939	82.0	55,599	4.05	57,851	29.67	33	-3.33	
Forsyth	H0229	Novant Health Medical Park Hospital	891	217.0	8,797	102.0	18,177	4.05	18,914	10.78	10	0.78	
<i>Novant Health Total</i>										40.59	47	-6.41	
Forsyth	AS0021	Wake Forest Baptist Health Outpatient Surgery Center - Clemmons****††††	0	0.0	178	86.8	258	4.05	268	0.20	3	-2.80	
Forsyth	H0011	North Carolina Baptist Hospital**	14,460	241.5	19,786	128.8	100,675	4.05	104,753	53.72	49	4.72	
<i>Wake Forest Baptist Health Total</i>										53.92	52	1.92	
Forsyth	AS0134	Piedmont Outpatient Surgery Center	0	0.0	2,385	48.0	1,908	4.05	1,985	1.51	2	-0.49	
Forsyth		Triad Center for Surgery	0	0.0	0	0.0	0		0	0.00	2	-2.00	

Using its projected surgical cases for CY 2025, which are not reasonable and supported as discussed in the comments below, Novant Health has a projected surplus of 6.75 operating rooms based on the proper case time, standard hours per operating room per year, and NHKMC operating room inventory assumptions with changes highlighted in green.

Revised Novant Health OR Deficit/Surplus Based on Proper Assumptions

Facility	CY 2025 Cases	Case Time (Hours)	Total Surgical Hours	Standard Hours per OR per Year	OR Demand	Existing/Approved /Proposed ORs	OR Need
NHMPH	10,693		19,799	1,755	11.3	12	0.72
Inpatient	846	3.62	3,059				
Outpatient	9,847	1.70	16,739				
NHFMC	14,018		28,521	1,950	14.6	20	5.37
Inpatient	7,470	2.62	19,572				
Outpatient	6,548	1.37	8,949				
NHKMC	3,523		6,392	1,950	3.3	4	0.72
Inpatient	1,259	2.62	3,298				
Outpatient	2,264	1.37	3,094				
NHCMC	3,773		7,634	1,950	3.9	5	1.09
Inpatient	1,976	2.62	5,178				
Outpatient	1,797	1.37	2,455				
NHCOS	1,836	1.19	2,178	1,312	1.7	2	0.34

Facility	CY 2025 Cases	Case Time (Hours)	Total Surgical Hours	Standard Hours per OR per Year	OR Demand	Existing/Approved /Proposed ORs	OR Need
NHKOS	2,137	0.73	1,567	1,312	1.2	2	0.81
NHHOS	8,980	1.37	12,273	1,950	6.3	4	(2.29)
Total	44,959		78,363		42.2	49	6.75

Notably, NHMPH demonstrates an operating room need of only 11.3 rooms, which when rounded to the nearest whole number consistent with the Operating Room Methodology in the 2020 SMFP results in a need for only 11 rooms and not the 12 rooms that NHMPH will operate after adding its proposed two operating rooms. Thus, NHMPH’s projected utilization fails to support the need for its project.

In conclusion, Novant Health overstated their operating room need due to the errors described above. Upon correction of these errors, Novant Health’s operating room need in Forsyth County is projected to be a 6.75 room surplus, or nearly 10 rooms fewer than Novant Health represented in its application.

	CY 2025 Cases	Total Surgical Hours	OR Demand	Existing/Approved /Proposed ORs	OR Need
Novant Health as Submitted	44,959	82,765	50.2	47	(3.17)
Novant Health Revised	44,959	78,363	42.2	49	6.75
Difference	0	4,402	7.9	-2	(9.92)

Based on the above issues, Triad Surgery Center believes that Novant Health should be found non-conforming with Criteria 1, 3, 4, 5, 6, and the performance standards in the operating room rules (10A NCAC 14C .2103).

Failure to demonstrate projected growth rates are reasonable and supported

On page 43 of its application, Novant Health provides its historical and projected operating room growth rates for inpatient and outpatient cases as follows:

	CAGR	Projected Growth Rate
NOVANT HEALTH MEDICAL PARK HOSPITAL		
Inpatient OR Procedures	-4.9%	0.5%
Outpatient OR Procedures	1.4%	1.4%
Total	0.8%	
NOVANT HEALTH FORSYTH MEDICAL CENTER		
Inpatient OR Procedures	-5.3%	0.5%
Outpatient OR Procedures	3.5%	3.5%
Total	-1.7%	
NOVANT HEALTH KERNERSVILLE MEDICAL CENTER		

Inpatient OR Procedures	2.7%	1.4%
Outpatient OR Procedures	-12.4%	0.7%
Total	-8.0%	
NOVANT HEALTH CLEMMONS MEDICAL CENTER		
Inpatient OR Procedures	78.0%	0.9%
Outpatient OR Procedures	9.3%	0.7%
Total	33.0%	

As shown, Novant Health projects positive growth for multiple facilities in several categories such as NHMPH inpatient cases, NHFMC inpatient cases, and NHKMC outpatient cases where the historical growth rates have been between negative 4.9 to 12.4 percent annually. Novant Health does not provide adequate or reasonable support that these categories that have experienced historical negative growth will grow positively in future years. Specifically, for NHMPH inpatient cases, Novant Health states on pages 41 to 42 that *“the historical decline in inpatient volume is due to shift from inpatient to outpatient due to technology advances and the shift from NH Medical Park to other Novant Health facilities. This shift is historical; it is anticipated that inpatient volume will grow steadily with the recruitment of additional surgeons.”* However, this statement that the shift from inpatient to outpatient is historical, and by implication, not a continuing trend, is contradicted by Novant Health’s statements on page 35 that, *“[t]he rising demand for outpatient surgery services is expected to increase in the future, primarily due to the fast pace of clinical and technological advancement that has given way for more surgical procedures to be performed in outpatient settings”* (emphasis added). Further, NHMPH has experienced declines in inpatient cases in each year over the last three years and those declines are increasing as shown in the table.

NHMPH Inpatient Operating Room Cases

	2017	2018	2019	CAGR
Inpatient Cases	908	878	821	-4.9%
Annual Growth		-3.3%	-6.5%	

Source: Novant Health application page 41.

Despite the increasing year over year losses in inpatient cases, Novant Health unreasonably assumes a positive, perpetual increase in inpatient cases of 0.5 percent annually beginning in 2020, with insufficient evidence that such a significant reversal in the trend is likely. As submitted, Novant Health projects an operating room need of 11.5 rooms at NHMPH and a surplus of 0.46 rooms after adding its proposed two operating rooms. As shown in the prior section of comments, NHMPH’s operating room need is reduced to 11.3 rooms and a surplus of 0.72 rooms when corrected for proper case time assumptions and fails to demonstrate the need for its proposed project. However, based on the discussion below, it is clear that NHMPH’s projected inpatient case growth rate assumption is unreasonable. In order to demonstrate more reasonable and supported NHMPH projected utilization, Triad Surgery Center analyzed two scenarios as presented below. Scenario 1 assumes that NHPMH’s inpatient cases do not decline at historical rates and remain at 2019 levels through 2025. Scenario 2 assumes that inpatient cases decline at the historical rate of 4.9 percent annually. Using 2020 SMFP case times, NHMPH has a projected surplus of 0.77 operating rooms in Scenario 1 and a projected surplus of 1.21 operating rooms in Scenario 2 after adding its two proposed operating rooms.

Medical Park Hospital OR Need Based on More Reasonable Assumptions

	<i>Projected Growth Rate</i>	<i>CY 2025 Cases</i>	<i>Case Time (Hours)</i>	<i>Total Surgical Hours</i>	<i>Standard Hours per OR per Year</i>	<i>OR Demand</i>	<i>Existing/Approved /Proposed ORs</i>	<i>OR Need</i>
As Submitted		10,693		20,252	1,755	11.5	12	(0.46)
Inpatient	0.5%	846	3.57	3,020				
Outpatient	1.4%	9,847	1.75	17,232				
Corrected Case Times		10,693		19,799	1,755	11.3	12	(0.72)
Inpatient	0.5%	846	3.62	3,059				
Outpatient	1.4%	9,847	1.70	16,739				
IP Growth Flat		10,668		19,709	1,755	11.2	12	(0.77)
Inpatient	0.0%	821	3.62	2,969				
Outpatient	1.4%	9,847	1.70	16,739				
IP Trend Continues		10,668		18,934	1,755	10.8	12	(1.21)
Inpatient	-4.9%	821	3.62	2,195				
Outpatient	1.4%	9,847	1.70	16,739				

Based on the above issues, Triad Surgery Center believes that Novant Health should be found non-conforming with Criteria 1, 3, 4, 5, and 6, and the performance standards in the operating room rules (10A NCAC 14C .2103).

COMPARATIVE COMMENTS

Given that a total of three applicants propose to meet the need for the two new operating rooms in Forsyth County, not all can be approved as proposed. To determine the comparative factors that are applicable in this review, Triad Surgery Center reviewed recent Agency findings for competitive OR reviews, including the Agency findings for the *2018 SMFP* Forsyth County operating room need determination. Based on that review, Triad Surgery Center compared the applications on the following factors:

- Conformity with Rules and Criteria
- Geographic Accessibility
- Documentation of Physician Support
- Patient Access to New Provider
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties
- Access by Underserved Groups-Charity Care
- Access by Underserved Groups-Medicare
- Access by Underserved Group-Medicaid
- Projected Net Revenue per Case
- Projected Operating Expense per Case
- History of Project Development/Operating History

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, only Triad Surgery Center is conforming with all applicable statutory and regulatory review criteria. The Novant Health and NC Baptist applications are each non-conforming with multiple applicable statutory and regulatory review criteria. Therefore, with regard to statutory and regulatory review criteria, Triad Surgery Center is the most effective alternative.

Geographic Accessibility

The *2020 SMFP* identifies a need for two additional operating rooms in Forsyth County. Triad Surgery Center proposes to develop two operating rooms in a freestanding ASF in Kernersville. Novant Health proposes to develop two operating rooms in Medical Park Hospital in Winston-Salem. NC Baptist proposes to develop two operating rooms in NC Baptist Hospital in Winston-Salem.

As Triad Surgery Center demonstrated in its application on pages 31-32 (excerpted below), assuming the operating room inventory in Forsyth County were distributed based on population, the Kernersville region has the largest operating room deficit in the county, as shown below. Cone Health's proposal represents less than one-fifth of the operating rooms needed in the Kernersville region. These analyses support the need for additional operating room capacity in the Kernersville region.

Forsyth Operating Room Need By Region

	2019 Population*	% of Total Population	OR Need based on Population %	Existing/ Approved ORs	OR Deficit/ (Surplus)
Kernersville (Forsyth County Portion)	67,425	16.5%	17.3	6	11.3
Clemmons	41,729	10.2%	10.7	10	0.7
Winston-Salem	299,098	73.3%	76.9	87	(10.1)
Total	408,252	100.0%	105	103	2.0

*Source: Esri.

Of note, “Geographic Accessibility” was included as a comparative factor in the Agency findings for the 2018 SMFP Forsyth County operating room need determination and the Agency’s analysis was similar to the one presented in the table above; however, the 2018 findings relied on 2017 United States (US) Census Bureau population data by village/town/city and did not include a detailed analysis of population by ZIP code. Nonetheless, if 2019 US Census Bureau population data is substituted in the analysis presented above, the Kernersville region still demonstrates the largest operating room deficit and Cone Health’s proposal still does not meet the entire need, as shown below.

Forsyth Operating Room Need by Village/Town/City per US Census

	2019 Population*	% of Total Population	OR Need based on Population %	Existing/ Approved ORs	OR Deficit/ (Surplus)
Kernersville (town)	24,660	8.4%	8.8	6	2.8
Clemmons (village)	20,867	7.1%	7.5	10	(2.5)
Winston-Salem (city)	247,945	84.5%	88.7	87	1.7
Total	293,472	100.0%	105	103	2.0

*Source: US Census Bureau. Accessed at <https://www.census.gov/quickfacts/fact/table/clemmonsvillagenorthcarolina,kernersvilletownnorthcarolina,winstonsalemcitynorthcarolina/PST045219>.

Triad Surgery Center is the only applicant to propose to develop operating rooms in Kernersville, the region which has the greatest need within Forsyth County for additional operating room. Therefore, with regard to geographic accessibility, Triad Surgery Center is the most effective alternative.

Documentation of Physician Support

Each application documents adequate physician support of their proposed projects. Therefore, with regard to the demonstration of physician support, the proposals are equally effective. However, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria.

Patient Access to New Provider

Novant Health and NC Baptist are both existing providers of surgical services in Forsyth County. Triad Surgery Center represents a new provider of surgical services in the county. Also, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad

Surgery Center is the most effective alternative with regard to providing Forsyth County patients with access to a new provider of surgical services.

Patient Access to Low Cost Outpatient Surgical Services

There are currently 103 operating rooms (the adjusted planning inventory excluding two dedicated C-Section and two Trauma Burn operating rooms) in Forsyth County (88 existing and 15 approved). Operating rooms can be licensed either under a hospital license or an ASF that does not operate under a hospital license. Many, but not all outpatient surgical services can be performed either in a hospital licensed operating room (either a shared operating room or a dedicated outpatient operating room) or in a non-hospital licensed operating room or ASF; however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive in a non-hospital licensed operating room of ASF. The following table identifies the existing and approved Forsyth County operating rooms by type of room.

Forsyth County Existing and Approved Operating Rooms

	<i>Total ORs*</i>	<i>Hospital Based</i>	<i>% Hospital Based</i>	<i>Freestanding ORs</i>	<i>% Freestanding</i>
Total ORs	103	92	89%	11	11%

Source: 2020 SMFP and 2020 LRAs.

*Total operating rooms includes existing and approved operating rooms and excludes dedicated C-section and burn operating rooms.

As Triad Surgery Center demonstrated in its application on page 24 (excerpted below), outpatient surgery represents nearly three quarters of the total surgery volume in North Carolina as shown below.

North Carolina Surgical Volume

<i>Year</i>	<i>Inpatient</i>	<i>Outpatient</i>	<i>Total</i>	<i>Percent Outpatient</i>
FFY 2015	250,229	652,632	902,861	72.3%
FFY 2016	252,707	657,664	910,371	72.2%
FFY 2017	256,617	666,204	922,821	72.2%
FFY 2018	254,677	665,492	920,169	72.3%
FFY 2019	257,040	681,914	938,954	72.6%

Source: 2017 - Proposed 2021 SMFPs.

By comparison only 67 percent of surgical cases performed at Forsyth County facilities are outpatient, which is lower than the statewide experience of 73 percent. This difference may be reflective of Forsyth County’s two large inpatient acute care hospitals which serve as regional referral centers for complex inpatients, drawing a larger proportion of inpatient cases. Please note that the cases in the table below are based on cases performed at Forsyth County facilities, regardless of the county of origin of the patient.

Forsyth County Surgical Volume

<i>Year</i>	<i>Inpatient</i>	<i>Outpatient</i>	<i>Total</i>	<i>Percent Outpatient</i>
FFY 2015	24,630	48,002	72,632	66.1%
FFY 2016	24,667	48,979	73,646	66.5%
FFY 2017	25,818	50,076	75,894	66.0%
FFY 2018	26,172	51,332	77,504	66.2%
FFY 2019	25,376	52,219	77,595	67.3%

Source: 2017 – Proposed 2021 SMFPs; data reflects cases performed at Forsyth County facilities.

A comparison of 2019 Forsyth County ASF surgical cases to total 2019 NC ASF surgical cases by specialty reported in 2020 LRAs, reveals a significant difference in types of surgeries performed in the two Forsyth County ASFs relative to ASFs across North Carolina.

Surgical Cases by Specialty in NC ASFs vs Forsyth County ASFs

<i>Surgical Specialty</i>	<i>2019 NC Total ASF Surgeries</i>	<i>Percent of 2019 NC Total ASF Surgeries</i>	<i>2019 Forsyth County Total ASF Surgeries</i>	<i>Percent of 2019 Forsyth County Total ASF Surgeries</i>
Ophthalmology	72,124	38.7%	1,068	20.0%
Orthopedics	53,806	28.9%	1,201	22.5%
Otolaryngology	28,681	15.4%	2,558	48.0%
General Surgery	9,609	5.2%	202	3.8%
Urology	4,923	2.6%	145	2.7%
Podiatry	3,644	2.0%	27	0.5%
Ob/Gyn	3,092	1.7%	129	2.4%
Neurosurgery	3,286	1.8%	-	0.0%
Plastic Surgery	2,055	1.1%	1	0.0%
Oral Surgery	4,004	2.1%	-	0.0%
Vascular	213	0.1%	-	0.0%
Other1	921	0.5%	-	0.0%
Other2	114	0.1%	-	0.0%
Total	186,472	100.0%	5,331	100.0%

Source: Healthcare Planning and Certificate of Need Section License Renewal Application Database.

As shown in the comparison above, Forsyth County ASFs perform a higher percentage of otolaryngology and lower percentage of ophthalmology and orthopedics (the top two of the largest percentages of specialties performed in an ASF in the state) than ASFs in North Carolina on average. These statistics, as shown above, support the development of a multi-specialty ASF in Forsyth County to provide patients in Forsyth County access to non-hospital based surgical services, at typically lower costs.

“Patient Access to Low Cost Outpatient Surgical Services” was included as a comparative factor in the Agency findings for the 2018 SMFP Forsyth County operating room need determination and the analysis for that factor found the development of additional ASF operating room capacity in Forsyth County to be more effective than the development of additional hospital operating room capacity, stating, “[B]ased

upon the fact that 64.4% of Forsyth County’s 2017 surgical cases were ambulatory cases and the lack of access to ASF ORs in Forsyth County...projects proposing the development of ASF ORs would be more effective.” As shown above, in FFY 2019, 67 percent of the surgeries performed in Forsyth County were outpatient and freestanding ASF operating rooms comprise 11 percent of total operating room capacity. Therefore, Triad Surgery Center, the only project proposing to develop ASF operating rooms, is the most effective alternative with regard to providing patient access to low cost outpatient surgical services.

Patient Access to Surgical Specialties

Each of the three applicants proposes to provide surgical services representing multiple specialties. According to the Healthcare Planning and Certificate of Need Section License Renewal Application Database, the top eight most performed surgical specialties in Forsyth County in 2019 were orthopedics, general surgery, ophthalmology, urology, neurosurgery, otolaryngology, Ob/Gyn, and plastic surgery, which comprise over 76 percent of total surgical cases in the county.

Surgical Cases by Specialty in All Forsyth County Operating Rooms

<i>Surgical Specialty</i>	<i>2019 NC Total ASF Surgeries</i>	<i>Percent of 2019 NC Total ASF Surgeries</i>
Orthopedics	15,883	19.2%
General Surgery	15,171	18.3%
Ophthalmology	8,316	10.0%
Urology	7,272	8.8%
Neurosurgery	5,090	6.1%
Otolaryngology	4,432	5.3%
Obstetrics and GYN	4,398	5.3%
Plastic Surgery	2,897	3.5%
Open Heart Surgery	2,780	3.4%
Vascular	2,564	3.1%
Cardiothoracic	2,103	2.5%
Podiatry	1,300	1.6%
Oral Surgery/Dental	1,051	1.3%
Other	9,592	11.6%
Total	82,849	100.0%

Source: Healthcare Planning and Certificate of Need Section License Renewal Application Database.

As shown in the following table, each of the applicants proposes to provide the surgical specialties that comprise the top eight most performed specialties.

Proposed Services to be Offered

<i>Surgery Specialties</i>	<i>NC Baptist</i>	<i>NH Medical Park</i>	<i>Triad Surgery Center*</i>
Orthopedic	X	X	X

Surgery Specialties	NC Baptist	NH Medical Park	Triad Surgery Center*
General	X	X	X
Ophthalmology	X	X	X
Urology	X	X	X
Neurosurgery or Spine	X	X	X
Otolaryngology	X	X	X
Ob/Gyn	X	X	X
Plastic	X	X	X
Cardiothoracic	X		
Vascular	X		
Surgical Oncology	X	X	

Source: Section C.1 and 2020 License Renewal Applications.

*Triad Surgery Center’s proposed surgical cases by specialty are provided on page 40 of its application, as well as in its Form C Assumptions and Methodology.

As the analysis above confirms, each applicant proposes to offer the top eight surgical specialties performed in Forsyth County; therefore, each applicant proposes to offer adequate access to multiple specialties. However, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to providing Forsyth County patients with access to multiple surgical specialties.

Access by Underserved Groups-Charity Care

The following table shows each applicant’s projected charity care to be provided in the project’s third full operating year.

Surgical Charity Care – Project Year 3

Applicant	Projected Total Charity Care	Charity Care per OR	Charity Care per Surgical Case	Percent of Net Surgical Revenue
NC Baptist	\$167,091,060	\$3,276,295	\$4,697	25.4%
Novant Health	\$4,167,385	\$347,282	\$390	4.1%
Triad Surgery Center	\$179,839	\$89,920	\$99	2.8%

Source: Form F.2 for operating rooms and Section Q.

*Includes Charity Care and “Self-Pay write offs”

As shown in the above table, NC Baptist projects the most charity care as a percent of net surgical revenue. There are differences between the applicants’ facilities: NC Baptist proposes to develop the operating rooms at an academic medical center, Novant Health proposes to develop the operating rooms at a hospital that “specializes in elective, outpatient and short-stay surgeries” (page 21 of the Novant Health application), and Triad Surgery Center proposes to develop the operating rooms at a freestanding ASF. Regardless, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to access by underserved groups-charity care.

Access by Underserved Groups-Medicare

The following table shows each applicant’s total number of projected surgical cases and the number of cases projected to be provided to Medicare patients in the applicant’s third full year of operation following completion of their projects.

Projected Medicare Cases – Project Year 3

<i>Applicant</i>	<i>Cases</i>	<i>Medicare Cases</i>	<i>% of Cases Medicare</i>
NC Baptist	35,576	12,752	35.8%
Novant Health	10,693	4,555	42.6%
Triad Surgery Center	1,809	599	33.1%

Source: Section L.3(a) response for operating rooms and Section Q.

As shown in the table above, Novant Health projects to provide care to the highest percentage of Medicare patients. As previously stated, there are differences among the applicants’ facilities. Regardless, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to access by underserved groups-Medicare.

Access by Underserved Groups-Medicaid

The following table shows each applicant’s total number of projected surgical cases and the number of cases projected to be provided to Medicaid patients in the applicant’s third full year of operation following completion of their projects.

Projected Medicaid Cases – Project Year 3

<i>Applicant</i>	<i>Cases</i>	<i>Medicaid</i>	<i>% of Cases Medicaid</i>
NC Baptist	35,576	6,454	18.1%
Novant Health	10,693	449	4.2%
Triad Surgery Center	1,809	18	1.0%

Source: Section L.3(a) response for operating rooms and Section Q.

As shown in the table above, NC Baptist projects to provide care to the highest percentage of Medicaid patients. As previously stated, there are differences among the applicants’ facilities. Regardless, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to access by underserved groups-Medicaid.

Projected Average Net Revenue per Case

The following tables show the projected net revenue per case in the third year of operation.

Net Revenue Per Case – Project Year 3

<i>Applicant</i>	<i>Net Revenue</i>	<i>Cases</i>	<i>Net Revenue / Case</i>
NC Baptist	\$656,941,979	35,576	\$18,466
Novant Health	\$101,255,263	10,693	\$9,470

Triad Surgery Center	\$6,462,116	1,809	\$3,572
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Source: Form F.2 for operating rooms and Section Q.

As shown in the table above, Triad Surgery Center projects to provide the lowest net revenue per case. As previously stated, there are differences among the applicants' facilities. Regardless, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to net revenue per case.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case in the third year of operation for each of the applicants.

Operating Expense Per Case – Project Year 3

<i>Applicant</i>	<i>Operating Expense</i>	<i>Cases</i>	<i>Operating Expense / Case</i>
NC Baptist	\$618,448,439	35,576	\$17,384
Novant Health	\$70,853,346	10,693	\$6,626
Triad Surgery Center	\$4,889,692	1,809	\$2,703

Source: Form F.2 for operating rooms and Section Q.

As shown in the table above, Triad Surgery Center projects to provide the lowest operating expense per case. As previously stated, there are differences among the applicants' facilities. Regardless, Triad Surgery Center is the only applicant that is conforming with all statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to operating expense per case.

History of Project Development/Operating History

As noted in the Agency findings for the 2016 Brunswick County OR review (see Attachment 1), Novant Health has a demonstrated history of failing to develop projects for which it has obtained CON approval. Specifically, Novant Health formed two wholly owned LLCs to apply for CONs to develop ambulatory surgery centers, both of which were subsequently approved: Same Day Surgery Center New Hanover (SDSCNH) / Project ID #O-7671-06 and Same Day Surgery Center Franklin, LLC (SDSCF) / Project ID #K-8357-09. While both of these proposals were approved and issued a CON, neither has been developed. SDSCNH was approved to develop a separately licensed ambulatory surgical facility with two operating rooms in New Hanover County, effective October 2007. Over four years later, having not developed the project, and pursuant to a July 2, 2012 declaratory ruling, New Hanover Regional Medical Center acquired 100% of Novant Health's interest in the proposed SDSCNH to develop the ORs in the hospital, not as a separately licensed ambulatory surgery center, as approved. Therefore, Novant Health did not develop the CON-approved ambulatory surgical facility in New Hanover County.

SDSCF was approved to develop a freestanding ambulatory surgery center in Franklin County, effective December 29, 2009. Approximately four years later, having not developed the project, Novant Health submitted a change of scope and cost overrun CON application, Project ID #K-10229-13, to relocate one OR from Novant Health Franklin Medical Center for a total of two ORs at the previously approved ASF in Franklin County. This project was approved effective December 3, 2014. In September 2016, per SDSCF's progress report dated September 21, 2016, the development of the project had not begun and Novant

Health was still in discussions with a possible joint venture partner. The Agency received prior written notice, dated November 22, 2016, stating Duke University Health System's intent to acquire 100 percent of the membership interest in SDSCF, the Novant Health LLC which has CON approval to develop a two-OR ambulatory surgery center in Franklin County. As of now, Novant Health has not developed the CON-approved ambulatory surgical center in Franklin County in a timely manner.

As noted in the Agency Findings for the 2017 Brunswick County OR Review, Novant Health's failure to develop these approved ASFs has denied New Hanover and Franklin counties access to ambulatory surgery services.

Additionally, Novant Health owns a now-closed and chronically underutilized ASF in Union County. As noted in the Agency Findings for the 2017 Union County OR Review, Presbyterian Same Day Surgery Center-Monroe is a chronically underutilized facility that has been licensed to operate as an ASF since 2009, but since January 2013 has not served any patients. As the Agency noted in those findings, Novant Health could have reopened its facility at any point since 2013 to serve patients, "[y]et, the Union County facility remains closed, chronically underutilized and excluded from the 2017 SMFP need determination methodology" (see excerpts from Agency Findings in Attachment 2).

In April 2013, NC Baptist was awarded a CON to develop seven additional operating rooms pursuant to Project ID #G-8460-10 which are yet to be developed. Based on previous CON applications, these seven additional operating rooms are not scheduled to be developed until July 2024, more than 11 years after receiving the CON. Pursuant to the 2018 SMFP Forsyth County operating room need determination, NC Baptist was approved to develop four additional operating rooms, which also will not be developed until July 2024 according to its application. In its current application, NC Baptist is proposing a development schedule that will develop its two additional operating rooms in July 2024, and that is before any unscheduled delays occur as they have with other recent operating room projects. Similarly, NC Baptist was awarded a CON in January 2012 to develop a three operating room ASF in Clemmons. That facility, now named Wake Forest Baptist Health Outpatient Surgery Center-Clemmons opened in February 2018, more than six years after receiving the CON. While these projects have been or will be undeveloped for many years, it is important to note that the delays were not contemplated in the original CON applications.

Thus, Novant Health's and NC Baptist's history of undeveloped, CON-approved operating room projects make their proposed projects less effective alternatives with regard to history of project development.

SUMMARY

In summary, Triad Surgery Center, the only ASF among the applicants, believes that it is clearly the most effective alternative for additional operating rooms in Forsyth County. Any perceived disadvantages which Triad Surgery Center may have in comparison is due to the scale of operation of a two operating room ASF relative to a full-sized hospital. Thus, objection to Triad Surgery Center on the grounds of its scale will always prevent new non-hospital providers and relatively smaller ASFs from serving any market which already has a hospital. Triad Surgery Center is the only applicant that conforms to all the statutory and regulatory review criteria and is comparatively superior on the relevant factors in this review. As such, Triad Surgery Center believes its proposal should be approved.

Attachment 1

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 28, 2017

Findings Date: May 4, 2017

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Assistant Chief: Martha J. Frisone

COMPETITIVE REVIEW

Project ID #: O-11282-16
Facility: Brunswick Surgery Center
FID #: 160564
County: Brunswick
Applicant(s): OWP3, LLC and Brunswick Surgery Center, LLC
Project: Develop a new ASC with one OR and two procedure rooms

Project ID #: O-11283-16
Facility: Novant Health Brunswick Outpatient Surgery
FID #: 160567
County: Brunswick
Applicant: Novant Health Brunswick Outpatient Surgery, LLC
Project: Develop a new ASC by relocating one OR from NHBMC and adding one new OR and a procedure room

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 – OWP3/BSC
C – NHBOS

Chapter 6 of the Proposed 2016 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional operating rooms (ORs) by service area. Application of the standard need methodology in the Proposed 2016 SMFP identified a need for one additional OR in the Brunswick County OR Service Area. There were no comments or petitions filed regarding the Brunswick County OR need determination in the Proposed 2016 SMFP during the Agency established petition and written comment periods. The Governor signed the 2016 SMFP on December 15, 2015. Therefore, the 2016 SMFP includes a need determination for one additional OR in Brunswick County based on the standard need methodology.

Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to develop one new OR and establish a new Ambulatory Surgical Center (ASC) in Brunswick County. Pursuant to the need determination, only one new OR may be approved in this review for Brunswick County.

A number of comments about the two proposed projects submitted to the Agency during the written comment period appear to have a misunderstanding of the proposed projects and the need for an additional OR in Brunswick County, pursuant to the standard methodology for determining need for additional ORs in the 2016 SMFP. Following are some of the misconceptions from the comments followed by the Agency response:

- Ambulatory services are being moved from Southport to Leland – Currently, there are no ambulatory surgery centers in Brunswick County. Novant Health is proposing to relocate an existing OR from Novant Health Brunswick Medical Center (NHBMC) to Novant Health Brunswick Outpatient Surgery (NHBOS) and develop one new OR (pursuant to the need determination). The relocation of one OR from NHBMC leaves NHBMC with a total of three shared ORs and one dedicated C-Section OR in their current location.
- The applications are both proposing three ORs – Both applications are proposing to develop an ASC in Leland with one new OR for Brunswick County (pursuant to the need determination). The Brunswick Surgery Center (BSC) application proposes to develop two procedure rooms in addition to the OR and NHBOS' application proposes to develop one procedure room and relocate an existing Brunswick County OR from NHBMC to the proposed ASC, in addition to the OR in the need determination. The Agency does not regulate the development of procedure rooms.
- Patients would be forced to travel significant distances to receive surgical care – Surgical services will still be available at both J. Arthur Doshier Memorial Hospital (Doshier) and NHBMC in the southern part of the county. No patients will be forced to travel to the proposed ASC; however, with the addition of an ASC in Leland, patients will also have access to outpatient surgical care in the northern part of the county.

- Approval of either application will result in duplication of services – The 2016 SMFP identified the need for one additional OR in Brunswick County, using the standard need methodology for determining the need for additional ORs; therefore, it is possible that either (or both) applications could demonstrate that approval of that application would not result in unnecessary duplication of existing or approved services.
- Surgeons at BSC “*will likely have little interest in continuing inpatient procedures at Doshier...*” – the BSC application clearly states that the BSC participating surgeons (page 76 of the application) will continue to utilize existing licensed hospital surgical facilities.
- The NHBOS application “*proposes to develop more than one operating room in Brunswick County in a location that is not easily accessible to most of the county. It would unnecessarily duplicate existing capabilities.*” – NHBOS proposes to develop only one new operating room in Leland, which is a large and fast growing area in northern Brunswick County, an area that currently has no surgical services. NHBOS also proposes to relocate one of four existing ORs from NHBMC and develop a procedure room at the ASC.

Need Determination

OWP3, LLC (OWP3) and Brunswick Surgery Center, LLC (BSC), collectively referred to as “**OWP3/BSC**”, or “the applicant”, proposes to develop a new ASC with one OR and two procedure rooms in Brunswick County. OWP3/BSC does not propose to develop more new ORs than are determined to be needed in the 2016 SMFP for Brunswick County. Therefore, the application is consistent with the need determination.

Novant Health Brunswick Outpatient Surgery, LLC (NHBOS), “the applicant”, proposes to establish a new ASC in Brunswick County by developing one new OR and one procedure room, and relocating one existing Brunswick County OR from Novant Health Brunswick Medical Center (NHBMC). The applicant does not propose to develop more new ORs than are determined to be needed in the 2016 SMFP for Brunswick County. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2016 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 39 of the 2016 SMFP, 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.”

Policy GEN-4, on pages 39-40 of the 2016 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

OWP3/BSC proposes to develop a new ASC with one OR and two procedure rooms in Brunswick County. Applicant OWP3 will build the building and Applicant BSC will lease space in a portion of the newly constructed medical office building to be located on South Dickinson Road in Leland (Brunswick County) and operate the ASC.

The applicant, OWP3/BSC, addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section III.1, pages 34-62, Section III.4, pages 64-66, Section II.8, page 26, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section III.1, pages 34-62, Section III.4, page 64, Section VI, pages 88-100, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III.1, pages 34-62, Section III.4, pages 63-64, and Section X, beginning on page 119. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. The application is consistent with Policy GEN-3.

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million; therefore, Policy GEN-4 is applicable. The applicant does not address Policy GEN-4 in Section III.4, where the application requests the applicant(s) to describe how the project is consistent with each applicable policy in the SMFP. However, in Section XI.8, page 130, the applicant describes its plan to maintain energy efficiency and water conservation, including, using energy guidelines of the U.S. Department of Housing and Urban Development, U.S. Department of Energy, and the American Society of Heating, Refrigeration, and Air Conditioning Engineers for the facility design; and incorporating a plumbing design which includes sensor-operated faucets and low flow toilets to minimize water usage. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is consistent with the need determination in the 2016 SMFP, Policy GEN-3 and Policy GEN-4. Consequently, the application is conforming to this criterion.

NHBOS proposes to establish a new ASC in Brunswick County by developing one new OR and one procedure room, and relocating one existing OR from NHBMC.

NHBOS addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section III.1, pages 22-38, Section III.4, pages 43-44, Section II.8, pages 13-15, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section III.1, pages 22-38, Section III.4, pages 44-45, Section VI, pages 66-76, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III.1, pages 22-38, Section III.4, pages 45-47, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

NHBOS addresses Policy GEN-4 as follows:

The proposed capital expenditure for this project is greater than \$5 million. In Section III.4, page 47, Section XI.8, page 106, and Exhibit 15, the applicant describes its plan to assure improved energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to the condition that the applicant shall develop an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

In summary, the application is consistent with the need determination in the 2016 SMFP, Policy GEN-3, and Policy GEN-4. Consequently, the application is conforming to this criterion.

Conclusion

In summary, both applicants adequately demonstrate that their proposals are consistent with the need determination in the 2016 SMFP for the development of one new OR to be located in Brunswick County. However, the limit on the number of ORs to be located in Brunswick County is one. Collectively, the two applicants propose a total of two new ORs. Therefore, even if both applications are conforming to all statutory and regulatory review criteria, both applications cannot be approved.

OWP3/BSC's application is conforming to the need determination, Policy GEN-3 and Policy GEN-4. NHBOS's application is conforming to the need determination, Policy GEN-3, and Policy GEN-4. Therefore, both applications are conforming to this criterion. See the Summary following the Comparative Analysis for the decision.

- (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 – Both Applications

OWP3/BSC proposes to develop a new ASC with one operating room and two procedure rooms. Applicant OWP3 will build the building on South Dickinson Road in Leland (Brunswick County) and Applicant BSC will lease space in the new medical office building and operate the ASC. In Section I.8, page 3, and Section I.10, page 4, respectively, the applicant describes the proposed project as follows:

“The proposed ASC will provide orthopaedic ambulatory surgical services and pain management procedures.

...

OWP3, LLC will incur the development and construction costs for the building where the proposed new ASC will be located. OWP3, LLC will lease a portion of the building to BSC for purposes of the proposed ASC project.”

In Section I.13(c), page 10, the applicant states that OWP3 and BSC are new entities that do not currently own, manage or operate any healthcare facilities. In Section I.12, pages 6-7, the applicant lists the physician owners of each entity and provide the addresses of medical office buildings owned and operated by the physicians. In Section I.12, Page 8, the applicant lists the officers for the two LLCs as Michael M. Marushack, MD, Eric J. Lescault, DO and Thomas B. Kelso II, MD, PhD. On page 10, the applicant states that OWP3/BSC physician members are also physician partners of OrthoWilmington, which the applicant refers to as a regional referral center for comprehensive orthopedic care, with satellite offices in New Hanover, Brunswick and Onslow counties. On page 12, the applicant states that on August 1, 2016, OrthoWilmington and three other independent orthopedic physician groups across North Carolina joined together to form a new practice called EmergeOrtho, with 49 offices in 21 counties statewide. Fifteen of the OrthoWilmington/EmergeOrtho orthopedic surgeons who own BSC will be responsible for provision of surgical services and the operation of the proposed ASC. The applicant further states on page 13 that although no surgical facilities in Brunswick County are

owned or operated by the applicant or any related parties, EmergeOrtho has experience owning and operating an orthopedic ASC: Triangle Orthopaedics Surgery Center. Triangle Orthopaedics Surgery Center is an orthopedic ambulatory surgical facility with two operating rooms developed pursuant to the demonstration project need determination in the 2010 SMFP: Project ID #J-8616-10 in Wake County. In Section II, the applicant discusses the scope of the proposed project, including listing the service components of the project (page 14) and identifying the necessary ancillary and support services (page 15) proposed for the ASC. In Section II.1, page 14, the applicant states:

“BSC proposes to develop an orthopaedic ambulatory surgery center with one operating room and two procedure rooms in Leland.”

Patient Origin

On page 62, the 2016 SMFP states, *“An operating room’s service area is 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.”* In Figure 6.1, page 67 of the 2016 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, in this application, the service area is Brunswick County. Providers may serve residents of counties not included in their service area.

In Sections III.6, page 68, the applicant provides the projected patient origin, by percentage, for the proposed facility for the first two operating years (CY2019-2020), as summarized in the table below.

Brunswick Surgery Center Projected Patient Origin

County	PY 1 CY2019	PY2 CY2020
Brunswick	95.8%	94.9%
Columbus	4.2%	5.1%
TOTAL	100.0%	100.0%

In Section III.6, page 68, with regard to the assumptions for projected patient origin, the applicant states:

“The projected patient origin is based on the methodology previously described in Section III.1, and is based on the historical ambulatory surgery patient origin for BSC’s anticipated user physicians.”

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1, page 34, the applicant describes the proposed project, stating:

“Pursuant to the need determination identified in the 2016 SMFP for one OR in Brunswick County, BSC proposes to develop a new ASC with one OR and two procedure rooms in Leland. The proposed project will:

- offer the first dedicated ambulatory surgery center to local residents,*
- help meet the growing demand for ambulatory surgical services in Brunswick County,*
- increase patient access to cost-effective ambulatory surgical services in Brunswick County, including access for the medically underserved,*
- improve geographic access to ambulatory surgical services in Brunswick County, and*
- improve patient satisfaction through offering an ambulatory surgical service with lower cost and charge structures compared to existing hospital-based surgical services.”*

In Section III.1, page 34, the applicant states it reviewed ambulatory surgery growth trends, ambulatory surgery utilization rates, service area demographics and growth trends, geography, and physician surgical utilization to determine need. On pages 34-62, the applicant describes its need analysis under the following headings:

Ambulatory Surgery Growth (pages 34-35),
Ambulatory Surgery Centers (pages 35-40),
Ambulatory Surgery for Brunswick County Residents (pages 40-43),
Orthopaedic Surgery (pages 43-46),
Service Area Demographics (pages 46-50),
Geography (pages 50-54), and
Physician Support (pages 54-55).

Ambulatory Surgery Growth

The applicant states that ambulatory surgery has grown from fewer than one in five procedures in 1980 being done without an overnight stay to four out of five surgical procedures now being performed on an outpatient basis. Ambulatory surgery accounts for approximately 72.3 percent of all surgical utilization in North Carolina, based on FY2015 data provided by the applicant on page 35 of the application. The applicant further states that as medical innovation continues to advance, more procedures will be able to be performed safely in the outpatient setting.

Ambulatory Surgery Centers

On page 35, the applicant states that ASCs are health care facilities that offer patients the convenience of having surgeries and procedures performed safely outside the hospital setting. On page 36, the applicant states that the number of ASCs has grown in response to demand from patients, physicians and insurers. The applicant further states:

“This demand has been made possible by technology, but has been driven by high levels of patient satisfaction, efficient physician practice, high levels of quality and the cost savings that have benefited all.”

The applicant discusses the benefits of the ASC setting to physicians and patients, including scheduling, physician ownership, the quality and safety of the care provided, and the cost-effectiveness of ASC services.

Ambulatory Surgery for Brunswick County Residents

On page 41, the applicant provides data illustrating that, *“the majority of Brunswick County residents who receive ambulatory surgery actually leave the county to receive care.”* In fact, more than half of all residents from Brunswick County seeking ambulatory surgery traveled to New Hanover County for care, which the applicant states, *“is indicative of the need for improved local access for Brunswick County residents.”*

Based on Brunswick County population and the number of Brunswick County patient outpatient surgery cases, the applicant calculated a 2015 Brunswick County ambulatory surgery use rate of 86.1 per 1,000 residents, significantly higher than the applicant’s calculated North Carolina ambulatory surgery use rate of 64.9 per 1,000 residents. The applicant concludes that as the Brunswick County service area population increases and third-party payors continue to direct patients to cost-effective settings, the service area will continue to experience increased ambulatory surgical utilization.

Orthopaedic Surgery

The applicant provides a table on page 43 representing calculations made from 2016 License Renewal Applications (LRAs) for Brunswick County Surgical Operating Rooms showing surgical cases by specialty with orthopedics (24.9%) representing the largest percentage of all outpatient surgical utilization, just ahead of general surgery (23.2%); and states:

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

The applicant further states that musculoskeletal conditions are among the most disabling and costly conditions suffered by Americans and that bone and joint disorders account for more than one-half of all chronic conditions in people older than 50 years of age in developed countries. On page 46, the applicant states that the high demand for outpatient orthopaedic surgery offers a tremendous opportunity to improve quality, value and access through an orthopaedic ambulatory surgery center.

Service Area Demographics

The applicant provides a table on page 47 representing the North Carolina Office of State Budget and Management (NCOSBM) Brunswick County projected population, which shows the county will grow by a compound annual growth rate (CAGR) of 2.4% from 2016 to 2021, while the statewide growth rate is only 1.0% during the same time period. The applicant also discusses the aging of the population and its impact upon the demand for orthopaedic surgical services. The applicant concludes that as the service area population ages, the resulting high demand for outpatient orthopaedic surgery offers a tremendous opportunity to improve quality, value and access through an orthopaedic ambulatory surgery center.

Geography

The applicant provides evidence on pages 50-54 that developing the need-determined OR in Leland is an effective alternative for improving geographic access to ambulatory surgical services for Brunswick County residents and BSC physician's Columbus County patients.

Physician Support

The applicant states that local physicians who currently refer patients to OrthoWilmington/EmergeOrtho are enthusiastic about the proposed project and that at least 12 orthopaedic surgeons are expected to utilize the proposed facility initially. Exhibit 11 contains support letters from 13 EmergeOrtho surgeons and three physicians who refer to OrthoWilmington/EmergeOrtho.

The following is a list of the 13 OrthoWilmington/EmergeOrtho surgeons identified in Exhibit 11, their current hospital affiliations as listed on the OrthoWilmington website (<http://www.orthowilmington.com/specialists-staff/physician-bios>), and their projected surgeries at BSC in the first operating year.

OrthoWilmington/ EmergeOrtho Surgeon	Hospital Affiliations*	BSC Cases Year 1
Michael M. Marushack, MD	DMH, NHBMC	370
Erick J. Lescault, DO	DMH, NHBMC, NHRMCOH	325
Jon K. Miller, MD	NHRMC, NHRMCOH, WS	20
Craig A. Rineer, MD	NHRMC, NHRMCOH, WS	125
Mark D. Foster, MD	NHRMC, NHRMCOH, DMH, NHBMC	190
Scott Q. Hannum, MD	NHRMC, NHRMCOH, WS	17
Richard S. Bahner, MD	NHRMC, NHRMCOH, WS	63
D. Todd Rose, MD	NHRMC, NHRMCOH, WS	40
Walter W. Frueh, MD	NHRMC, NHRMCOH, WS	12
Albert W. Marr, MD	NHRMC, NHRMCOH, WS	85
Thomas B. Kelso, MD	DMH, NHBMC	220
R. Mark Rodger, MD	NHRMC, NHRMCOH, WS	12
David W. Zub, MD	NHBMC	300
Total Projected		1,779

*DMH – Doshier Memorial Hospital
 NHBMC - Novant Health Brunswick Medical Center
 NHRMC – New Hanover Regional Medical Center
 NHRMCOH - New Hanover Regional Medical Center Orthopaedic Hospital
 WS – Wilmington Surgcare

In addition, Exhibit 11 contains support letters from three area referral physicians who pledge to continue to refer surgical cases to EmergeOrtho surgeons at the proposed ASC. The information provided by the applicant on the pages and Exhibit referenced above is reasonable and adequately supported.

Projected Utilization

In Section IV.1, page 77, the applicant provides the projected utilization for the operating room at its proposed facility for the first three years of operation following completion of the project, as summarized below.

**Brunswick Surgery Center
 Projected Utilization (CY2019-CY2021)**

	Year 1 CY2019	Year 2 CY2020	Year 3 CY2021
Number of Operating Rooms	1	1	1
Number of Orthopedic Surgical Cases	1,294	1,462	1,642

As shown in the above table, the applicant projects the proposed facility will perform 1,642 surgical cases in the one operating room in the third operating year (CY2021), which exceeds the annual utilization standard of 1,872 hours per operating room as required in 10A NCAC 14C.2130(b)(1) [1,642 surgical cases x 1.5 hours = 2,463 / 1,872 = 1.3].

The applicant describes its methodology and assumptions for projecting utilization at the proposed ASC in Section III.1 (b), beginning on page 55 of the application, and as summarized below.

Step 1. Determine Historical Utilization

On pages 55-56, the applicant provides the historical ambulatory surgical cases for the orthopaedic surgeons who have indicated their intent to utilize the proposed OR, as shown below.

**Brunswick Surgery Center
 Historical Utilization**

County	CY2014	CY2015	CY2016*
Brunswick	991	1,153	1,431
Columbus	41	88	170
Total	1,032	1,241	1,601
Annual Growth		20.3%	29.0%

Source: BSC member surgeons: Totals may not sum due to rounding
 *7 months of data annualized

Step 2. Project Orthopaedic Ambulatory Surgery Cases

On page 57, the applicant states that they reviewed historical ambulatory surgical growth rates (2012-2015) for Brunswick and Columbus counties in addition to the review of the BSC physicians' growth rates in Step 1. The 3-Yr CAGR was 7.4% and 3.4% for Brunswick and Columbus county residents, respectively. The applicant determined that applying two-thirds of the respective county's 3-Yr CAGR was reasonable and conservative, compared to the BSC physicians' historical annual surgical growth for the last two years and produces the following projected utilization for Brunswick and Columbus county orthopaedic ambulatory surgery cases.

**Projected Orthopaedic Ambulatory Surgery Cases
 BSC User Surgeons**

County	Growth Rate	CY2017	CY2018	CY2019	CY2020	CY2021
Brunswick	4.9%	1,502	1,576	1,653	1,735	1,820
Columbus	2.3%	174	178	182	186	190
Total Cases		1,675	1,753	1,835	1,920	2,010

Totals may not sum due to rounding

Step 3. Project Orthopaedic Ambulatory Surgery Cases to be Performed at BSC

On page 58-60, the applicant projects the number of ambulatory surgical cases expected to be performed at the proposed ASC. The applicant assumes that 75%, 80% and 85% of the BSC physicians' Brunswick County patients' ambulatory surgeries will be performed at the proposed ASC in the first three years of operation, respectively. The applicant

assumes a more conservative rate for its Columbus County patients' surgeries in the proposed ASC in the first three years of 30%, 40% and 50%, respectively, resulting in the following projection.

**Brunswick Surgery Center
 Projected Surgical Cases**

County	CY2019	CY2020	CY2021
Projected Total Brunswick Patient Surgeries	1,653	1,735	1,820
Projected % of Brunswick Patients' Surgeries	75%	80%	85%
Brunswick Surgeries	1,240	1,388	1,547
Projected Total Columbus Patient Surgeries	182	186	190
Projected % of Columbus Patients' Surgeries	30%	40%	50%
Columbus Surgeries	54	74	95
Total BSC Surgeries	1,294	1,462	1,642

Totals may not sum due to rounding

On page 59, the applicant states that the projections are reasonable and based on supported assumptions, including conservative growth rates, a reasonable portion of cases performed at the ASC, demographic growth and aging data, and the physician case estimates provided in their support letters in Exhibit 11. In addition, the applicant states that the proposed ASC will be available to any orthopaedic surgeon or pain management physician who meets the credentialing criteria for the proposed facility.

Non-Surgical Procedures Performed in Procedure Rooms

In addition to the projected surgical procedures, on page 61, the applicant projects 296, 303, and 310 procedure room cases, based on a percentage of its pain management physicians' historical utilization projected forward, during CY2019, CY2020, and CY2021, respectively. Exhibit 11 includes a letter from an EmergeOrtho surgeon who plans to practice in the proposed procedure rooms and projects performing 300 procedures in the first year. In addition, on page 62, the applicant discusses the use of portable C-Arm imaging in conjunction with surgical and pain management procedures.

Projected utilization at the proposed ASC is based on reasonable and adequately supported assumptions.

Therefore, based on the review and analysis of: 1) the information provided by the applicant in Section III, pages 34-76, including referenced exhibits; 2) the written comments received during the first 30 days of the review cycle; and 3) the applicant's response to the written comments submitted at the public hearing, the applicant adequately demonstrates the need to develop the proposed operating room and two procedure rooms, which will be licensed as a freestanding ambulatory surgery center.

Access

In Section VI.2, pages 88-89, the applicant states that BSC will not discriminate against anyone and will provide medical services without regard to race, ethnicity, creed, color, age, religion, national origin, gender, or handicap. Exhibit 10 contains the EmergeOrtho non-discrimination policy, which the applicant states is the model for the proposed ASC. In Section VI.14, page 97, the applicant projects that 24.76 percent of patients to be served will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed project, and demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

NHBOS proposes to develop a new multi-specialty, separately licensed ASC in Brunswick County by relocating one existing OR from NHBMC and developing one new OR and one procedure room. In Section I.12, page 3, the applicant states that Novant Health, Inc. owns one hundred percent of the applicant LLC. In Section I.13, pages 4-8, the applicant discusses Novant Health's experience in the development of surgical and other healthcare facilities, and the provision of surgical services and other healthcare services. In Section II, the applicant discusses the scope of the proposed project, including listing the service components of the project (page 9) and identifying the necessary ancillary and support services (pages 10-11) proposed for the ASC. In Section III.1, page 22, the applicant describes the proposed project as follows:

“Novant Health Brunswick Outpatient Surgery (NHBOS) is planning to develop a freestanding separately licensed outpatient surgery facility with two operating rooms located in Leland in Brunswick County. One of the operating rooms will be a new operating room identified as needed in the 2016 State Medical Facilities Plan (SMFP). The second operating room at NHBOS will be an existing operating room which will be relocated from NHBMC. Both NHBMC and NHBOS will be owned by Novant Health and operated by the administrative and surgical team at NHBMC. At completion of the project there will be two outpatient surgery rooms at NHBOS in Leland, and four hospital-based operating rooms at NHBMC, three shared operating rooms and one C-Section operating room.”

In Section III.8, page 51, the applicant states:

“The proposed project creates a more appropriate setting for clinically appropriate outpatient surgical cases in a variety of surgical specialties.”

Exhibit 4 contains support letters from 18 Novant Health surgeons who intend to seek OR privileges at the proposed ASC in the following specialties: General Surgery (4), OB/GYN (6), Ophthalmology (1), Orthopedics (1), Otolaryngology (2), Podiatry (1), Plastic Surgery (1), and Urology (2).

In addition, the applicant is proposing a minor procedure room at the proposed ASC. Exhibit 4 contains letters from two surgeons who state they will utilize the procedure room.

Patient Origin

In Section III.6, page 48, the applicant provides the projected patient origin for the proposed facility for the first two operating years (CY2019-2020), as shown in the table below.

NHBOS Projected Patient Origin

County	CY2019		CY2020	
	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Brunswick	2,843	88.4%	1,070	89.5%
Other	373	11.6%	125	10.5%
TOTAL	3,216	100.0%	1,196	100.0%

Other is not identified by the applicant.

However, from the tables provided in Exhibit 3, it is apparent that the applicant erroneously transferred columns of data from other tables to the above table in the application. The number of patients identified above for NHBOS in CY2019 is actually the number of patients recorded for NHBMC in FFY2015 in Exhibit 3, Table 14 and on its 2016 LRA. The number of patients shown above for CY2020 is actually the number of patients projected for NHBOS in CY2019. Per Tables 2 and 14 in Exhibit 3, the projected patient origin should be as shown below.

NHBOS Projected Patient Origin, per Tables 2 and 14, Exhibit 3

County	CY2019		CY2020	
	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Brunswick	1,070	89.5%	1,657	90.6%
Other	125	10.5%	171	9.4%
TOTAL	1,196	100.0%	1,828	100.0%

Other is not identified by the applicant.

The patient origin, as provided by the applicant does not identify “Other”, which represents approximately 10% of the total patient population. In Section III.6, page 48, the applicant states:

“Projected patient origin for NHBOS is based upon current outpatient surgical patient origin at NHBMC adjusted to reflect the projected decrease in outmigration, 1% in Project Year 1 and 3% in Project Year 2, expected because of the development of the proposed freestanding ambulatory surgical facility in Leland.”

Per the 2016 LRA submitted by NHBMC, 11.6% of its ambulatory surgical cases were performed on patients from outside Brunswick County. In addition to the 88.4% of patients from Brunswick County, the LRA lists outpatient surgical patients originating from Bladen, Burke, Cabarrus, Caldwell, Catawba, Chatham, Columbus, Cumberland, Davidson, Davie, Duplin, Durham, Forsyth, Gaston, Guilford, Hoke, Lincoln, Mecklenburg, New Hanover, Onslow, Pender, Randolph, Richmond, Robeson, Rowan, Scotland, Stokes, Union, Wake counties, and other states. Only New Hanover County (1.5%), Columbus County (2.2%), and South Carolina (5%) contributed as much as 2% to the total of outpatient surgical patients at NHBMC.

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describes the factors which it states support the need for the proposed project, including:

- NHBMC surgical utilization (pages 22-24),
- Brunswick County outpatient surgery market share, outmigration and outpatient surgery use rates (pages 24-25),
- Increasing number of surgeons on NHBMC medical staff (pages 25-26),
- Changes in outpatient services reimbursement (pages 26-28), and
- Growth in population for Brunswick County residents (pages 28-30).

NHBMC Surgical Utilization

On page 23, the applicant provides a table showing NHBMC operating above 80% of total surgical capacity since 2013. The applicant states that it is NHBMC’s utilization which resulted in the 2016 SMFP need determination for one new operating room in Brunswick County. The applicant further states that NHBMC surgeons have difficulty scheduling cases at NHBMC due to the constricted surgical capacity at NHBMC.

Brunswick County Outpatient Surgery Market Share, Outmigration and Outpatient Surgery Use Rates

On page 24, the applicant states that the limited surgical capacity at NHBMC has caused NHBMC's outpatient surgical market share to decrease as the Brunswick County population and the total outpatient surgical volume for Brunswick County residents has increased. The applicant provides a table showing surgical market share for Brunswick County residents and illustrating the large outmigration to two New Hanover surgical facilities: New Hanover Regional Medical Center and Wilmington SurgCare.

The applicant calculates an increasing Brunswick County outpatient surgery use rate and three year trend on page 25, utilizing population data from the NCOSBM and hospital and ambulatory surgery center data reported on annual LRAs. The applicant further states that it expects the aging population to impact the outpatient surgical utilization in Brunswick County.

Increasing Number of Surgeons on NHBMC Medical Staff

On page 25, the applicant states that NHBMC has increased its surgical staff from 17 in 2012 to 26 surgeons in 2016, including the specialties of general surgery, orthopedics, urology, OB/GYN, ENT, ophthalmology, oral and maxillary surgery, plastic surgery and podiatry. The applicant states that NHBMC is actively recruiting an additional orthopedic surgeon to meet the growing demand for surgical services in Brunswick County. The applicant further states (page 26) that the impact of one new orthopedic surgeon at NHBMC and NHBOS could exceed 500 additional surgical cases annually by the fourth year.

Therefore, the applicant says that the growth in surgical staff at NHBMC supports the need for the proposed NHBOS. Support letters from 18 NHBMC surgeons in multiple specialties are included in Exhibit 4.

Changes in Outpatient Services Reimbursement

The applicant discusses what it expects to be the impact of the Affordable Care Act and the implementation of value-based purchasing (VBP) for payments under the Medicare program for hospitals and ASCs on pages 26-28. The applicant states the proposed project reflects the efforts currently underway within Novant Health to address the changes that the Affordable Care Act and VBP will bring to the consumption of healthcare services.

Growth in Population for Brunswick County Residents

On page 28 of the application, the applicant states that the population growth of Brunswick County has outpaced state and national population growth by a large margin and provides data from the NCOSBM that shows that Brunswick County is growing

faster than Wake or Mecklenburg counties and further states that Brunswick County is growing faster than any county in North Carolina, based upon percentage growth from 2010 to 2016. In addition, the applicant provides data indicating a steady growth of the age 55+ population in Brunswick County. The applicant further states that the Leland zip code, where it proposes to locate NHBOS, in northeastern Brunswick County, has the largest population base in the county.

On page 30, the applicant states:

“NHBOS has documented the need for expanded outpatient surgery services located in Brunswick County: the growing population in Brunswick County, especially in the Leland and surrounding zip codes; the increasing utilization of outpatient surgery services by the Brunswick County population; and the need for a lower cost freestanding alternative for outpatient surgery. All these factors support the development of a freestanding outpatient surgery ambulatory surgical facility in Brunswick County.”

In Section III.2, pages 37-38, the applicant discusses the need for a general use minor procedure room, stating:

“NHBOS is proposing to add this space for the convenience of the surgeons on staff at NHBOS. The availability of a minor procedure room will allow surgeons to schedule patients for surgical cases and minor procedures at one location on those days the surgeon will be operating at NHBOS.”

Exhibit 4 contains letters from two Novant Health surgeons stating they will utilize the procedure room. The information provided by the applicant on the pages and exhibits referenced above is reasonable and adequately supported.

Projected Utilization

In Section IV.1, page 53, the applicant provides the projected utilization for the operating rooms at its proposed facility for the first three years of operation following completion of the project, which is summarized below.

**New Hanover Brunswick Outpatient Surgery
Projected Utilization (CY2019-CY2021)**

Surgical Suite	PY1 CY2019	PY2 CY2020	PY3 CY2021
Number of Operating Rooms	2	2	2
Number of Surgical Cases	1,196	1,828	2,300

As shown in the above table, the applicant projects the proposed facility will perform 2,300 surgical cases in the two operating rooms in the third operating year (CY2021), which

exceeds the annual utilization standard of 1,872 hours per operating room as required in 10A NCAC 14C.2130(b)(1) [2,300 surgical cases x 1.5 hours = 3,450 / 1,872 = 1.8].

The applicant describes its methodology and assumptions for projecting utilization at the proposed ASC in Section III.1(a) and (b) and Exhibit 3 of the application.

Step 1: Determine NHBMC Baseline Volume

Using available Trendstar and internal data, the applicant states that it determined September 2015-August 2016 utilization in Exhibit 3, Table 6 to be the most reasonable and conservative baseline data for use in projecting future surgical volume for Novant Health surgical facilities in Brunswick County: 883 for inpatient surgeries and 3,334 for outpatient surgeries.

Step 2: Project Inpatient Surgical Cases at NHBMC

The applicant states that it reviewed historical inpatient surgical utilization at NHBMC as shown in Exhibit 3, Table 6, and determined for the purposes of projecting inpatient surgical cases, to hold the inpatient surgical utilization constant at 883 cases through August 2022.

Step 3: Project Outpatient Surgical Utilization at NHBMC

The applicant states that it reviewed historical outpatient surgical utilization at NHBMC from Step 1 above and uses a baseline of 3,334 cases. For the purposes of projecting outpatient surgical cases, the applicant determined to use the Brunswick County projected population 2016-2022 CAGR of 2.3%, as calculated in Exhibit 3, Table 9, as shown on page 33 and below.

NHBMC Projected Outpatient Surgical Volume

	Sept 15- Aug16	Sept 16- Aug17	Sept 17- Aug18	Sept 18- Aug19	Sept 19- Aug20	Sept 20- Aug21	Sept 21- Aug22
Outpatient Cases	3,334	3,412	3,492	3,573	3,657	3,743	3,830

Totals may not foot due to rounding

Source per applicant: Exhibit 3, Table 1. Note that the applicant erroneously labeled the row of projections as "Inpatient" in the table on page 33.

Step 4: Determine Percentage of Outpatient Surgical Cases for NHBOS

Based on the level of surgeon support (Exhibit 4), the acuity level of outpatient surgical cases at NHBMC, and input from the NHBMC and Novant Health leadership teams, the applicant determined the percentage of the projected NHBMC outpatient surgical volume that will shift to the proposed ASC, as shown below.

**Shift of Outpatient Surgeries
 from NHBMC to NHBOS**

	PY1	PY2	PY3
Percentage Shift	30%	40%	45%

Step 5: Project OR Need for NHBOS

Based on the applicant’s assumptions regarding projected outpatient surgical cases at NHBMC for September 2018 through August 2022 (Exhibit 3, Table 1) and the shift of cases to NHBOS in Step 4, the applicant converts the projected shift of cases from fiscal year to calendar year for CY2019 through CY2020 in a table on page 34, which is summarized below.

Projected Shift of Outpatient Surgical Cases from NHBMC to NHBOS

	Sept 2018- Aug 2019	Sept 2019- Aug 2020	Sept 2020- Aug 2021	Sept 2021- Aug 2022
Projected Outpatient Surgical Cases	3,573	3,657	3,743	3,830
		PY1	PY2	PY3
		CY2019	CY2020	CY2021
NHBMC Outpatient Cases Converted to CY		3,601	3,686	3,772
Percentage Shift to NHBOS		30%	40%	45%
Cases Shifted to NHBOS		1,080	1,474	1,697

Totals may not sum due to rounding

In addition to the shift in cases from NHBMC, on page 34, the applicant states:

“With additional capacity, and a surgical facility located in the northeastern section of Brunswick County, NHBOS projected a 5% decrease in outpatient surgical outmigration by the end of the third year of operation of NHBOS”

On page 35, the applicant provides the calculation for the reduction in outmigration, utilizing projected volume based on projected population and the 2015 outpatient surgical use rate for Brunswick County residents (Exhibit 3, Table 4).

	PY1	PY2	PY3
	CY2019	CY2020	CY2021
Brunswick County Projected Population	133,941	137,032	140,123
2015 Outpatient Surgical Use Rate/1,000	86.09	86.09	86.09
Projected Total Brunswick County Outpatient Surgical Volume	11,531	11,797	12,063
Projected Percent Decrease in Outmigration for NHBOS	1%	3%	5%
NHBOS Volume Due to Decrease in Outmigration	115	354	603

The applicant's projected impact on NHBOS of the 5% decrease in outmigration by the third operating year results in an increase of 600+ outpatient surgical cases in CY2021 as shown in the tables on page 35 and below.

Projected Total NHBOS Surgical Cases and OR Need

	PY1	PY2	PY3
	CY2019	CY2020	CY2021
NHBMC Outpatient Cases Shifted to NHBOS	1,080	1,474	1,697
New Volume Recapture Due to Decrease in Outmigration	115	354	603
Projected Cases	1,196	1,828	2,300
Weighted Outpatient Surgical Hours (1.5)	1,794	2,742	3,451
Total ORs Needed (1,872)	0.96	1.46	1.84
Total ORs Needed Rounded per SMFP	1	2	2

Totals may not sum due to rounding

The table above shows the applicant's projection of 2,300 surgical cases for CY2021 at NHBOS, and demonstrates the volume is sufficient to support two ambulatory ORs by the third year of operation, using the SMFP methodology which assumes 1.5 surgical hours per ambulatory surgery and 1,872 surgical hours per OR.

Step 6: Project OR Need for NHBMC

The applicant utilizes the inpatient and outpatient surgical volumes projected in Steps 1, 2 and 3 to project the future operating rooms needed at NHBMC as presented on page 36 of the application and resulting in the following OR need at NHBMC, as summarized below.

NHBMC Total Projected Surgical OR Need

	PY1	PY2	PY3
	CY2019	CY2020	CY2021
Inpatient Cases	883	883	883
Weighted Inpatient Surgical Hours (3)	2,649	2,649	2,649
Outpatient Cases after Shift to NHBOS	2,521	2,211	2,074
Weighted Outpatient Surgical Hours (1.5)	3,781	3,317	3,112
Total Weighted Surgical Hours	6,430	5,968	5,761
Total ORs Needed (1,872)	3.4	3.2	3.1
Total ORs Needed Rounded per SMFP*	4	3	3

Totals may not sum due to rounding

*SMFP OR methodology (page 65 of 2016 SMFP) states that OR need fractions of 0.30 or greater are rounded to the next highest whole number in service areas with six to ten ORs. Brunswick County has six ORs.

Step 7: Project OR need for NHBOS and NHBOS

The applicant provides a table on page 37 of the application combining the operating room need for NHBMC and NHBOS (Steps 5 and 6 and Exhibit 3) and reflecting a need for 5 operating rooms (excluding one dedicated C-Section OR) in the third project year, utilized at 78.7%.

NHBOS and NHBMC Operating Room Need

	PY1	PY2	PY3
	CY2019	CY2020	CY2021
NHBOS OR Need	0.96	1.46	1.84
NHBMC OR Need	3.44	3.19	3.08
Total Combined Need	4.40	4.65	4.92
Total ORs Needed Rounded*	5	5	5
Total Combined Projected Weighted Surgical Hours	8,224	8,708	9,211
Combined Capacity (Surgical Hours Available for 5 ORs)	11,700	11,700	11,700
Projected Utilization of the 5 Novant Health ORs in Brunswick County	70.3%	74.4%	78.7%

Totals may not sum due to rounding

*Rounded per SMFP and CON Criteria and Standards

The applicant erroneously identified the project years in the table on page 37 as April through March. The Project Analyst corrected the table above to show the project years as calendar years, as specified throughout the application.

Non-Surgical Minor Procedures at NHBOS

In addition, Exhibit 3, Table 16 projects 344, 527, and 663 procedure room cases for NHBOS during CY2019, CY2020 and CY2021, respectively. Exhibit 4 includes letters from surgeons who plan to practice in the proposed procedure room. On page 37, the applicant states that minor procedure volume is estimated based upon discussion with NHBMC surgical management staff, a review of procedure volume data for the surgeons who signed procedure room support letters and a review of other multispecialty ambulatory surgical facilities with procedure rooms in North Carolina.

Projected utilization at the proposed ASC is based on reasonable and adequately supported assumptions.

Therefore, based on the review and analysis of: 1) the information provided by the applicant in Section III, pages 22-52, including referenced exhibits; 2) the written comments received during the first 30 days of the review cycle; and 3) the applicant's response to the written comments submitted at the public hearing, the applicant adequately demonstrates the need to establish the proposed freestanding ASC by developing one new OR and one procedure room, and relocating one existing NHBMC OR.

Access

In Section VI.2, page 66, the applicant states it will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay. Exhibit 8 contains copies of Novant Health's non-discrimination policy. In Section VI.14, page 75, the applicant projects that 65.6 percent of surgical cases will be provided to Medicare or Medicaid recipients at the proposed facility. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project, and demonstrates the extent to which all residents, including underserved groups, will 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– OWP3/BSC
C – NHBOS

NHBOS. In Section III.8, page 51, the applicant states:

“Relocating one operating room from NHBMC and adding one new SMFP operating room allows NHBMC and NHBOS to put Novant Health OR resources in Brunswick County to their best and most productive uses.”

The applicant discusses projected utilization for NHBMC and the impact NHBOS will have on utilization at NHBMC in detail in Section III.1.b., projecting a shift in clinically appropriate volume from NHBMC to NHBOS, with the result indicating a need for three shared operating rooms at NHBMC to meet the needs of the surgery patients remaining at NHBMC.

In Section III.3(d), page 41, the applicant states that the proposed project will not have a negative impact on the patients served in terms of any changes in services, costs to the patient, or level of access by medically underserved populations. In Section VI.13, the applicant states that the proposed payor mix at NHBOS is based on the current payor mix at NHBMC. The discussions regarding need and access found in Criteria (3) and 13(c)

are incorporated herein by reference. The applicant adequately demonstrates that the relocation of the one surgical operating room from NHBMC will not have a negative effect 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.

In summary, the applicant adequately demonstrates that the needs of the population presently served by NHBMC will be adequately met following the proposed relocation of the operating room from NHBMC to NHBOS. Therefore, the application is conforming to this 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.

C – Both Applications

OWP3/BSC. In Section III.8, pages 69-75, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not the most effective alternative at this time because it would not meet the need for additional surgical services, decrease the financial cost of surgical services or expand access to high quality outpatient surgical services for Brunswick County patients.
- Develop the Proposed ASC in Another Location – The applicant states that they determined that the proposed location was the best location for *“improving geographic access to ambulatory surgical services for Brunswick County residents.”*
- Develop An ASC Without Procedure Rooms – The applicant states that developing the ASC without two procedure rooms is not the most effective alternative because the procedure rooms enable pain management specialists to rotate procedures between each room while the other is being cleaned between patients. Additionally, the applicant states that the combination of one OR and two procedure rooms leverages facility staff and resources to maximize economies of scale, making the ASC more efficient and productive.
- Develop a Multi-Specialty ASC with Procedure Rooms - The applicant states that developing a multi-specialty ASC would have resulted in increased capital costs associated with the relevant equipment needed for the various surgical specialties involved. The applicant also states OR room turnover time could increase between different surgical specialties, decreasing the facility’s efficiency. Moreover, the applicant states that only orthopaedic surgeons and pain management specialists have documented intent to utilize the proposed facility at this point. For these reasons, the applicant states that this alternative is not the most effective alternative.

After considering the above alternatives, the applicant determined the proposed project as represented in the application is the most effective alternative to meet the identified need. 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 applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

NHBOS. In Section III.8, pages 49-51, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo –The applicant states that maintaining the status quo is not considered a viable alternative because the four ORs at NHBMC have been operating at functional capacity for the last four years. The applicant states that with the continued population growth, the existing capacity at NHBMC is no longer sufficient to meet the future need for surgical capacity as discussed in Section III.1.
- Develop a hospital-based outpatient surgery center – The applicant states that developing a hospital-based outpatient surgery center is not an effective alternative because outpatient surgical care can be offered at a lower cost than hospital based surgery.
- Develop a freestanding, separately licensed surgery center in another location - The applicant states that it rejected this alternative because Leland, the proposed location, is the largest and fastest growing population base in Brunswick County.
- Develop a freestanding, separately licensed surgery center with one operating room – The applicant states that “*One operating room surgical centers are inefficient and rarely successful in North Carolina.*” The applicant further states that five of the nine NC surgical facilities with only one OR are “*chronically underutilized*” (pages 49-50 of the application). Therefore, the applicant determined this was not a reasonable alternative.
- Develop a freestanding, multi-specialty separately licensed surgery center with two operating rooms - The applicant states that this alternative will permit clinically appropriate NHBMC outpatient surgical cases to shift to a freestanding multi-specialty surgery center setting in Brunswick County and will provide additional capacity for the growing demand for outpatient surgical services at NHBMC and in Brunswick County.

After considering the above alternatives, the applicant states that developing a freestanding, multi-specialty separately licensed surgery center with two ORs in Leland, as proposed in the application, is the most effective alternative to meet the identified need.

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 applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this 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.

C – Both Applications

OWP3/BSC proposes to develop a new ASC with one operating room and two procedure rooms in leased space in a new office building located in Leland, Brunswick County.

Capital and Working Capital Costs

In Section VIII.1, pages 109-113, the applicant states the total capital cost is projected as follows:

Proposed Project Capital Cost

	OWP3*	BSC	Total Project Costs
Site Costs	\$ 528,846	\$ 0	\$ 528,846
Construction Contract	\$ 2,149,934	\$ 0	\$ 2,149,934
Landscaping	\$ 21,442	\$ 0	\$ 21,442
Fixed Equipment	\$ 0	\$ 424,401	\$ 424,401
Movable Equipment	\$ 0	\$ 291,862	\$ 291,862
Equipment and Furniture	\$ 0	\$ 596,629	\$ 596,629
Consultant Fees	\$ 46,401	\$ 0	\$ 46,401
Financing Costs/Interest during Construction	\$ 130,000	\$ 8,000	\$ 138,000
Contingency	\$ 0	\$ 50,000	\$ 50,000
Total Capital Cost	\$ 2,876,623	\$ 1,370,892	\$ 4,247,515

*Per page 111 of the application, site costs, construction costs, landscaping and consultant fees totals “reflect a prorated share of the estimated cost of developing the entire 33,280 SF building, based on the ASC comprising 28.34% (9,433/33,280) of the facility.”

Exhibit 13 contains the estimated construction costs as prepared by William B. Adams III, a North Carolina licensed General Contractor. In Section IX.1, page 117, the applicant states that OWP3 will have no start-up costs associated with the proposed project; however, BSC is projecting \$120,000 in start-up expenses and \$210,000 in initial

operating expenses, for total working capital required in the amount of \$330,000. In Section XI.1, page 122, the applicant states:

“BSC will incur the tenant improvement costs via the lease agreement. Thus, the facility lease costs are operational, and are reflected in the proforma financial statements shown in Section XIII.”

Availability of Funds

In Section VIII.3, page 113, the applicant states that the project capital costs will be funded by conventional loans for both OWP3 and BSC. In Section IX.2, page 117, the applicant states that the working capital incurred by BSC will also be funded by a conventional loan. In Exhibit 15, the applicant provides letters dated November 14, 2016, from BB&T Commercial Banking documenting its intention to fund the capital costs for OWP3, in an amount up to \$8,500,000 and the capital and working capital costs for BSC, in an amount up to \$2,000,000, for the proposed project. The financing for BSC of up to \$2,000,000 provides an additional \$299,000 contingent financing, to cover underestimated expenses, if any. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital of the project.

Financial Feasibility

In the pro forma financial statements for OWP3/BSC, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the following table.

Brunswick Surgery Center

	CY2019	CY2020	CY2021
Projected Surgical Cases	1,294	1,462	1,642
Projected Average Charge per Case	\$ 4,841	\$ 4,913	\$ 4,987
Gross Surgical Revenue	\$ 6,265,251	\$ 7,182,181	\$ 8,187,055
Deductions from Surgical Revenue	\$ 3,325,405	\$ 3,812,084	\$ 4,345,440
Net Surgical Revenue	\$ 2,939,846	\$ 3,370,097	\$ 3,841,615
Projected Procedure Room Cases	296	303	310
Projected Average Charge per Case	\$ 894	\$ 908	\$ 922
Gross Procedure Room Revenue	\$ 264,618	\$ 275,061	\$ 285,916
Deductions from Proc. Room Rev	\$ 164,307	\$ 170,791	\$ 177,531
Net Procedure Room Revenue	\$ 100,311	\$ 104,270	\$ 108,385
Total Gross Income	\$ 6,529,869	\$ 7,457,242	\$ 8,472,971
Deductions from Gross Patient Revenue, including CC and BD*	\$ 3,603,332	\$ 4,112,631	\$ 4,670,401
Net Patient Revenue	\$ 2,926,537	\$ 3,344,611	\$ 3,802,570
Total Expenses less Bad Debt*	\$ 2,382,493	\$ 2,532,778	\$ 2,704,325
Net Income	\$ 544,044	\$ 811,833	\$ 1,098,245

Totals may not sum due to rounding

*For comparison purposes in the Comparative Analysis, bad debt (BD) was removed from operating expenses and included in deductions from gross revenue with charity care (CC)

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 utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital, working capital, and operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

NHBOS proposes to develop a new ASC in Brunswick County by relocating one existing OR from NHBMC and adding one new OR and one procedure room.

Capital and Working Capital Costs

In Section VIII.1, page 89, the applicant states the total capital cost is projected to be as follows:

NHBOS Project Capital Cost

Site Costs	\$ 2,705,303
Construction Contract	\$ 5,796,101
Equipment	\$ 2,602,433
IT, Nurse Call, Other	\$ 940,000
Furniture	\$ 232,764
Consultant Fees	\$ 652,070
Financing Costs	\$ 406,918
Contingency	\$ 787,769
TOTAL CAPITAL COST	\$ 14,123,358

Exhibit 14 contains a construction cost estimate prepared by Wayne Lee Gregory, a North Carolina licensed architect. In Section IX.1, page 98, the applicant states there will be \$273,280 in start-up expenses and \$141,291 in initial operating expenses, for total working capital required of \$414,571.

Availability of Funds

In Section VIII.3, page 90, and Section IX.2, page 98, the applicant states that the project capital costs and working capital, respectively, will be funded with Novant Health accumulated reserves. However, the applicant states, if market conditions dictate, it may be more financially advantageous to finance all or part of the project through tax-exempt bonds; therefore, the applicant included the cost of financing in the projected capital costs. In Exhibit 7, the applicant provides letters documenting Novant Health's intention to fund the capital costs and working capital costs for the proposed project. Exhibit 7 also contains the consolidated financials for Novant Health, Inc. and Affiliates, documenting \$354 million in cash and cash equivalents, \$991 million in current assets (excluding receivables and limited use assets), and \$2.8 billion in total unrestricted net assets, as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the pro forma financial statements for NHBOS (Form B), the applicant projects that revenues will exceed operating expenses in the second and third full fiscal years of operation of the project, as shown in the table below.

NHBOS

	CY2019	CY2020	CY2021
Projected Surgical Cases	1,196	1,828	2,300
Projected Average Charge per Case	\$ 7,544	\$ 7,695	\$ 7,848
Gross Surgical Revenue	\$ 9,022,237	\$ 14,065,637	\$ 18,051,414
Deductions from Surgical Revenue	\$ 6,114,978	\$ 9,533,230	\$ 12,234,659
Net Surgical Revenue	\$ 2,907,259	\$ 4,532,407	\$ 5,816,755
Projected Procedure Room Cases	344	527	663
Projected Average Charge per Case	\$ 2,186	\$ 2,230	\$ 2,275
Gross Procedure Room Revenue	\$ 752,070	\$ 1,175,197	\$ 1,508,043
Deductions from Proc. Room Rev	\$ 531,028	\$ 829,793	\$ 1,064,811
Net Procedure Room Revenue	\$ 221,042	\$ 345,404	\$ 443,232
Total Gross Income	\$ 9,774,307	\$ 15,240,834	\$ 19,559,457
Deductions from Gross Patient Revenue, including CC and BD	\$ 6,646,005	\$ 10,363,022	\$ 13,299,471
Net Patient Revenue	\$ 3,128,302	\$ 4,877,812	\$ 6,259,987
Total Expenses	\$ 4,065,221	\$ 4,714,914	\$ 5,243,436
Net Income	\$ (936,919)	\$ 162,898	\$ 1,016,551

Totals may not sum due to rounding

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 utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital, working capital, and operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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 – Both Applications

On page 62, the 2016 SMFP states, “An operating room’s service area is 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.” In Figure 6.1, page 67 of the 2016 SMFP, Brunswick County is shown as a single-county

operating room service area. Thus, in this application, the service area is Brunswick County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved outpatient (OP), inpatient (IP) and shared operating rooms located in the service area of Brunswick County, and the outpatient and inpatient case volumes for each provider, per page 68 of the 2016 SMFP.

Brunswick County 2014 Operating Room Inventory

	IP ORs	OP ORs	Shared ORs	Excluded C-Section ORs	OP Surgery Cases	IP Surgery Cases
J. Arthur Doshier Memorial Hospital	0	0	2	0	950	329
Novant Health Brunswick Medical Center	1	0	4	-1	3,279	1,137
Total Brunswick County ORs	1	0	6	-1		

As the table above indicates, there are two hospitals in Brunswick County and a total of 6 operating rooms, excluding the C-Section OR. Brunswick County has no ambulatory surgery centers.

Table 6B: Projected Operating Room Need for 2018, on pages 81-82 of the 2016 SMFP, shows that the number of projected ORs needed in 2018 in Brunswick County is 6.37 (Column L) and the projected OR deficit is 0.37 (Column U). Table 6C: Operating Room Need Determination, on page 89 of the SMFP, identifies a need for 1 operating room in Brunswick County, based on the need methodology as outlined in Step 5 on page 65 of the SMFP, which states:

“For each operating room service area with six to 10 operating rooms and a projected deficit of 0.30 or greater, the “Operating Room Need Determination” is equal to the “Projected Operating Room Deficit” rounded to the next whole number. (In this step, fractions of 0.30 or greater are rounded to the next highest whole number.) For each operating room service area with six to 10 operating rooms and a projected deficit that is less than 0.30 or in which there is a projected surplus, the Operating Room Need Determination is zero. (Column U)”

OWP3/BSC proposes to develop a new ASC with one operating room and two procedure rooms to be located in Leland in Brunswick County. The 2016 SMFP identifies the need for one additional OR in Brunswick County. The applicant adequately demonstrates the need to develop a new ASC with one operating room and two procedure rooms and that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Brunswick County. Therefore, the application is conforming to this criterion.

NHBOS proposes to develop a new ASC by relocating one existing OR from NHBMC and developing one new OR and one procedure room, to be located in Leland in Brunswick County. The 2016 SMFP identifies the need for one additional OR in Brunswick County. The applicant adequately demonstrates the need to relocate the existing Brunswick County operating room from NHBMC to NHBOS, and adequately demonstrates the need for an additional OR and procedure room and that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Brunswick County. Therefore, 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 – Both Applications

OWP3/BSC. In Section VII.2, page 101, the applicant provides the proposed staffing for the facility in Operating Year 2 (CY2020), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Registered Nurse	5.0
Surgical Technician	2.0
Radiological Tech	1.0
Medical Record Tech	0.5
Non-Health Professionals and Technical Personnel	2.5
TOTAL	12.0

In Section VII.3, page 102, and Section VII.7, page 105, the applicant describes the EmergeOrtho experience and process for recruiting and retaining staff and state its expectation of being effective in recruiting staff via internal recruiting for the proposed facility. In Section II.1, page 14, and Section VII.9(b), page 108, the applicant states that anesthesiology services will be provided via contract with American Anesthesiology of the Carolinas. Exhibit 19 contains a letter from the American Anesthesiology of the Carolinas, Wilmington indicating their ability and willingness to provide anesthesia services to the proposed ASC. Exhibit 11 contains signed letters of support from surgeons who intend to practice at the proposed facility. Exhibit 8 contains Medical Staff bylaws and credentialing information. Exhibit 5 contains a copy of a letter from Albert W. Marr, MD, expressing his interest in serving as the Medical Director for the proposed facility. In Section VII.7, page 105, the applicant states:

“All qualified surgeons who meet the credentialing criteria will be invited to use the proposed ambulatory surgery center.”

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

NHBOS. In Section VII.2, page 78, the applicant provides the proposed staffing for the facility in Operating Year 2 (CY2020), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Certified Registered Nurse Anesthetist	2.0
Registered Nurse	6.0
Clinical Coordinator (RN)	1.0
CNA	1.0
Surgical Technician	4.0
OR Assistant	1.0
Sterile Processing Tech	1.0
Patient Access Specialist	1.0
TOTAL	18.0

In Section VII.3, pages 78-79, and Section VII.7, pages 83-84, the applicant describes Novant Health’s experience and process for recruiting and retaining staff. Exhibit 4 contains signed letters of support from surgeons who intend to practice at the proposed ASC. Exhibit 5 contains copies of letters from an anesthesiologist, pathologists, and radiologist who have agreed to provide support and professional coverage for NHBOS outpatient surgery patients. Exhibit 5 also contains a letter from Mark Tillotson, MD committing his support and willingness to serve as the Medical Director for the proposed ASC. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 – Both Applications

OWP3/BSC. In Sections II.1 and II.2, pages 14-15, the applicant identifies the necessary ancillary and support services, and describes how they will be provided. On page 15, the

applicant states, *“All necessary ancillary and support services will be in place upon completion of the proposed project.”* Exhibit 6 contains a copy of the proposed facility’s transfer policy and correspondence regarding transfer agreements with area hospitals. Exhibits 5 and 11 contain copies of support letters from physicians and surgeons. The applicant adequately demonstrates that 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.

NHBOS. In Sections II.1 and II.2, pages 9-11, the applicant identifies the necessary ancillary and support services, and describes how they will be provided. Exhibits 4 and 5 of the application contain copies of letters from area physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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.

C – Both Applications

OWP3/BSC proposes to develop a new ambulatory surgery center in 9,433 square feet of leased space to be constructed on 2.63 acres at South Dickinson Drive in Leland, Brunswick County. Exhibit 13 contains the line drawings identifying reception/registration, waiting, pre-operative, operating rooms, and post-operative/recovery areas. Exhibit 13 also contains the general contractor's construction cost estimate for the 33,280 square foot building in which the ASC surgical space will be leased. Per the footnote on the project capital cost sheet in Section 8, page 111, the ASC represents 28.24% (9,433/33,280) of the total building space and cost. This is consistent with the project capital cost projections provided by the applicant in Section VIII, page 111 of the application. In Section XI.8, page 130, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

NHBOS proposes to develop a new ambulatory surgery center in 14,651 square feet of space to be constructed on 4.11 acres at the intersection of US Highway 17 and Olde Regent Way in Leland, Brunswick County. Exhibit 14 contains the line drawings identifying receiving/registering, waiting, pre-operative, recovery, operating and procedure rooms, and support areas. Exhibit 14 also contains a certified cost estimate from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 89 of the application. In Section XI.8, page 106, and Exhibit 15, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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;

NA– OWP3/BSC
 C – NHBOS

NHBOS. The applicant is a new limited liability company with 100% of its LLC membership interests owned by NH. As such, the applicant does not currently provide services, however, the application often refers to NH's ownership, experience and policies as being relevant to NHBOS, as in Section II.8, pages 13-15. In Section VI.14, page 75, the applicant states that its projected payor mix for NHBOS is based upon the historical outpatient surgical payor mix for NHBMC averaged over CY2014 through year to date 2016. NHBMC provided 65.6% of its outpatient surgery care to Medicare and Medicaid patients during that time period.

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**
Brunswick	27%	51%	19%	16%	12%	19%
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 adequately demonstrates that NHBMC currently provides access to medically underserved populations in its outpatient surgical program. 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;

NA– OWP3/BSC
C – NHBOS

NHBOS is a new limited liability company with 100% of its LLC membership interests owned by NH. As such, the applicant does not currently provide services, however, the application often refers to NH's ownership, experience and policies as being relevant to NHBOS, as in Section II.8, pages 13-15.

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 73, the applicant states:

“Novant Health’s hospitals NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago. ... Novant Health facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.”

In Section VI.10 (a), page 73, the applicant states that no civil rights equal access complaints have been filed against NH or its affiliated licensed hospitals and surgery centers during the last five years. 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 – Both Applications

OWP3/BSC. In Section VI.14, page 97, the applicant projects the payor mix for the proposed ASC in the second operating year (CY2020), as summarized below:

BSC Payor Category	Projected Cases as Percent of Total
Self-Pay/Indigent	2.9%
Medicare/ Medicare Managed Care	14.2%
Medicaid	10.6%
Commercial Insurance/Managed Care/ BCBS	69.0%
Other (Workers Comp, TRICARE, VA)	3.4%
Total	100.0%

On page 98, the applicant states:

“BSC projects the facility payor mix based on the historical ambulatory surgery case payor mix of Brunswick and Columbus County residents who obtained outpatient surgery from EmergeOrtho physicians during 2015.”

On page 99, the applicant compares the projected payor mix to the 2015 ambulatory surgery payor mix for the two licensed facilities within Brunswick County. As the table on page 99 shows, and is confirmed by an analysis of the two facilities’ 2016 LRAs, the ambulatory surgeries at the hospitals had a much larger percentage of Medicare recipients (54.4%), as compared to the percentage for EmergeOrtho for its Brunswick and Columbus patients and the applicant’s projected Medicare percentage (14.2%). However, the ambulatory surgeries at the hospitals include all surgical specialties, not just orthopedics. The 14% Medicare is consistent with the average Medicare percentages reported in Becker’s Orthopedic Review¹ for orthopedic-driven ASCs, which report that on average Medicare equals 17% of gross charges, but Medicare equals only 11% for the bottom 25 percent of the ASCs. Note that a discussion of percent of cases and percent of gross revenue is the same here because the applicant uses the same average charge for all payors.

In Section V.4, page 82, the applicant states that BSC physician members (via EmergOrtho) serve the orthopedic needs for patients of Cape Fear Health Net and Cape Fear Clinic, at no charge. In Section VI.4(b), page 90, the applicant states:

“BSC will adopt the Federal Poverty Guidelines estimated by income, family members, medical expenses, and living expenses for determining eligibility for charity care. For patients matching these guidelines, BSC will write off charges.”

The applicant adequately demonstrates that the medically underserved population will have access to the proposed services. Therefore, the application is conforming to this criterion.

¹<http://www.beckersasc.com/asc-coding-billing-and-collections/orthopedics-driven-asc-payer-mix-12-statistics.html>

NHBOS. In Section VI.14, page 75, the applicant projects the following payor mix for the proposed ASC in the second operating year (CY2020):

NHBOS Payor Category	Projected Cases as Percent of Total
Self-Pay/Indigent	3.1%
Medicare/ Medicare Managed Care	52.2%
Medicaid	13.4%
Commercial Insurance/Managed Care	28.6%
Other (not specified) and Workers Compensation	2.7%
Total	100.0%

On page 75, the applicant describes its assumptions regarding its payor mix projections, which it states are based on NHBMC historical experience as well as the experience of outpatient surgical providers in Brunswick and neighboring counties. The applicant adequately demonstrates that the medically underserved population 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 – Both Applications

OWP3/BSC. In Section VI.9, pages 94-95, the applicant describes the range of means by which a person will have access to the proposed ASC. The applicant adequately demonstrates 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.

NHBOS. In Section VI.9, page 72, the applicant describes the range of means by which a person will have access to the proposed ASC. The applicant adequately demonstrates 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 – Both Applications

OWP3/BSC. In Section V.1, page 79, the applicant states its intent to establish relationships with health professional training programs and make reference to the existing relationships that BSC’s physician owners currently have with area training

programs via OrthoWilmington and EmergeOrtho. Exhibit 12 contains copies of letters of support from Miller-Motte College and Cape Fear Community College which document the intent to develop training agreements with BSC. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

NHBOS. In Section V.1, page 54, the applicant states that Novant Health has extensive relationships with health education programs in the market area and that these agreements will include NHBOS once it becomes operational. Exhibit 9 contains a list of educational institutions in the market area with which Novant Health has training arrangements, including Brunswick Community College, Cape Fear Community College, Duke University, and East Carolina University, among others. The information provided 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 – Both Applications

On page 62, the 2016 SMFP states, *“An operating room’s service area is 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.”* In Figure 6.1, page 67 of the 2016 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, in this application, the service area is Brunswick County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved outpatient (OP), inpatient (IP) and shared operating rooms located in Brunswick County, and the outpatient and inpatient case volumes for each provider, per page 68 of the 2016 SMFP.

Brunswick County 2014 Operating Room Inventory

	IP ORs	OP ORs	Shared ORs	Excluded C-Section ORs	OP Surgery Cases	IP Surgery Cases
J. Arthur Doshier Memorial Hospital	0	0	2	0	950	329
Novant Health Brunswick Medical Center	1	0	4	-1	3,279	1,137

The 2017 SMFP reflects the following inventory and utilization for Brunswick County in 2015.

Brunswick County 2015 Operating Room Inventory

	IP ORs	OP ORs	Shared ORs	Excluded C-Section ORs	OP Surgery Cases	IP Surgery Cases
J. Arthur Doshier Memorial Hospital	0	0	2	0	1,113	351
Novant Health Brunswick Medical Center	1	0	4	-1	3,216	1,091

As the tables above show, there are two hospitals and no ambulatory surgery centers providing surgical services in Brunswick County.

OWP3/BSC proposes to develop a new ASC with one operating room and two procedure rooms in Leland, Brunswick County. The 2016 SMFP identifies the need for one additional OR in Brunswick County. Neither of the applicant entities, nor the physician owners, or any related party, own or operate a surgical facility in Brunswick County; therefore, OWP3/BSC proposes the addition of a new competitor to the surgical marketplace in the Brunswick County service area. In Section V.7, pages 84-87, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states that the proposed project will increase cost effectiveness, quality, and access to services. On page 84, in reference to cost effectiveness, the applicant states:

“This project represents a cost-effective alternative to being treated in a hospital because the facility will not carry large overhead and administrative costs.

...

Additionally, dedicated outpatient providers are more attractive to payors than hospital-based providers. ... Patients typically pay less coinsurance for procedures performed in an ASC than for comparable procedures in the hospital setting.

...

BSC will provide the best clinical expertise in the community, and will pass to its patients the reduced cost of care savings that comes from its smaller environment, reduced overhead and supply chain management expertise.”

On pages 84-85, in reference to access, the applicant states:

“The proposed project will increase access to cost-effective surgical services for the underserved population of the service area. ... BSC will serve Medicare, Medicaid and Charity Care/Self-pay patients at the proposed facility.

BSC will also improve geographic access to residents of Brunswick County.”

The applicant addresses the provision of quality services on pages 85-87 and state its intent to seek Joint Commission and AAAHC accreditation.

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

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

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

Therefore, the application is conforming to this criterion.

NHBOS proposes to develop a new ASC in Leland, Brunswick County by relocating one existing OR from NHBMC and developing one new OR and one procedure room. The 2016 SMFP identifies the need for one additional OR in Brunswick County. In Section V.7, pages 58-65, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states that NHBOS is proposing the development of a new separately licensed outpatient surgery center with two operating rooms and a procedure room, the first separately licensed, multi-specialty, outpatient surgery center in Brunswick County. On pages 58-59, in reference to cost effectiveness, the applicant states:

“As a licensed outpatient surgery center, NHBOS will have the opportunity to offer outpatient surgeries at a lower price point than a hospital-based outpatient surgery program. ... This approach will offer a new, more cost effective option for local access to outpatient surgical care in Brunswick County.

...

Novant Health has also formed a value-based strategy team launched to accelerate strategies for assuming risk and shifting further towards value-based case and payment models to demonstrate greater value for the patients we serve.”

The applicant addresses Novant Health's provision of quality services on pages 60-61; and access to those services is addressed on pages 61-65.

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

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

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

NA- OWP3/BSC
C - NHBOS

NHBOS is a new limited liability company with 100% of its LLC membership interests owned by NH. As such, the applicant does not currently provide services, however, the application often refers to NH's ownership, experience and policies as being relevant to NHBOS, as in Section II.8, pages 13-15.

In Section I.13, pages 4-5, the applicant lists the facilities and programs owned by NH. NH owns and operates 11 licensed hospital facilities in North Carolina and nine licensed outpatient surgery or endoscopy centers, including four freestanding ambulatory surgery facilities like the proposed center. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, incidents (which did not warrant non-compliance status) occurred at one of the 11 licensed hospitals within the eighteen months immediately preceding submission of the application through the date of this

decision related to quality of care. There were no incidents occurring at any of the four existing ambulatory surgery facilities within that time period. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Novant Health facilities, 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 Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to this review. The specific criteria are discussed below.

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

.2103 PERFORMANCE STANDARDS

.2103(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks per year.

-C- **OWP3/BSC.** In Section II.10, page 28, the applicant states that the proposed facility will be available for use five days per week and 52 weeks per year.

-C- **NHBOS.** In Section II.10, page 17, the applicant states that the proposed facility will be open five days per week and 52 weeks per year.

.2103(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 is based on the following formula: {[(Number of facility 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) plus (Number of facilities projected outpatient cases times 1.5 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1,872 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 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, 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 of less than 0.2; and the difference is a negative number or a positive number less than 0.2, the need is zero; or

The Brunswick County operating room service area has six to 10 operating rooms; therefore (2)(B) above is applicable to this review.

- C- **OWP3/BSC.** In Section II.10, pages 28-29, the applicant refers to Section IV for the number of outpatient surgical cases projected to be performed in each of the initial three operating years of the proposed project and Section III.1 for a detailed description of the assumptions and methodology used for the projection. In Section IV(c), page 77, the applicant provides the following table:

Brunswick Surgery Center

	CY2019	CY2020	CY2021
# of Operating Rooms	1	1	1
# of Ambulatory Surgical Cases	1,294	1,462	1,642

In Section III.1(b), pages 55-59, the applicant provides the methodology and assumptions that resulted in the above projection of cases. The applicant did not translate the number of surgical cases to the number of weighted surgical hours divided by 1,872 hours to demonstrate the proposed project's need for operating rooms. The project analyst provides those calculations below:

BSC Total Projected OR Need

	PY1 CY2019	PY2 CY2020	PY3 CY2021
Projected Ambulatory Surgical Cases	1,294	1,462	1,642
Weighted Surgical Hours (cases x 1.5 hrs/case)	1,941	2,193	2,463
ORs Needed at 1,872 hrs per room*	1.0	1.2	1.3
BSC OR Need*	1	1	2

*Rounded per SMFP and CON Criteria and Standards

Therefore, based on the application of the above rule for demonstrating the need for the proposed operating room; and its applicable assumptions: 1.5 hours per case, 1,872 hours per operating room, and rounding to the next highest whole number for fractions of 0.3 and greater in service areas of six to 10 ORs, the applicant has justified the need for the one operating room proposed in this application.

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

- C- **NHBOS.** In Section II.10, pages 17-18, the applicant demonstrates the need for two freestanding ambulatory surgical operating rooms (one

relocated from NHBMC and one new OR) in Brunswick County in its third operating year.

NHBOS Total Projected Outpatient Surgical Cases and OR Need

	PY1 CY2019	PY2 CY2020	PY3 CY2021
Projected Outpatient Cases	1,196	1,828	2,300
Weighted Surgical Hours (cases x 1.5 hrs/case)	1,794	2,742	3,450
ORs Needed at 1,872 hrs per room*	1.0	1.5	1.8
NHBOS OR Need*	1	2	2

Totals may not sum due to rounding

*Rounded per SMFP and CON Criteria and Standards

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

.2103(c)

A proposal to increase the number of operating rooms (excluding dedicated C-Sections 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 report 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' times 1.5 hours)] divided by 1,872 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, 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, 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 of less than 0.2; and if the difference is a negative number or a positive number less than 0.2, the need is zero.

The need determination identified in the 2016 SMFP will increase the number of ORs in the service area by one OR, upon approval of one of the two competing applications in this review. The Brunswick County operating room service area has six to 10 operating rooms; therefore, .2103(c)(2)(B) above is applicable to this review.

- C- **OWP3/BSC.** See the discussion above in Criterion .2103(b). No other ORs are owned or operated in the Brunswick County service area by OWP3/BSC or a related entity.
- C- **NHBOS.** In Section III, pages 35-36, the applicant provides projected utilization and need for ORs at NHBOS and NHBMC, which results in the following table as discussed in Criterion (3) on pages 22-23 of the Findings.

NHBOS and NHBMC Operating Room Need

	PY1	PY2	PY3
	CY2019	CY2020	CY2021
NHBOS OR Need	0.96	1.46	1.84
NHBMC OR Need	3.44	3.19	3.08
Total Combined Need	4.40	4.65	4.92
Total ORs Needed Rounded*	5	5	5
Total Combined Projected Weighted Surgical Hours	8,224	8,708	9,211
Combined Capacity (Surgical Hours Available for 5 ORs)	11,700	11,700	11,700
Projected Utilization of the 5 Novant Health ORs in Brunswick County	70.3%	74.4%	78.7%

Totals may not sum due to rounding

*Rounded per SMFP and CON Criteria and Standards

As the table above shows, the applicant projects a need for all five of the Novant Health proposed and existing operating rooms (one new OR and the four existing NHBMC ORs).

.2103(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- **Both Applicants.** The applicants do not propose to develop an additional dedicated C-section room.

.2103(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 1,872 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 for the conversion 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- **Both Applicants.** The applicants do not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

.2103(f) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- **OWP3/BSC.** In Section III.1(b), pages 55-59, the applicant provides a detailed description of the assumptions and methodology used for the projection of its ambulatory surgical cases. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

-C- **NHBOS.** In Section III.1(b), pages 31-38, and Exhibit 3, the applicant provides a description of the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2016 State Medical Facilities Plan, no more than one additional operating room may be approved for Brunswick County in this review. Because the two applications in this review collectively propose to develop two additional operating rooms to be located in Brunswick County, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by OWP3, LLC and Brunswick Surgery Center, LLC, Project I.D. O-11282-16, is approved and the other application, Project I.D. O-11283-16, submitted by Novant Health Brunswick Outpatient Surgery, LLC, is denied.

Conformity with Review Criteria

Both applications are conforming with the Review Criteria as discussed throughout the Findings. Therefore, with regard to conformity with the Review Criteria, the two proposals are comparable.

Demonstration of Need

Both applications adequately demonstrate the need for their respective proposals. See the discussions regarding need found in Criterion (3). Therefore, with regard to demonstration of need, the two proposals are comparable.

Geographic Accessibility

The 2016 State Medical Facilities Plan identifies the need for one additional operating room to be located in Brunswick County.

OWP3/BSC propose to develop a new ASC with one OR and two procedure rooms in Leland, Brunswick County.

NHBOS proposes to develop a new ASC by relocating one existing OR from NHBMC, and adding one new OR and one procedure room to be located in Leland, Brunswick County.

Both applicants propose to develop one additional Brunswick County OR in a new ASC in Leland. Therefore, with regard to geographic accessibility to the proposed OR, the two proposals are comparable.

Demonstration of Physician Support

OWP3/BSC. In Section III.1(b), page 55, the applicant lists 12 physicians who the applicant states are expected to utilize the proposed ASC. Exhibit 11 contains support letters from 13 surgeons, stating its intent to perform surgery at BSC; three physicians who propose to refer patients to the surgeons and one local resident who states intent to use the facility.

NHBOS. In Section III.1(a), page 26, NHBOS states that “*many of the surgeons*” at NHBMC express support for the project and provides a list on page 56 of 18 surgeons who it says intend to utilize NHBOS to perform surgery. Exhibit 4 contains support letters from those surgeons. The applicant also discusses the recruitment of an additional orthopedic surgeon and his expected impact on surgical cases at NHBMC and NHBOS.

Both applications document physician support of their proposed projects. Therefore, with regard to demonstration of physician support, the two proposals are comparable.

Patient Access to Surgical Specialties

Currently, Brunswick County has two hospitals that provide surgical services and does not have any existing ambulatory surgical centers. The approval of either of the applications in this review will develop the first and only ASC in Brunswick County. A review of the surgical data reported in the 2016 Hospital LRAs submitted by Doshier and NHBMC, the two hospitals in Brunswick County, shows that 76% of all surgeries (excluding C-Sections) performed in Brunswick County were ambulatory surgeries. The following table shows the percentages of the ambulatory surgeries performed in Brunswick County by specialty:

**Brunswick County Ambulatory Surgeries by Specialty
As a Percent of Total Surgeries**

Specialty	Percent of Total
General Surgery	69.8%
Obstetrics	83.8%
Ophthalmology	100.0%
Orthopedics	60.0%
Otolaryngology	98.3%
Plastic Surgery	98.6%
Urology	80.8%
Other	81.9%
Total (excluding C-Section)	76.05%

Source: J. Arthur Doshier Memorial Hospital and Novant Health Brunswick Medical Center FY2015 data as reported on the 2016 LRAs and queried by Healthcare Planning

These statistics, as shown above, support the development of an ambulatory surgery center in Brunswick County to provide patients in Brunswick County access to non-hospital based surgical services, at typically lower costs.

The approval of OWP3/BSC will add one ambulatory OR and two procedure rooms in Brunswick County. The approval of NHBOS will add two ambulatory ORs and one procedure room in Brunswick County. This is because NH is relocating one shared OR from NHBMC to NHBOS and converting it to an ambulatory OR. Relocating one shared OR from NHBMC will leave three shared ORs at NHBMC, in which both inpatient and ambulatory surgeries can be performed. The approval of NHBOS would increase the number of ambulatory ORs and decrease the number of shared ORs in Brunswick County. NH did not have to wait for the SMFP to show the need for an additional OR in Brunswick County to create an ambulatory surgery center; NH could have submitted a CON to relocate one or more ORs from NHBMC to a separately licensed freestanding ambulatory surgery setting at any point that NH determined that to be an effective use of its Brunswick County OR inventory.

OWP3/BSC proposes to offer orthopedic ambulatory surgical services. NHBOS proposes to offer the following ambulatory surgical services: general surgery, OB/GYN, ophthalmology, orthopedic, otolaryngology, podiatry, plastic surgery and urology.

Generally, in a service area without existing access to any other non-hospital-based ambulatory surgical services, the application proposing to provide access to the broader range of different specialty surgical services in a freestanding ambulatory setting would appear the more effective alternative with regard to this comparative factor. An analysis of the specialty surgical services provided in Brunswick County compared with the number of residents leaving Brunswick County to obtain the specialty services revealed the following statistics:

- Of the 5,692 total surgeries performed in FY2015 in Brunswick County, excluding C-Sections, 1,793 (31.5%) were orthopedic; 1,076 (24.9%) of the 4,329 ambulatory surgeries performed were orthopedic.
- 60% of all 2015 orthopedic surgery performed in Brunswick County was done on an ambulatory (outpatient) basis.
- Of the 10,467 ambulatory surgeries performed on Brunswick County residents, only 3,854 (36.8%) were performed in Brunswick County; 5,981 (57.1%) of the ambulatory surgeries performed on Brunswick County residents were in performed New Hanover County.

The available data does not include the number of orthopedic patients leaving Brunswick County for ambulatory surgery. However, it is possible to estimate the number based on the percentage performed in Brunswick County. Assuming 24.9% of the ambulatory surgeries performed on Brunswick County residents in New Hanover County results in 1,489 orthopedic surgeries ($0.249 \times 5,981 = 1,489$). Thus, 4,492 ambulatory surgeries performed on Brunswick County residents in New Hanover County were in specialties other than orthopedics ($5,981 - 1,489 = 4,492$).

OWP3/BSC. In Section III.1(b), page 55, the applicant provides the names of 12 orthopedic surgeons who are expected to utilize the proposed ASC and state in a footnote:

“Please note that only orthopaedic surgeons are expected to utilize the proposed OR. BSC’s pain management specialists will utilize the proposed procedure rooms.”

Exhibit 11 of OWP3/BSC’s application contains support letters from 13 EmergeOrtho surgeons and three physicians who refer to OrthoWilmington/EmergeOrtho.

NHBOS. In Section V.3(b), page 56, the applicant provides a list of 18 surgeons in eight surgical specialties who intend to utilize NHBOS to perform surgery. The specialties listed include otolaryngology, general surgery, OB/GYN, ophthalmology, orthopedics, podiatry, plastic surgery and urology. Exhibit 4 contains support letters from those surgeons.

Therefore, based the number of ambulatory ORs proposed and on the expected surgical specialties that will utilize the proposed ASCs, the application submitted by NHBOS is the more effective alternative with regard to patient access to a broader range of specialty surgical services in a non-hospital-based ambulatory surgical center.

Patient Access to a New Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

OWP3/BSC. In Section I.13(c), page 10 of its application, the applicant states that OWP3 and BSC are new entities that do not currently own, manage or operate any healthcare facilities. In Section I.12, pages 6-7, the applicant lists the physician owners of each entity. Neither the entities nor the physician owners own a surgical facility in Brunswick County. In the applicant’s comments and response to comments presented at the Public Hearing, the applicant states:

“Our proposal would introduce a new provider in the surgical marketplace in Brunswick County and development of Brunswick Surgery Center will improve competition in Brunswick County. This competitive environment will be highly beneficial to local patients and payors in terms of both healthcare quality and cost. ... competition amongst healthcare facilities fosters continuous quality improvement in the local market place and encourages providers to offer competitive prices.”

NHBOS. In Section I.12, page 3 of its application, the applicant states that Novant Health, Inc. owns one hundred percent of the applicant LLC. Novant Health, Inc. is the parent company of NHBMC in Brunswick County, which is one of only two existing surgical programs in Brunswick County. NHBMC currently owns and operates four operating rooms and one C-Section room in Brunswick County.

As discussed above, Novant Health already provides surgical services in Brunswick County. The development of NHBOS will increase the OR capacity of an existing related provider. OWP3/BSC is proposing to add another provider of surgical services in Brunswick County, thereby enhancing competition. Therefore, the application submitted by OWP3/BSC is the more effective alternative with regard to access to a new provider of surgical services.

Access by Underserved Groups

Both applications project approximately 3% of the proposed surgeries will be provided to Self-pay/Indigent payors (Form D of each application); therefore the applications are comparable in that respect.

The following table shows each applicant’s projected Charity Care to be provided in the second operating year (CY2020) and the percentage of total net revenue. Generally, the application proposing to provide the highest percentage of Charity Care is the more effective alternative with regard to this comparative factor.

**SURGICAL CHARITY CARE
 OPERATING YEAR 2**

APPLICANT	Projected Total Charity Care	Projected Percentage of Total Net Revenue
OWP3/BSC	\$52,201	1.6%
NHBOS	\$590,000	12.1%

Source: Section VI.8(c) and Form B for each application. OWP3/BSC Net Revenue was adjusted to include bad debt for comparison purposes.

As shown in the table above, NHBOS projects the highest charity care as a percent of net revenue to be provided to patients. Therefore, the application submitted by NHBOS is the most effective alternative with regard to access to charity care.

The following tables show each applicant’s projected total number of projected surgical cases and the number of cases projected to be provided to Medicaid and Medicare recipients in the second and third full year of operation following completion of the projects (CY2020 and CY2021), based on the information provided in the applicant’s pro forma financial statements. Generally, the application proposing to serve the higher percent of total surgical cases to Medicaid and Medicare patients is the more effective alternative with regard to those comparative factors.

**SURGICAL MEDICAID CASES
 OPERATING YEARS 2 AND 3**

Applicant	Projected Total Cases		Projected Total Cases Provided to Medicaid Recipients		Projected Percentage of Total Cases Provided to Medicaid Recipients	
	Operating Year 2	Operating Year 3	Operating Year 2	Operating Year 3	Operating Year 2	Operating Year 3
OWP3/BSC	1,462	1,642	155	174	10.6%	10.6%
NHBOS	1,828	2,300	245	308	13.4%	13.4%

Source: Form D of each application

**SURGICAL MEDICARE CASES
 OPERATING YEARS 2 AND 3**

Applicant	Projected Total Cases		Projected Total Cases Provided to Medicaid Recipients		Projected Percentage of Total Cases Provided to Medicaid Recipients	
	Operating Year 2	Operating Year 3	Operating Year 2	Operating Year 3	Operating Year 2	Operating Year 3
OWP3/BSC	1,462	1,642	207	233	14.2%	14.2%
NHBOS	1,828	2,300	954	1,201	52.2%	52.2%

Source: Form D of each application

As shown in the tables above, NHBOS projects the highest percentage of total surgical cases to be provided to Medicaid and Medicare recipients. However, due to significant differences in the types of surgical services proposed by the applicants, it is not possible to make conclusive comparisons with regard to percentage of Medicaid and Medicare cases. Thus, this comparative factor may be of little value.

Projected Surgical Revenue per Surgical Case

The following table shows the projected average gross and net surgical revenue per case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lowest average gross and net revenue per case is the more effective alternative with regard to this comparative factor.

**Revenue Per Surgical Case
 CY2021**

	OWP3/BSC		NHBOS	
	Gross Revenue	Net Revenue	Gross Revenue	Net Revenue
Surgical Revenue	\$ 8,187,055	\$ 3,841,615	\$ 18,051,414	\$ 5,816,755
Cases	1,642	1,642	2,300	2,300
Revenue/Case	\$ 4,987	\$ 2,340	\$ 7,848	\$ 2,529

Source: Forms D and E for surgical revenue in each application

As shown in the table above, OWP3/BSC projects the lower average gross and net revenue. However, due to significant differences in the types of surgical services proposed by the applicants, it is not possible to make conclusive comparisons with regard to revenue per surgical case. Thus, this comparative factor may be of little value.

Projected Average Operating Expense per Surgical Case

The following table compares the projected average operating expense in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form B). Generally, the application proposing the lowest average operating expense per case is the more effective alternative with regard to this comparative factor. However, both applicants provide operating expenses for the entire ASC, including procedure rooms, which means a direct comparison of only surgical expenses (only those expenses related directly to the provision of surgical cases) is not possible. The following table compares the total operating expenses for each facility based on number of proposed surgical cases.

Operating Expense CY2021	OWP3/BSC	NHBOS
Total Operating Expenses	\$ 2,704,325	\$ 5,243,436
Surgical Cases	1,642	2,300
Total Operating Expense/Surgical Case	\$ 1,647	\$ 2,280

Source: Pro Forma Financials of each application

For comparison purposes OWP3/BSC bad debt was included as a deduction from total gross patient revenue rather than an operating expense, which reduces total operating expense and increases total deductions from gross patient revenue by \$77,555 and \$88,119 in PY1 and PY2, respectively. Conversely, bad debt could have been added to NHBOS' total operating expenses to compare to OWP3/BSC's total operating expenses, which already includes bad debt. Comparing operating expenses in this manner results in Total Operating Expense/Surgical Case of \$1,701 and \$2,450 for OWP3/BSC and NHBOS, respectively.

As shown in the table above, OWP3/BSC projects the lower average operating expense per case in the third operating year. However, due to differences in the types of surgical services proposed by the applicants, it is not possible to make conclusive comparisons with regard to projected average operating expense per surgical case. Thus, this comparative factor may be of little value.

History of Project Development

OWP3/BSC has not applied for any other CONs and therefore have no history of project development to review.

NHBOS is a new limited liability company with 100% of its LLC membership interests owned by Novant Health. Novant Health has formed two similar LLCs to apply for CONs to develop ambulatory surgery centers: Same Day Surgery Center New Hanover (SDSCNH) / Project ID #O-7671-06 and Same Day Surgery Center Franklin, LLC (SDSCF) / Project ID #K-8357-09, which were never developed.

SDSCNH was approved to develop a separately licensed ambulatory surgical facility with two operating rooms in New Hanover County, effective October 2007. Over four years later, having

not developed the project, and pursuant to a July 2, 2012 declaratory ruling, New Hanover Regional Medical Center acquired 100% of NH's interest in the proposed SDSCNH to develop the ORs in the hospital, not as a separately licensed ambulatory surgery center, as approved. Therefore, NH did not develop the CON-approved ambulatory surgical facility in New Hanover County.

SDSCF was approved to develop a freestanding ambulatory surgery center in Franklin County, effective December 29, 2009. Approximately four years later, having not developed the project, NH submitted a change of scope and cost overrun CON application, Project ID #K-10229-13, to relocate one OR from Novant Health Franklin Medical Center for a total of two ORs at the previously approved ASC in Franklin County. This project was approved effective December 3, 2014. In September 2016, per SDSCF's progress report dated September 21, 2016, the development of the project had not begun and NH was still in discussions with a possible joint venture partner. The Agency received prior written notice, dated November 22, 2016, stating Duke University Health System's intent to acquire 100% of the membership interest in SDSCF, the NH LLC which has CON approval to develop a two-OR ambulatory surgery center in Franklin County. On March 30, 2017, the Agency received its most recent progress report on this project, which states a Letter of Intent (LOI) was executed and discussions with the joint venture partner continue. As of the date of this decision, the Agency has had no further word on this project development. Therefore, NH has not developed the CON-approved ambulatory surgical center in Franklin County in a timely manner.

NHBOS's project is not unlike the two projects discussed above. Not developing the above projects, as approved, has left New Hanover and Franklin County residents without the proposed ambulatory surgery facilities: New Hanover County residents were denied access to the approved ambulatory surgical services, because those ORs were subsequently developed by New Hanover Regional Medical Center as hospital-based ORs; and Franklin County residents have yet to be provided access to the approved ambulatory surgery services, eight years later.

Thus, NH's history of undeveloped, CON-approved ambulatory surgery services make its project a less effective alternative with regard to history of project development.

SUMMARY

The following is a summary of the comparative factors in this review:

Comparative Factor	More Effective	Less Effective
Conformity with Review Criteria	The two applications are comparable.	
Demonstration of Need	The two applications are comparable.	
Geographic Accessibility	The two applications are comparable.	
Demonstration of Physician Support	The two applications are comparable.	
Access by Underserved Groups: Medicaid and Medicare	Inconclusive comparison.	
Projected Gross and Net Surgical Revenue per Surgical Case	Inconclusive comparison.	
Projected Operating Expense per Surgical Case	Inconclusive comparison.	
Patient Access to Surgical Services	NHBOS	OWP3/BSC
Patient Access to a New Provider	OWP3/BSC	NHBOS
Access by Underserved Groups: Charity Care	NHBOS	OWP3/BSC
History of Project Development	OWP3/BSC	NHBOS

As shown in the table above:

- With respect to conformity with Review Criteria, geographic accessibility, and physician support, the applications are comparable. See Comparative Analysis for discussion.
- NHBOS projects to offer access to a broader range of surgical specialties. See Comparative Analysis for discussion.
- OWP3/BSC projects access to a new provider and enhanced competition. See Comparative Analysis for discussion.
- NHBOS projects the higher percentage of Charity Care in the third operating year. See Comparative Analysis for discussion.
- NHBOS projects the higher percentage of Medicaid and Medicare in the third operating year, but the analysis arrives at an inconclusive comparison. See Comparative Analysis for discussion.
- OWP3/BSC project the lower average gross and average net surgical revenue per surgical case in the third operating year, but the analysis arrives at an inconclusive comparison. See Comparative Analysis for discussion.
- OWP3/BSC project the lower average total operating expense per surgical case in the third operating year, but the analysis arrives at an inconclusive comparison. See Comparative Analysis for discussion.
- OWP3/BSC has no history related to the development of CON ambulatory surgical projects, while NHBOS has failed to develop two CON approved ambulatory surgical projects. See Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by OWP3/BSC is determined to be the more effective alternative in this review:

- OWP3/BSC’s proposal provides access to a new provider in the service area and therefore, enhances competition. See Comparative Analysis for discussion.

- NHBOS's parent company has a history of failing to develop approved CON projects for ambulatory surgery facilities. See Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by OWP3, LLC and Brunswick Surgery Center, LLC, Project I.D. O-11282-16, is the more effective alternative proposed in this review for one new operating room to be located in Brunswick County and is therefore approved. The approval of the application submitted by Novant Health Brunswick Outpatient Surgery, LLC, would result in operating rooms in excess of the need determination for Brunswick County. Consequently, the application submitted by Novant Health Brunswick Outpatient Surgery, LLC is denied.

The application submitted by OWP3, LLC and Brunswick Surgery Center, LLC is approved subject to the following conditions.

- 1. OWP3, LLC and Brunswick Surgery Center, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. OWP3, LLC and Brunswick Surgery Center, LLC shall develop an ambulatory surgery center with no more than one operating room.**
- 3. OWP3, LLC and Brunswick 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.**
- 4. OWP3, LLC and Brunswick 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.**

Attachment 2

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 16, 2017

Findings Date: October 16, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

COMPETITIVE REVIEW

Project ID #: F-11343-17
Facility: Novant Health Monroe Outpatient Surgery, LLC
FID #: 050748
County: Union County
Applicant: Novant Health Monroe Outpatient Surgery, LLC
Project: Add one OR pursuant to the need determination in the 2017 SMFP and one procedure room for a total of two ORs and one procedure room

Project ID #: F-011348-17
Facility: Union West Surgery Center
FID #: 050752
County: Union County
Applicants: The Charlotte-Mecklenburg Hospital Authority and Union Health Services, LLC
Project: Add a third OR pursuant to the need determination in the 2017 SMFP and one procedure room for a total of three ORs and one procedure room

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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 – Both Applicants

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) includes a Need Determination for one additional operating room (OR) in the Union County Operating Room Service Area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section or Agency) for development of the OR. The two applicants each applied for one OR, for a combined total of two additional ORs. Pursuant to the need determination in the 2017 SMFP, only one new or additional OR can be approved in this review.

Novant Health Monroe Outpatient Surgery, LLC [NHMOS] (formerly Presbyterian Same Day Surgery Center-Monroe) proposes to renovate and expand its existing licensed but unutilized ambulatory surgical facility (ASC) in Monroe and add one OR and one procedure room for a total of two ORs and one procedure room. The application is consistent with the need determination for one additional OR in Union County.

The Charlotte-Mecklenburg Hospital Authority [CMHA] and Union Health Services, LLC [UHS] propose to renovate and expand the existing ASC, **Union West Surgery Center [UWSC]**. UWSC proposes to renovate the ASC and add one OR and one procedure room for a total of three ORs and one procedure room. The application is consistent with the need determination for one OR in Union County.

Policies

There are two policies in the 2017 SMFP which are applicable to this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 33 of the 2017 SMFP, 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.”

Policy GEN-4, on page 33 of the 2017 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

NHMOS proposes to renovate and expand its existing licensed but unutilized ambulatory surgical facility in Monroe and add one OR and one procedure room for a total of two ORs and one procedure room. NHMOS addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 13 – 15, Section III.1, pages 23 - 31, Section III.4, pages 40 -41, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section III.1, pages 23 - 31, Section III.4, pages 41 - 42, Section VI, pages 64 - 73, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III.1, pages 23 - 31, Section III.4, pages 42 - 44, Section X.1, page 97 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

NHMOS addresses Policy GEN-4 as follows:

The proposed capital expenditure for this project is greater than \$5 million. In Section III.4, pages 44 - 45, Section XI.8, pages 104 - 105, and Exhibit 15, the applicant describes its plan to assure improved energy efficiency and water conservation in the proposed facility. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is consistent with the need determination in the 2017 SMFP, Policy GEN-3, and Policy GEN-4. Consequently, the application is conforming to this criterion.

UWSC proposes to renovate its existing licensed ambulatory surgical facility in Indian Trail and add one OR and one procedure room for a total of three ORs and one procedure room.

UWSC addressed Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section III.1, pages 28 - 38, Section II.8, pages 19 - 21, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section III.1, pages 28 - 38, Section VI, pages 67 - 73, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section III.1, pages 28 - 38 and Section X.1, page 89. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. The application is consistent with Policy GEN-3.

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million; therefore, Policy GEN-4 is applicable. The applicant does not address Policy GEN-4 in Section III.4, where the application requests the applicant(s) to describe how the project is consistent with each applicable policy in the SMFP. However, in Section XI.8, pages 96 - 97, the applicant describes its plan to maintain energy efficiency and water conservation, including a commitment to facility design that will meet or exceed the North Carolina Building Code requirements and will meet the United States Green Building Council LEED guidelines. The applicant states the renovations will also update plumbing design to

maximize efficiency and life cycle benefits. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is consistent with the need determination in the 2017 SMFP, Policy GEN-3 and Policy GEN-4. Consequently, the application is conforming to this criterion.

Conclusion

In summary, both applicants adequately demonstrate that their proposals are consistent with the need determination in the 2017 SMFP for one new OR in Union County. However, the limit on the number of ORs to be developed in Union County is one. Collectively, the two applicants propose a total of two new ORs. Therefore, even if both applications are conforming to all statutory and regulatory review criteria, both applications cannot be approved.

NHMOS's application is conforming to the need determination, Policy GEN-3 and Policy GEN-4. UWSC's application is conforming to the need determination, Policy GEN-3, and Policy GEN-4. Therefore, both applications are conforming to this criterion. See the Summary following the Comparative Analysis for the decision.

- (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 – Both Applicants

NHMOS proposes to renovate its existing licensed but unutilized ambulatory surgical facility (ASC) in Monroe. The ASC was awarded a CON in 2005 and was named Presbyterian Same Day Surgery Center – Monroe (see Project ID #F-7310-05). According to the applicant on page 24, the facility operated until January 31, 2013. The facility has not operated or served patients since that date, though the license remains active. In this application, the applicant proposes to renovate and expand that facility and add one additional OR and one procedure room, for a total of two ORs and one procedure room. The applicant proposes to rename the facility **Novant Health Monroe Outpatient Surgery**. In Section I.8, page 2, the applicant describes the proposed project as follows:

“The applicant [proposes to] develop a freestanding, separately licensed ambulatory surgical facility with a procedure room and two operating rooms based on the need

for one new Union County OR identified in the 2017 SMFP, plus one existing previously CON-approved OR at 2000 Wellness Blvd in Monroe, NC....”

In Section I.10, page 2, the applicant states the building in which the ASC currently exists and will be renovated is leased by NH.

Exhibit 4 contains support letters from 19 Novant Health surgeons, 17 of whom intend to seek OR privileges at the proposed ASC in the following specialties: ENT (1), OB/GYN (8), Ophthalmology (2), Orthopedics (2), General Surgery (2) and GI Endoscopy (2).

Patient Origin

In Section III.6, page 46, the applicant provides the projected patient origin for the proposed facility for the first two operating years of the project. The applicant projects that 100% of its patients will be from Union County. The applicant states on page 46 that it may serve patients from surrounding counties as well, but does not include any surrounding counties in its projected patient origin. The applicant states:

“...the utilization projections for the proposed two operating rooms at NHMOS are based upon shifting outpatient surgical volume performed at Novant Health operating rooms in Mecklenburg County for residents of Union County. Therefore, the projected patient origin ... is based upon providing a more cost effective and accessible location for residents of Union County currently using Novant Health surgical facilities.”

The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1, pages 25 - 37, the applicant describes the factors which it states support the need for the proposed project, including:

- The need identified in the 2017 SMFP (page 26).
- Increased utilization of NH outpatient surgical services by Union County residents (pages 26 - 28).
- Increasing market share of Union County outpatient surgical services (pages 28 - 29).
- Population growth in NHMOS outpatient surgery market area (pages 29 - 30).
- Changes in outpatient surgery reimbursement (pages 30 - 31).
- Strong physician and surgeon support for the project, as well as from members of the community (page 25, exhibits 4, 16, 17).

Each of the factors is briefly described below:

Need in 2017 SMFP

The 2017 SMFP shows a need for one additional OR in Union County. The applicant states that its projected utilization shown in Exhibit 3, Table I supports a need for the additional OR in its facility in Monroe. Table 6A on page 70 of the 2017 SMFP provides the following OR inventory in Union County:

FACILITY	INPATIENT ORS	AMBULATORY ORS	SHARED ORS	EXCLUDED C-SECTION ORS
Presbyterian SD Surgery Center-Monroe*	0	1	0	0
Union West Surgery Center	0	2	0	0
Carolinas HealthCare System Union	2	0	6	-2
Total	2	3	6	-2

*This is the facility that is currently closed, but licensed

There are a total of 11 licensed ORs in Union County, 2 of which are licensed dedicated C-Section ORs and are not included in the inventory for purposes of determining OR need. Novant Health’s ambulatory OR (Presbyterian Same Day Surgery Center-Monroe) is considered a “*chronically underutilized*” facility, which is defined on page 58 of the 2017 SMFP as a facility “*operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications*”. Chronically underutilized facilities are excluded from the “*Adjusted Planning Inventory*” for ORs in Union County, as stated on page 72 of the 2017 SMFP. Therefore, there are a total of 8 ORs included in the OR need determination in Union County.

Increased Utilization of Outpatient Surgical Services

On page 26, the applicant states the overall outpatient surgical utilization by Union County residents increased by a compound annual growth rate (CAGR) of 2.6% from 2014 to 2016; and increased by 4.1% for the 12-month period from 2015 – 2016, as shown in the following table:

Union County OP surgical growth – All NC Surgical Facilities							
	2013	2014	2015	2016	CAGR 2013- 2016	CAGR 2014- 2016	AGR 2015- 2016
# Procedures	13,285	13,099	13,259	13,798	1.3%	2.6%	4.1%
Annual Growth Rate		-1.4%	1.2%	4.1%			

On pages 27 – 28, the applicant shows that Novant Health Matthews Medical Center and Novant Health Matthews Surgical Center in Mecklenburg County, near the Mecklenburg and Union county borders, have historically served a large portion of Union County residents. The growth in Union County residents who seek outpatient surgical services in NH Mecklenburg County facilities has increased by a CAGR of 10.3% from 2014 to 2016. The applicant states the growth in outpatient surgical services provided to Union County residents in the Matthews facilities (Novant Health Matthews Medical Center and Matthews Surgery Center) alone grew by a CAGR of 16.8% during the same time. Matthews is located near the

southeastern border of Mecklenburg County, approximately five miles from Indian Trail, which is located in Union County, near the northwestern border. Therefore, the applicant states the growth of total outpatient surgical volume for Union County residents, and specifically the growth of Union County residents seeking outpatient surgical services in NH Matthews facilities supports the need for an additional OR and utilizing the existing OR in the Indian Trail ASC.

Union County Outpatient Surgical Market Share

On pages 28 – 29, the applicant states Novant Health’s overall market share of Union County residents who seek outpatient surgical services has increased by 2.8 percentage points from FFY 2013 to FFY 2016; similarly, the market share of Union County residents seeking outpatient surgical services in the Matthews facilities alone increased by 3.2 percentage points during the same time [overall NH market share of Union County outpatient surgeries grew from 39.9% in FFY 2013 to 42.7% in FFY 2016; Matthews facilities Union County outpatient surgeries grew from 14.1% in FFY 2013 to 17.3% in FFY 2016]. The applicant states NH facilities overall and in particular in Matthews are serving an increasing number of Union County residents who seek outpatient surgical services.

Population Growth of NHMOS Market Area

On pages 28 and 29 of the application, citing information from the North Carolina Office of State Budget and Management (NCOSBM), the applicant states that the population of Union County grew by 12.8% from 2010 to 2017, or 1.8% per year, and is projected to increase by a CAGR of 1.7% from 2017 to 2021.

Changes in Outpatient Services Reimbursement

The applicant discusses what it expects to be the impact of potential changes to the Affordable Care Act and the implementation of value-based purchasing (VBP) for payments under the Medicare program for hospitals and ASCs on pages 30 – 31 of the application. The applicant states the proposed project reflects the efforts currently underway within Novant Health to address the effects of changes to the Affordable Care Act and the potential effects those changes could bring to healthcare services provided by Novant Health.

Strong Physician and Community Support

In Exhibit 4, the applicant provides copies of letters of support from Novant Health and other area physicians, in which the physicians indicate he or she will seek privileges at the ambulatory surgical facility when it becomes licensed. In Exhibits 16 and 17, the applicant provides copies of letters from Novant Health management, local government and the Novant Health Chairman of the Board, all of whom express support for the proposal.

Projected Utilization

In Section III.1(b), pages 32 – 37, the applicant provides the assumptions and a four-step methodology it used to project utilization of the two ORs in the ASC in Union County. The steps and assumptions are summarized below.

Step 1: Determine Baseline Volume for Use in Outpatient Surgical Projections

On pages 32 – 33, the applicant states it compared its own internal data with the data reflected on the Hospital License Renewal Applications (LRAs). NH's data is reported in a *Trendstar* database and reports calendar year (CY) information, while the LRA data reports FY information. The applicant determined that CY 2016 was the most reasonable baseline data for use in its projections, since it is the most recent data available from *Trendstar*. The applicant states that NH facilities in Mecklenburg County performed 6,307 outpatient surgical procedures on Union County residents in CY 2016.

Step 2: Project Future Union County Outpatient Surgical Procedures at NH Mecklenburg Facilities

On page 34, the applicant examines four variables that it states affect growth in outpatient surgical volume at NH facilities that serve Union County residents. The applicant averaged four different variables to come up with a growth rate with which to project future outpatient surgical growth of Union County residents at NH outpatient surgical facilities, as shown in the following table:

VARIABLE	GROWTH RATE	GROWTH RATE**
Union County Population Growth 2016 – 2021 (NCOSBM)	1.7%	CAGR
Union County OP Surgical Growth 2013 – 2016 [2015 – 2016]	4.1%	AAGR
NH Union County OP Surgical Growth 2013 – 2016 [2015 – 2016]	6.9%	AAGR
Population Growth NHMOS ZIP Code (28110)	1.1%	CAGR
Average of Four Growth Rates	3.5%	

*Source: Table on page 34 of the application

**AAGR = Average Annual Growth Rate

However, the information provided in the table is unclear. The applicant states the second and third rows represent growth from 2013 – 2016; however, the numbers in the corresponding columns represent the growth from 2015 – 2016. Therefore, the project analyst utilized the numbers that correspond to the years that the applicant indicates, as illustrated in the following table:

**Novant Health Union County Projected OP Surgery
Calculated by Analyst**

VARIABLE	GROWTH RATE
Population Growth 2016 – 2021 (NCOSBM)	1.7% (CAGR)
Union County Outpatient Surgical Growth 2013 - 2016	1.3% (AAGR)
NH Union County Outpatient Surgical Growth 2013 - 2016	10.3% (CAGR)
Population Growth NHMOS ZIP Code (28110)	1.1% (AAGR)
Average of Four Growth Rates	3.6%

*Source: Tables on pages 34 and 135 - 136 of the application

	HISTORICAL	PROJECTED					
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
NH Union County Pop.*	6,307	6,525	6,751	6,985	7,227	7,477	7,736
Projected Growth Rate		3.5%	3.5%	3.5%	3.5%	3.5%	3.5%

*Represents Union County residents being served in a NH Mecklenburg County outpatient surgical facility

Therefore, while there are inconsistencies in the table as presented in the application, when the numbers the applicant states it used are actually used, the number of ORs needed is the same. Thus, the inconsistencies are not material to the outcome of the applicant's demonstration of the need for 2 ORs in its application.

The applicant uses a growth rate to project future outpatient surgical procedures to be performed at NHMOS that is lower than the historical growth rate of outpatient surgical procedures that were performed on Union County residents in NH facilities from 2013 to 2016.

Step 3: Determine the Percentage of Outpatient Cases That are "Acuity Appropriate" for NHMOS

On page 35, the applicant states it analyzed total NH Union County outpatient surgical volume in Mecklenburg County facilities and input from surgeons whose letters are provided in Exhibit 4. The applicant states the data shows that 40% of NH Union County outpatient surgical volume is provided in the two NH surgical facilities in Matthews. The applicant projects, based on its analysis, that 30% of the Union County residents who currently receive outpatient surgical services at the NH Mecklenburg County facilities will shift their care to NHMOS when it opens. See the following table, which shows that from CY 2014 to CY 2016, the volume of Union County residents seeking outpatient surgical services at a NH Matthews facility increased from 35.7% to 40.0% of total NH Union County volume:

Surgical Provider	CY 2014	CY 2015	CY 2016
Total NH Outpatient Surgery	5,184	5,824	6,307
NH Outpatient Surgical Volume in Matthews	1,849	2,424	2,522
NH Matthews and Matthews Surgery Center % of Total NH Union County Volume	35.7%	41.6%	40.0%

Source: table page 35

Step 4: Calculate Projected Outpatient Surgical Volume at NHMOS

Based on the assumption in Step 3, that 30% of the outpatient surgical volume that will be served at NH facilities in Mecklenburg County will be Union County residents, the applicant projects that 100% of the projected outpatient surgical volume at NHMOS will be comprised of the 30% of patients who currently go to Mecklenburg County NH facilities for outpatient surgical procedures. See the following table, from page 36:

Projected NHMOS Outpatient Surgery Volume, PYs 1 - 3

	CY 2019	CY 2020	CY 2021	CY 2022
NH Union County Pop. Served in Mecklenburg County	6,985	7,227	7,477	7,736
Percent Projected to Shift to NHMOS	30%	30%	30%	30%
Projected NHMOS Outpatient Surgery Volume	2,096	2,168	2,243	2,321
CONVERT TO PROJECT YEARS		PY 1	PY 2	PY 3
		(4/19 – 3/20)	(4/20 – 3/21)	(4/21 – 3/22)
Projected NHMOS Outpatient Surgery Volume		2,114	2,187	2,263

Based on that data, the applicant calculates the OR need in Union County, as shown in the following table from page 36:

Novant Health Monroe Projected OR Need

CONVERTED TO PROJECT YEARS	PY 1	PY 2	PY 3
	(4/19 – 3/20)	(4/20 – 3/21)	(4/21 – 3/22)
Projected NHMOS Volume	2,114	2,187	2,263
Projected NHMOS Outpatient Surgical Volume	3,171	3,280	3,394
ORs Needed at 1.872 Hrs per OR	1.69	1.75	1.81
OR Need Rounded per SMFP and CON Regulations	2.0	2.0	2.0

The applicant shows that approximately 40% of its outpatient surgical volume in its Mecklenburg County facilities is from Union County residents, and projects that 30% of the future volume of its Union County outpatient surgical procedures will shift to the proposed NHMOS. Further, the applicant shows that the projected volume is consistent with the OR need determination in the 2017 SMFP. Thus, the applicant’s projections of future Union County outpatient surgical volume at NHMOS is reasonable.

Non-Surgical Minor Procedures at NHMOS

The applicant proposes to develop one procedure room as part of this application. In Section III.1, pages 36 – 37, the applicant projects to perform 619, 640, and 662 procedures at NHMOS during PY 1, PY 2 and PY 3, respectively. In Exhibit 4 the applicant provides letters from surgeons who plan to utilize the proposed procedure room. On page 37, the applicant states that minor procedure volume is estimated based upon discussion with NHMOS surgical management staff, a review of procedure volume data for the surgeons who signed procedure room support letters and a review of other multispecialty ambulatory surgical facilities with procedure rooms in North Carolina.

Projected utilization at the proposed ASC is based on reasonable and adequately supported assumptions.

Therefore, based on the review and analysis of: 1) the information provided by the applicant in Section III, pages 26 - 37, including referenced exhibits; 2) the written comments received during the first 30 days of the review cycle; and 3) the applicant's response to the written comments submitted at the public hearing, the applicant adequately demonstrates the need to add one new OR and one procedure room at NHMOS, for a total of two ORs and one procedure room.

Access

In Section VI.2, pages 64 - 66, the applicant states it will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin, sexual orientation, gender identity or expression, and/or ability to pay. Exhibit 8 contains copies of Novant Health's non-discrimination policy. In Section VI.14, page 73, the applicant projects that 54.2% of the surgical cases performed at NHMOS will be provided to Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project, and demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

UWSC proposes to renovate its existing ASC, Union West Surgery Center, and add one OR and one procedure room for a total of three ORs and one procedure room. The application is consistent with the need determination for one OR in Union County. In Section I.8, page 7, the applicant describes the proposed project as follows:

“Union Health Services, LLC proposes to develop a third operating room at Union West Surgery Center in response to the need identified in the 2017 State Medical Facilities Plan for one additional operating room in Union County.”

In Section I.10, page 8, the applicant states the building in which the ASC currently exists and will be renovated is leased by CMHA and sub-leased to UHS, which operates UWSC.

In Exhibit 16 the applicants provide 49 support letters signed by physicians and surgeons. However, 16 of those letters are dated May 17, 2017 and express support for the development of a separately licensed ASC in Huntersville, in Mecklenburg County. Those letters must have been included erroneously, as they appear to be related to Project ID #F-11349-17, which was approved in July 2017. Therefore, the analyst will not consider the 16 letters provided in Exhibit 16 which are in support of the CHS Huntersville ASC. There are 27 letters signed by CHS surgeons who currently have privileges at UWSC in the following

specialties: OB/GYN (1), Ophthalmology (5), General Surgery (2), Orthopedics (2), Podiatry (7), ENT (8) and Urology (2). Six additional CHS surgeons indicated their support for the project in separate letters.

Patient Origin

In Section III.6, page 50, the applicants provide the projected patient origin for the first two operating years of the project (CY 2020 and CY 2021), as shown in the following table:

UWSC Projected Patient Origin

COUNTY	CY 2020 # PATIENTS	CY 2020 % OF TOTAL	CY 2021 # PATIENTS	CY 2021 % OF TOTAL
Union	1,811	53.1%	1,935	53.1%
Mecklenburg	682	20.0%	729	20.0%
Lancaster, SC	389	11.4%	415	11.4%
Anson	218	6.4%	233	6.4%
Chesterfield, SC	119	3.5%	128	3.5%
York, SC	55	1.6%	58	1.6%
Other*	136	4.0%	146	4.0%
Total	3,410	100.0%	3,644	100.0%

*The applicants state ‘other’ includes Cabarrus, Catawba, Cleveland, Cumberland, Forsyth, Gaston, Graham, Hertford, Iredell, Lincoln, McDowell, Montgomery, Richmond, Rowan, Rutherford, Sampson, Scotland, and Stanly counties as well as other states, based on historical patient origin.

The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III, pages 28 - 46, the applicants describe the factors which they state support the need for the proposed project, including:

- Need determination in the 2017 SMFP for one OR in Union County (pages 28 - 31)
- Demand for freestanding ambulatory surgery services (pages 31 – 34)
- Population growth and distribution in Union County (pages 35 – 37)
- Growth and capacity constraints at existing Union County facilities (pages 37 – 38)

Each of the factors is briefly described below:

Need in the 2017 SMFP

On pages 28 – 31, the applicants reiterate the methodology and need outlined in the 2017 SMFP for one additional OR in Union County. Table 6A on page 70 of the 2017 SMFP provides the following OR inventory in Union County:

FACILITY	INPATIENT ORS	AMBULATORY ORS	SHARED ORS	EXCLUDE C-SECTION ORS
Presbyterian SD Surgery Center Monroe*	0	1	0	0
Union West Surgery Center	0	2	0	0
Carolinas HealthCare System Union	2	0	6	-2
Total	2	3	6	-2

*This facility is currently closed, but licensed

There are a total of 11 licensed ORs in Union County, including 2 licensed dedicated C-Section ORs and one “*chronically underutilized*” OR, all of which are excluded from the inventory for purposes of determining OR need.

NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is a “*chronically underutilized*” facility, defined on page 58 of the 2017 SMFP as “*licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.*” NHMOS has been licensed to operate as an ambulatory surgical facility since 2009, but since January 2013 has not served any patients. Thus it has submitted at least three license renewal applications to the Division of Health Service Regulation since it closed in January 2013, and its utilization has been less than 40% for each year since January 2013. NHMOS is therefore a “*chronically underutilized facility*” as defined in the 2017 SMFP. Furthermore, on page 72 of the 2017 SMFP, NHMOS is listed as “*chronically underutilized*” and thus excluded from the “*Adjusted Planning Inventory*” for ORs in Union County.

Continued Demand for Freestanding Ambulatory Surgery Services

On pages 31 – 34, the applicants explain how the trend in surgery over the past several decades has been to shift many surgical procedures from an inpatient to an outpatient setting. Recent and continuing reform efforts in healthcare reimbursement and in the North Carolina Medicaid program continue to encourage patients in need of a less-invasive surgical procedure to continue to select ambulatory surgical facilities for their surgical procedures. Additionally, the applicants state that advances in clinical practices and technology continue to make ambulatory surgery an attractive option for many people. The applicants state that surgical procedures performed in an outpatient setting in North Carolina increased by a CAGR of 1.5% from FFY 2013 to FFY 2016, and by 3.7% from FFY 2015 – FFY 2016. Similarly, the applicants state Union County inpatient surgical volume has been flat, but outpatient surgical volume increased by a CAGR of 7.8% from FFY 2013 – FFY 2016. See the following table from page 34:

YEAR	CHS UNION	UWSC	TOTAL OP CASES
FFY 2013	4,456	1,723	6,179
FFY 2014	4,695	1,991	6,686
FFY 2015	4,804	2,395	7,199
FFY 2016	4,987	2,744	7,731
CAGR 2013 - 2016	3.8%	16.8%	7.8%

Population Growth and Distribution in Union County

On pages 35 – 37, relying on data obtained from ESRI, the applicants examined population growth projections in Union County as a whole and in different areas within the county. The applicant determined that the population in the western part of Union County, which is where UWSC is located, is projected to increase by 2.2% annually from 2016 to 2021; whereas the population in the central and eastern portions of the county are projected to increase by 1.3% and 1.2%, respectively. The applicants also state the Western portion of Union County represents approximately 80% of the total county population, but only has two ORs. The other ORs in the county are located in the central portion of the county at CHS Union, located in Monroe.

Growth and capacity constraints at existing Union County facilities

On pages 37 – 38, the applicants state that the outpatient surgical volume at UWSC has increased faster than the surgical growth at CHS Union, in part because CHS Union has more OR capacity than UWSC (6 shared ORs and 2 inpatient ORs). In addition, UWSC’s ORs are more highly utilized than CHS Union’s ORs. See the following table, from page 37:

	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016
UWSC					
OP Cases	321	1,723	1,991	2,395	2,744
Total Surgical Hours	482	2,585	2,987	3,593	4,116
Annual Growth		437%	16%	20%	15%
CHS Union					
IP Cases	1,766	1,453	1,384	1,391	1,453
OP Cases	4,846	4,456	4,695	4,804	4,987
Total Surgical Hours	12,567	11,043	11,195	11,379	11,840
Annual Growth		-12%	1%	2%	4%

Source: 2014 – 2017 SMFPs and 2017 LRAs

On page 37, the applicants state that UWSC’s surgical growth in FFY 2016 already exceeded the projected utilization for FFY 2019 in the 2017 SMFP (the 2017 SMFP’s methodology projected that UWSC would perform 3,893 surgical hours in 2019). In FFY 2016, UWSC performed 4,116 total surgical hours.

Projected Utilization

In Section III.1(b), page 41, the applicants provide the projected utilization of the three ORs at UWSC, as shown in the following table:

	FIRST FULL FY (CY 2020)	SECOND FULL FY (CY 2021)	THIRD FULL FY (CY 2022)
# Outpatient OR Cases	3,410	3,644	3,894
# Dedicated Outpatient ORs	3	3	3

As shown in the table above, the applicants project to perform 3,894 outpatient surgical cases in the third operating year in the three operating rooms, which exceeds the annual utilization standard of 1,872 hours per operating room as required in 10A NCAC 14C.2130(b)(1) [3,894 surgical cases x 1.5 hours = 5,841 / 1,872 = 3.1]. The applicants note on page 29 that fiscal years for UWSC are calendar years; therefore, the utilization projections are provided in calendar years to match their fiscal years.

The applicant describes its methodology and assumptions for projecting utilization in Section III.1(a) and (b), pages 39 – 46 of the application.

Historical Union County Outpatient Surgical Utilization and UWSC Utilization

The applicants state that, from 2013 - 2016, UWSC's outpatient surgical utilization has increased by a CAGR of 13.7%. The applicants state that growth slowed from CY 2015 to CY 2016 due to capacity constraints and the surgeons' inability to schedule surgical time blocks because the ORs were utilized in excess of 89% of capacity. The applicants note that outpatient surgical utilization at UWSC from CY 2013 to CY 2016 increased at a higher rate than population growth in Union County during the same time. The applicants believe that the historical growth and the need in the 2017 SMFP indicate a continued need for additional capacity at UWSC.

Projected Utilization at UWSC

On page 41, the applicants project future utilization of ambulatory surgical services at UWSC at lower rates than the historical utilization. The applicants state that during the "interim" years, pending completion of the additional OR, the number of cases at the ASC will grow by one quarter of the historical growth rate of 13.7%, or a projected growth rate of 3.4% [$13.7 / 4 = 3.425$]. Following completion of the additional OR at the ASC, the applicants project growth will increase to one-half the historical growth rate, or 6.9% [$13.7 / 2 = 6.85$]. The applicants believe the projections are reasonable, given the historical utilization at UWSC and the fact that the utilization has already exceeded the 2019 projections in the 2017 SMFP.

Factors Supporting Projected Growth

On pages 42 – 45, the applicants provide additional information which they state supports the need for the growth projections in Section IV. Specifically, the applicants provide a table on pages 42 and 43 to illustrate the 27 support letters in Exhibit 16 which project a total of 4,369 cases that will be referred by the surgeons who signed letters. Sixteen letters in Exhibit 16 are in support of CHS Huntersville, which is a project that was recently approved, and six physician letters support the project but do not indicate privileges or projected referrals to UWSC. The applicants state that five surgeons have joined UWSC in the last year. In addition, the number of surgical cases projected to be referred by the surgeons represented in the table on pages 42 – 43 exceeds the applicants' projection of the number of cases to be performed in its third project year (4,369 cases to be referred according to the physician letters; 3,894 cases projected to be performed).

Projected Utilization at Both Facilities

On pages 44 – 46, the applicants project utilization for CHS Union for each of the three project years, based on a projected growth rate of one-half of the historical CAGR of outpatient surgical procedure performed at each facility from CY 2013 to CY 2016. The applicants convert projected utilization for UWSC from calendar years to project years.

Based on the Agency's review of the information provided by the applicant in Section III, pages 28 - 46, including referenced exhibits, and Section IV, page 58; comments received during the first 30 days of the review cycle; and the applicant's response to the comments received at the public hearing, the applicants adequately document the need for an additional OR at UWSC.

Access

In Section VI.2, page 67, the applicants state they will provide services to all persons regardless of race, sex, age, creed, national origin, or ability to pay. Exhibit 22 contains the applicants' financial policies which outline the provision of services to those who cannot pay.

In Section VI.14, page 74, the applicants project that 57.5% of surgical cases will be provided to Medicare or Medicaid recipients at UWSC. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identify the population to be served, demonstrate the need the population has for the project, and demonstrate the extent to which all residents, including underserved groups, will 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 – Both Applications

- (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.

C – Both Applicants

NHMOS: In Section III.8, pages 47 - 48, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it determined that operating a freestanding ambulatory surgical facility with only one OR could not be financially viable.
- Develop a Freestanding Separately Licensed Surgery Center in Another Location – The applicant states that this is not an effective alternative because Monroe is the county seat and is located in the largest population base in Union County. Furthermore, the applicant states expanding the existing facility results in more cost savings than construction of a new facility.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need for one OR in Union County.

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 applicant adequately demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the Union County Operating Room Service Area. Therefore, the application is conforming to this criterion.

UWSC: In Section III.8, pages 51 - 56, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicants state that maintaining the status quo is not an effective alternative because it ignores the need in the community for an additional OR.
- Locate the Additional OR at CHS Union – (CHS Union is a hospital owned by CMHA located in Union County) The applicants state that this is not an effective alternative because developing the OR at CHS Union would fail to address the capacity and growth issues at UWHC.
- Relocate an Existing Shared OR from CHS Union to UWHC – The applicants state this is not an effective alternative because it would not address existing capacity constraints at UWSC or the existing OR deficits at both CHS Union and UWSC. Additionally, relocating an existing OR would not address the need identified in the 21017 SMFP for an additional OR in Union County.
- Develop a New Ambulatory Surgical Center – The applicants state this is not an effective alternative because the capital costs associated with developing a new facility are high; furthermore, it would not address current capacity constraints that exist at UWSC.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need for one OR in Union County.

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 applicant adequately demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the Union County Operating Room Service Area. Therefore, the application is conforming to this 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.

C – Both Applicants

NHMOS: In Section VIII.1, page 87, the applicant projects the total capital cost as follows:

DESCRIPTION	COST
Site Costs	N/A
Construction/Renovation Costs	\$3,135,380
Equipment	\$3,423,387
Miscellaneous	\$1,993,720
TOTAL CAPITAL COST	\$8,552,487

Source: Table on page 87 of the application.

In Section IX.1, page 96, the applicant projects \$305,300 in start-up expenses and \$330,015 in initial operating expenses associated with the project, for a total working capital of \$635,315.

Availability of Funds

In Section VIII.3, page 88, the applicant states that the entire capital and working capital costs will be funded with the accumulated reserves of Novant Health, Inc. In Exhibit 7, the applicant provides an April 15, 2017 letter from the Senior Vice President of Finance at Novant Health, Inc. which documents Novant Health's intent to fund the capital and working capital costs for the proposed project. Exhibit 7 also contains an April 5, 2017 letter from the President and Chief Operating Office of Novant Health, Inc. which commits the funds to the development of the project.

In Exhibit 7 the applicant provides copies of its consolidated financial statements for years ending 2015 and 2016 for Novant Health, Inc. and Affiliates, documenting \$260,988,000 in

cash and cash equivalents and \$3,448,337,000 in total net assets as of December 31, 2016. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

The applicant 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 (Form B), the applicant projects 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
Total Number of Cases and Procedures	2,733	2,797	2,925
Total Gross Revenues (Charges)	\$18,425,096	\$19,193,309	\$21,689,490
Total Net Revenue	\$6,870,725	\$7,156,452	\$8,091,713
Average Net Revenue per Case/Procedure	\$2,514	\$2,559	\$2,766
Total Operating Expenses (Costs)	\$6,195,034	\$6,351,416	\$6,564,999
Average Operating Expense per Case/Procedure	\$2,267	\$2,271	\$2,244
Net Income	\$675,691	\$805,036	\$1,526,714

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the Financials 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 applicant adequately demonstrates 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 applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

UWSC: In Section VIII.1, pages 83 - 84, the applicant projects the total capital cost as follows:

DESCRIPTION	COST
Site Costs	N/A
Construction/Renovation Costs	\$1,820,000
Equipment	\$1,601,500
Miscellaneous	\$ 678,500
TOTAL CAPITAL COST	\$4,100,000

Source: Table on pages 83 - 84 of the application.

In Section IX.1, page 88, the applicant projects no start-up expenses or initial operating expenses associated with the project, since the ASC is currently operational.

Availability of Funds

In Section VIII.3, page 84, the applicant states that the entire capital cost will be funded with the accumulated reserves of CHS. In Exhibit 25, the applicant provides a May 15, 2017 letter from the Executive Vice President and CFO of CMHA/CHS which documents CMHA/CHS’s intent to fund the entire capital cost of the proposed project. Exhibit 25 also contains a May 15, 2017 letter from the CFO of CHS which commits the funds to the development of the project. An additional letter from a manager of UHS commits to repay the capital cost of the project to CMHA/CHS.

In Exhibit 26 the applicant provides copies of its consolidated financial statements for years ending 2015, 2014 and 2013 for The Charlotte-Mecklenburg Hospital Authority, documenting \$173,937,000 in cash and short term investments, and \$3,889,878 in net assets (total assets less total liabilities) as of December 31, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

The applicant 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 (Form B), the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1ST OPERATING YEAR (CY 2020)	2ND OPERATING YEAR (CY 2021)	3RD OPERATING YEAR (CY 2022)
Total Number of Cases and Procedures	3,731	3,987	4,260
Total Gross Revenues (Charges)	\$20,874,903	\$22,975,002	\$25,286,380
Total Net Revenue	\$6,844,299	\$7,532,863	\$8,290,699
Average Net Revenue per Case/Procedure	\$1,834	\$1,889	\$1,946
Total Operating Expenses (Costs)	\$6,689,722	\$7,030,926	\$7,400,921
Average Operating Expense per Case/Procedure	\$1,793	\$1,763	\$1,737
Net Income	\$154,577	\$501,937	\$889,778

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the Financials 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 applicant adequately demonstrates 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 applicant adequately demonstrates the financial feasibility of the project 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 – Both Applicants

On page 57, the 2017 SMFP states, “An operating room’s service area is 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.” Figure 6.1 on page 60 of the 2017 SMFP shows Union County as a single-county OR service area. Thus, in this application, the service area is Union County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved Ambulatory (AMB), inpatient (IP) and shared operating rooms located in the service area of Union County, and the ambulatory and inpatient case volumes for each provider, as listed in Table 6A on page 70 of the 2017 SMFP.

Union County Operating Room Inventory, 2017 SMFP

	IP ORs	AMB ORs	SHARED ORs	EXCLUDED C-SECTION ORs	AMB SURGERY CASES	IP SURGERY CASES
Presbyterian Same Day Surgery Center*	0	1	0	0	0	0
Union West Surgery Center	0	2	0	0	2,395	0
Carolinas HealthCare System Union	2	0	6	-2	4,804	1,391
Total Union County ORs	2	3	6	-2	7,199	1,391

*Currently closed

As the table above indicates, there are a total of 11 operating rooms, excluding the two C-Section ORs, and one “chronically underutilized” OR.

NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is a “chronically underutilized” facility, defined on page 58 of the 2017 SMFP as “licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.” NHMOS has been licensed to operate as an ambulatory surgical facility since 2009, but since January 2013 has not served any patients. Thus it has submitted at least three license renewal applications to the Division of Health Service Regulation since

it closed in January 2013, and its utilization has been less than 40% for each year since January 2013. NHMOS is therefore a “*chronically underutilized facility*” as defined in the 2017 SMFP. Furthermore, on page 72 of the 2017 SMFP, NHMOS is listed as “*chronically underutilized*” and thus excluded from the “*Adjusted Planning Inventory*” for ORs in Union County.

Table 6B: Projected Operating Room Need for 2019, on page 81 of the 2017 SMFP shows that the projected OR deficit is 0.67 (Column T), and the projected number of ORs needed in 2019 in Union County is 1 (Column U). Additionally, Table 6C: Operating Room Need Determination on page 82 of the 2017 SMFP identifies a need for 1 operating room in Union County, based on the need methodology as outlined in Step 5 on page 59 of the 2017 SMFP, which states in part:

“For each operating room service area with six to 10 operating rooms and a projected deficit of 0.30 or greater, the “Operating Room Need Determination” is equal to the “Projected Operating Room Deficit” rounded to the next whole number. (In this step, fractions of 0.30 or greater are rounded to the next highest whole number.) For each operating room service area with six to 10 operating rooms and a projected deficit that is less than 0.30 or in which there is a projected surplus, the Operating Room Need Determination is zero. (Column U)”

NHMOS proposes to add one OR and one procedure room to a licensed but unutilized ASC with one operating room in Monroe in Union County for a total of two ORs and one procedure room. The 2017 SMFP identifies the need for one additional OR in Union County. The applicant adequately demonstrates the need to add one OR and one procedure room to its existing but unutilized ASC with one OR and that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Union County. Therefore, the application is conforming to this criterion.

UWSC proposes to add one OR and one procedure room to its existing facility for a total of three ORs and one procedure room. The 2017 SMFP identifies the need for one additional OR in Union County. The applicant adequately demonstrates the need to add one OR and one procedure room to its existing ASC with two ORs, and that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved operating rooms in Union County. Therefore, 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 – Both Applications

NHMOS: In Section VII.2, page 75, the applicant provides the proposed staffing for the facility in Operating Year 2, as shown in the following table:

POSITION	# FULL TIME EQUIVALENTS (FTES)
Administrator	1.0
CRNA	1.5
Clinical Coordinator	2.0
Registered Nurse	8.0
Surgical Technician	3.0
Certified Nursing Assistant	1.5
Sterile Processing Technician	1.0
Patient Access Specialist	1.5
Total	19.5

In Section VII.3, pages 75 - 77, and Section VII.7, pages 80 - 81, the applicant describes Novant Health's experience and process for recruiting and retaining staff. Exhibit 4 contains signed letters of support from surgeons who intend to seek privileges at the ASC. Exhibit 5 contains copies of letters from an anesthesiologist, pathologist, and radiologist who have agreed to provide support and professional coverage for NHMOS's ambulatory surgery patients. Exhibit 5 also contains a letter from William A. Walker, MD indicating his support and willingness to serve as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

UWSC currently operates two ORs with 28 FTEs. In Section VII.2, page 76, the applicant states it projects to employ two additional registered nurses and one additional surgical technician, for a total of 27.8 FTEs as part of this project. In Section VII.3(c), page 76, the applicant states CHS Union recruits the necessary staff for UWSC and will continue to do so. In Section VII.9, page 80, the applicant states Stephen Houser, M.D. is current medical director and will remain medical director following the addition of one OR. Exhibit 11 contains a copy of a letter from Dr. Houser expressing his commitment to continue to serve as the Medical Director of UWSC. Exhibit 16 of the application contains copies of letters from area physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 – Both Applications

NHMOS: In Sections II.1 and II.2, pages 9-11, the applicant identifies the necessary ancillary and support services, and describes how they will be provided. Exhibits 4 and 5 of the application contain copies of letters from area physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

UWSC: In Section II.2, pages 17 - 18, the applicant states the necessary ancillary and support services for the project will be provided by CHS Union or by existing support staff. Exhibit 6 contains a copy of CMC-Union's Purchased Services Agreement, and Exhibit 16 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing healthcare 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.

C – Both Applicants

NHMOS proposes to add one OR and one procedure room to its existing but unutilized ambulatory surgery center on Wellness Drive in Monroe, in Union County. The existing facility currently has 10,019 square feet of space, 5,345 of which the applicant proposes to renovate. In addition, the applicant proposes to add 2,279 square feet (1,338 square feet of waiting area, 516 square feet of registration area, and 425 new square feet of support space), for a total of 12,298 square feet in the finished facility. Exhibit 14 contains line drawings that identify existing receiving/registering, waiting, pre-operative, recovery and operating room as well as the proposed OR, procedure room and support areas. Exhibit 14 also contains a certified cost estimate from an architect regarding construction, upfit and renovation costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.1, page 87 of the application. In Section XI.8, page 104 and Exhibit 15, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative. Further, the applicant adequately demonstrates that the construction cost will not unduly increase costs and charges for health services, and that applicable energy savings features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

UWSC proposes to add one OR and one procedure room by renovating 4,437 existing square feet of unused space at its existing ambulatory surgical center on Highway 74 West in Indian Trail, Union County. Exhibit 7 contains the line drawings identifying reception/registration, waiting, pre-operative, operating rooms, and post-operative/recovery areas. Exhibit 29 contains the general contractor's construction cost estimate for the renovation of the existing building in which the proposed OR will be developed. The cost estimate is consistent with the project capital cost projections provided by the applicants in Section VIII, page 83 of the application. In Section XI.8, pages 96 - 97, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative. Further, the applicants adequately demonstrate that the construction cost will not unduly increase costs and charges for health services, and that applicable energy savings features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

(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 – UWSC
NA - NHMOS

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**
Union	11%	51%	27%	11%	6%	16%
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.

NHMOS: In Section VI.13, page 72, the applicant states the facility is not currently operational and thus has no current payor mix to report. In Section VI.12, page 72, the applicant provides payor mix information for the last operating year of Presbyterian Same Day Surgery Center, which was FFY 2013, as illustrated in the following table:

**Presbyterian Same Day Surgery Center Monroe
FFY 2013 Data**

PAYOR CATEGORY	# CASES AS PERCENT OF TOTAL
Self Pay/Indigent	0.58%
Commercial Insurance	32.8%
Medicare/Medicare Managed Care	45.6%
Medicaid	15.4%
Managed Care	2.9%
Other	2.6%
Total	100.0%

The applicant does not currently provide any services in its licensed ambulatory surgical facility.

UWSC: In Section VI.13, page 73, the applicants provide the UWSC payor mix for CY 2016, as shown in the following table:

UWSC CY 2016 Payor Mix

PAYOR CATEGORY	# CASES AS PERCENT OF TOTAL
Medicare	45.7%
Medicaid	11.8%
Commercial / Managed Care	40.0%
Other*	1.8%
Self Pay	0.8%
Total	100.0%

*Other includes workers compensation and other government payors, according to the applicant on page 73.

The applicants adequately demonstrate that they currently provide 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 – Both Applications

NHMOS: Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 71, the applicant states:

“Novant Health’s hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago. ... Novant Health facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons.”

In Section VI.10 (a), page 71, the applicant states that no civil rights equal access complaints have been filed against NH or its affiliated licensed hospitals and surgery centers during the last five years. The application is conforming to this criterion.

UWSC: In Section VI.11, page 72, the applicants state, “*UWSC does not have any obligations to provide uncompensated care. ... UWSC does not discriminate with regard to ability to pay in full. Uninsured patients are offered a 50 percent discount off gross charges if the amount is paid in full at the time of service. ... Patients who are financially unable to pay for healthcare services according to these provisions and are in need of financial assistance have their cases reviewed by the medical director.*” In Section VI.10 (a), page 72, the applicant states that no civil rights access complaints have been filed against it or any related entities in the last five years. 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 – Both Applications

NHMOS: In Section VI.14, page 73, the applicant projects payor mix for the second operating year:

PAYOR	NUMBER OF CASES AS % OF TOTAL
Self Pay/Indigent	1.0%
Commercial Insurance	39.1%
Medicare/Medicare Managed Care	36.3%
Medicaid	17.9%
Other	5.7%
Total	100.0%

*In the table in Section VI.13, on page 73, the applicant includes an extra row for “*Managed Care: 39.1%*”; however, the Pro Formas at the end of the application are consistent with the information in the above table. The extra row in the table on page 73 appears to be a typographical error.

On page 73, the applicant describes its assumptions regarding its payor mix projections, which it states are based on the historical experience of other NH outpatient surgical facilities that serve Union county residents. The applicant adequately demonstrates that the medically underserved population will have access to the proposed ambulatory surgical services. Therefore, the application is conforming to this criterion.

UWSC: In Section VI.14, page 74, the applicants project the payor mix during the second operating year, as shown in the table below.

**UWSC Second Operating Year
(CY 2021)**

PAYOR CATEGORY	# CASES AS PERCENT OF TOTAL
Medicare	45.7%
Medicaid	11.8%
Commercial / Managed Care	40.0%
Other*	1.8%
Self Pay	0.8%
Total	100.0%

On page 74 the applicants state the projected payor mix is based on the historical payor mix at UWSC. The applicants adequately demonstrate that medically underserved groups 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 – Both Applications

NHMOS: In Section VI.9, pages 70 - 71, the applicant describes the range of means by which a person will have access to its outpatient surgical services. The applicant adequately demonstrates 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.

UWSC: In Section VI.9, page 71, the applicants describe the range of means by which a person will have access to its outpatient surgical services. 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 – Both Applications

NHMOS: In Section V.1, page 52, the applicant states that Novant Health has extensive relationships with health education programs in the market area and that these agreements will include NHMOS once it becomes operational. In Exhibit 9 the applicant provides a list of educational institutions in the market area with which Novant Health has training arrangements, including Appalachian State University, Cabarrus College of Health Science, Central Piedmont Community College, and Cleveland Community College, among others. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

UWSC: In Section V.1, pages 59 - 61, the applicants state that CHS Union has existing relationships with local health professional training programs in the area, including Caldwell Community College and Technical Institute, South Piedmont Community College and York Technical College, among others. Exhibit 17 contains copies of some existing agreements. The information provided 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 – Both Applicants

On page 57, the 2017 SMFP states, “An operating room’s service area is 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.” Figure 6.1 on page 60 of the 2017 SMFP shows Union County as a single-county operating room service area. Thus, in this application, the service area is Union County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved ambulatory (AMB), inpatient (IP) and shared operating rooms located in the service area of Union County, and the ambulatory and inpatient case volumes for each provider, as listed in Table 6A on page 70 of the 2017 SMFP.

Union County Operating Room Inventory, 2017 SMFP

	IP ORs	AMB ORs	SHARED ORs	EXCLUDED C-SECTION ORs	AMB SURGERY CASES	IP SURGERY CASES
Presbyterian Same Day Surgery Center*	0	1	0	0	0	0
Union West Surgery Center	0	2	0	0	2,395	0
Carolinas HealthCare System Union	2	0	6	-2	4,804	1,391
Total Union County ORs	2	3	6	-2	7,199	1,391

*Currently closed

As the table above indicates, there are a total of 11 operating rooms, including the two dedicated C-Section ORs, and one “chronically underutilized” OR.

NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is a “*chronically underutilized*” facility, defined on page 58 of the 2017 SMFP as “*licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.*” NHMOS has been licensed to operate as an ambulatory surgical facility since 2009, but since January 2013 has not served any patients. Thus it has submitted at least three license renewal applications to the Division of Health Service Regulation since it closed in January 2013, and its utilization has been less than 40% for each year since January 2013. NHMOS is therefore a “*chronically underutilized facility*” as defined in the 2017 SMFP. Furthermore, in a table on page 72 of the 2017 SMFP, NHMOS is listed as “*chronically underutilized*” and thus excluded from the “*Adjusted Planning Inventory*” for ORs in Union County. Therefore, the adjusted planning inventory consists of 8 ORs in Union County.

Table 6B: Projected Operating Room Need for 2019, on page 81 of the 2017 SMFP shows that the projected OR deficit is 0.67 (Column T), and the projected number of ORs needed in 2019 in Union County is 1 (Column U). Additionally, Table 6C: Operating Room Need Determination on page 82 of the 2017 SMFP identifies a need for 1 OR in Union County, based on the need methodology as outlined in Step 5 on page 59 of the 2017 SMFP.

NHMOS proposes to renovate and expand an existing but unutilized ambulatory surgical facility with one OR, and develop one new OR and one procedure room, for a total of two ORs and one procedure room. The 2017 SMFP identifies a need for one additional OR in Union County. In Section V.7, pages 57 - 63, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“As a licensed outpatient surgery center, NHMOS will have the opportunity to offer outpatient surgeries at a lower price point than a hospital-based outpatient surgery program. ... This approach will offer a new, more cost effective option for local access to outpatient surgical care in the Union County market area. As a result, NHMOS will also promote beneficial competition and choice with other surgery centers in neighboring counties. Competition can be a useful tool in expanding local geographic access to services, promoting cost effectiveness by putting downward pressure on costs of care, and encouraging the consistency in the delivery of quality care.

...

Excellent access to healthcare services is an important feature of the quality of life in the communities served by Novant Health, NHMOS and Novant Medical Group physicians. The Novant Medical Group physicians also adhere to the Novant Health Charity Care Policy, Novant Health’s eligibility criteria for charity care allows patients with annual household incomes up to 300% of the Federal Poverty Level,

which is \$72,900 for a family of four in 2017, to seek Charity Care coverage from Novant Health.

...

...Novant Health and NHMOS will continue to foster competition through cost effectiveness, patient safety, and financial accessibility to care, proactive preventative care, and access to care through the electronic health record, and diversity and inclusion.”

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

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

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

Therefore, the application is conforming to this criterion.

UWSC proposes to add one OR and one procedure room to its existing facility for a total of three ORs and one procedure room. The 2017 SMFP identifies a need for one additional OR in Union County. In Section V.7, pages 65 - 66, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state:

“The proposed project will result in the expansion of the existing freestanding ASC in Union County. Competition will be enhanced because the proposed facility will improve access to high-quality, value-based services, specifically outpatient surgery, in Union County and surrounding areas.

...

In addition, as UHS is currently seeking physician investment in UWSC, the proposed project will be developed with physician ownership and oversight of clinical services.

As such, physicians will be actively engaged in decision making ... in innovation ... and in achieving excellent patient experience and outcomes.

...

UWSC provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap or ability to pay in full and will continue to provide such access upon completion of the proposed project.

...

The proposed project, which involves the renovation of existing space in a leased facility, is less costly than the construction of a new facility or the renovation of existing hospital space. UHS has thus proposed the most value-conscious alternative for developing the additional operating room”

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the 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 project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicants adequately demonstrate that they will provide access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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 – Both Applicants

NHMOS: In Section III.4, pages 40 - 43, the applicant describes the methods used by NH to ensure and maintain quality care. NHMOS is a new limited liability company with 100% of its LLC membership interests owned by NH. As such, the applicant does not currently

provide services, however, the application often refers to NH's ownership, experience and policies as being relevant to NHMOS, as in Section II.8, pages 13-16, and Exhibit 10.

In Section I.13, pages 4 - 7, the applicant lists the facilities and programs owned by NH. NH owns and operates 11 licensed hospital facilities in North Carolina and nine licensed outpatient surgery or endoscopy centers, including four freestanding ambulatory surgery facilities like the one proposed in this application to be re-opened. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, incidents occurred at one of the 11 licensed hospitals within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems have been corrected. No incidents occurred at any of the four existing ambulatory surgical facilities with that time period. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all 11 Novant Health facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore the application is conforming to this criterion.

UWSC: In Section II.7(b), pages 19 - 21, the applicants describe the methods to be used to ensure and maintain quality care. UHS is wholly owned by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System.

In Exhibit 5, the applicant lists the facilities and programs owned and/or managed by CMHA/CHS. CHS owns and operates 24 licensed hospital facilities and licensed outpatient surgery or endoscopy centers in North Carolina, including freestanding ambulatory surgery facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, incidents occurred at five of the 24 licensed hospitals within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the problems have been corrected. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all 11 Novant Health facilities, 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 – Both Applications

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to this review. The specific criteria are discussed below.

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

.2103 PERFORMANCE STANDARDS

.2103 (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- **NHMOS:** In Section II.10, page 17, the applicant states the facility will be open five days per week, 52 weeks per year.

-C- **UWSC:** In Section II.10, page 22, the applicants state the facility will be open five days per week, 52 weeks per year.

.2103 (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- **NHMOS:** In Section II.10, pages 18 - 20, the applicant states there are a total of nine ORs in Union County, and calculates a need based on the instruction in subsection (B) above. In fact, NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is excluded from the need determination because it is a “*chronically underutilized*” facility. Therefore, the “*Adjusted Planning Inventory*” is reduced from 9 to 8 in Table 6B on page 81 of the 2017 SMFP. However, if NHMOS were not closed and not considered a “*chronically underutilized facility,*” there would be no need for an additional OR in Union County. The applicant nevertheless demonstrates the need for one additional operating room, for a total of two ORs and one procedure room in its ambulatory surgical facility in Union County in the third operating year, as illustrated in the following table:

NHMOS Total Projected Outpatient Surgical Cases and OR Need

SURGICAL CASES	PY 1	PY 2	PY 3
Projected Outpatient Cases	2,114	2,187	2,263
X 1.5 = Weighted Surgical Hours	3,171	3,280	3,394
ORs Needed at 1,872 Hours per Room*	1.69	1.75	1.81
NHMOS OR Need	2	2	2

Totals may not sum due to rounding

* Since the difference in each of the first three Project Years is a positive number that is greater than or equal to 0.3, the need is the next highest number.

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

- C- **UWSC:** In Section II.10, pages 24 - 25, the applicant demonstrates the need for one additional operating room for a total of three ORs and one procedure room in its

ambulatory surgical facility in Union County in the third operating year, as illustrated in the following table:

**UWSC Total Projected Outpatient Surgical Cases
and OR Need, PY 3**

	UWSC
Inpatient Cases	0
Outpatient Cases	3,852
Total Surgical Hours	5,778
OR Need at 1,872 hours per room	3.1
# Existing ORs	2
Deficit	1.1

Totals may not sum due to rounding

* Since the difference in each of the first three Project Years is a positive number that is greater than or equal to 0.3, the need is the next highest number.

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

.2103 (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: $\{[(\text{Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$ 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.

The need determination identified in the 2017 SMFP will increase the number of ORs in the Union County service area by one OR, upon approval of one of the two competing applications in this review. The Union County operating room service area has six to 10 operating rooms; therefore, .2103(c)(2)(B) above is applicable to this review.

- C- **NHMOS:** In Section II.10, pages 24 - 25, the applicant demonstrates the need for one additional operating room for a total of three ORs and one procedure room in its ambulatory surgical facility in Union County in the third operating year.

In Section II.10, pages 18 - 20, the applicant states there are a total of nine ORs in Union County, and calculates a need based on the instruction in subsection (B) above. In fact, NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is excluded from the need determination because it is a “*chronically underutilized*” facility. Therefore, the “*Adjusted Planning Inventory*” is reduced from 9 to 8 in Table 6B on page 81 of the 2017 SMFP. However, if NHMOS were not closed and not considered a “*chronically underutilized facility*,” there would be no need for an additional OR in Union County. The applicant nevertheless demonstrates the need for one additional operating room, for a total of two ORs and one procedure room in its ambulatory surgical facility in Union County in the third operating year, as illustrated in the following table, from page 18 and Exhibit 3, Table 1:

NHMOS Total Projected Outpatient Surgical Cases and OR Need			
SURGICAL CASES	PY 1	PY 2	PY 3
Projected Outpatient Cases	2,114	2,187	2,263
X 1.5 = Weighted Surgical Hours	3,171	3,280	3,394
ORs Needed at 1,872 Hours per Room*	1.69	1.75	1.81
NHMOS OR Need	2	2	2

Totals may not sum due to rounding

* Since the difference in each of the first three Project Years is a positive number that is greater than or equal to 0.3, the need is the next highest number.

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

- C- **UWSC:** The applicants currently operate a total of two ambulatory ORs in Union County. CHS Union, a related entity in the service area, owns six shared ORs and two dedicated C-section ORs. In Section II.8, pages 24 – 25 and in Section III, pages 28 – 46, the applicants demonstrate the need for one additional OR in UWSC, for a total of three ORs and one procedure room in its ambulatory surgical facility in Union County in the third operating year, as illustrated in the following table:

**UWSC Total Projected Outpatient Surgical Cases
and OR Need, PY 3**

	UWSC	CHS UNION	COMBINED TOTAL
Inpatient Cases	0	1,508	1,508
Outpatient Cases	3,852	5,380	9,232
Total Surgical Hours	5,778	12,594	18,372
OR Need at 1,872 hours per room	3.1	6.7	9.8
# Existing ORs	2	6	8
Deficit	1.1	0.7	1.8

Totals may not sum due to rounding

* Since the difference in each of the first three Project Years is a positive number that is greater than or equal to 0.3, the need is the next highest number.

The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference.

.2103 (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- **NHMOS:** The applicant does not have an existing or approved dedicated C-section OR and is not proposing to develop a dedicated C-section OR.

- NA- **UWSC:** The applicants are not proposing to develop a dedicated C-section OR.

.2103(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- **NHMOS:** The applicant is 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.
- NA- **UWSC:** 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.
- .2103(f) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*
- C- **NHMOS:** In Section III.1, pages 25 - 37 and Exhibit 3, the applicant documents 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.
- C- **UWSC:** In Section III.1, pages 28 – 46, the applicants document the assumptions and provide 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.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. §131E-183(a) (1) and the 2017 State Medical Facilities Plan (2017 SMFP), no more than one new or additional OR may be approved in this review for Union County. Because the two applications in this review collectively propose two new ORs (1 OR each), only one of the applications can be approved to develop the new OR. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal could be approved to develop the new OR. For the reasons set forth below and in the rest of the findings, the application submitted by UWSC is approved and the application submitted by NHMOS is disapproved.

Conformity with Statutory and Regulatory Review Criteria

Both applications are conforming to the statutory and regulatory review criteria as discussed throughout the Agency Findings. Therefore, with regard to conformity to the Review Criteria, the two proposals are comparable.

Operating History

NHMOS (currently named Presbyterian Same Day Surgery Center-Monroe) is a “*chronically underutilized*” facility, defined on page 58 of the 2017 SMFP as “*licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.*” NHMOS has been licensed to operate as an ambulatory surgical facility since 2009, but since January 2013 has not served any patients. Thus it has submitted at least three license renewal applications to the Division of Health Service Regulation since it closed in January 2013, and its utilization has been less than 40% for each year since January 2013. NHMOS is therefore a “*chronically underutilized facility*” as defined in the 2017 SMFP. Furthermore, on page 72 of the 2017 SMFP, NHMOS is listed as “*chronically underutilized*” and thus excluded from the “*Adjusted Planning Inventory*” which was reduced from nine to eight ORs in Union County. Furthermore, if NHMOS were not closed and not considered a “*chronically underutilized facility,*” there would be no need determination for an additional OR in Union County.

In addition, page 56 of the 2017 SMFP states:

“...The objective of the [OR need] methodology is to arrive at a reasonable assessment of the adequacy of current resources for performing surgery, compared with an estimate of need for additional capacity.”

NHMOS could have reopened its facility at any point since its closure in 2013 and could have begun to serve patients. As noted in its own need methodology, NH serves Union County patients in its Mecklenburg County facilities. Yet the Union County facility remains closed, chronically underutilized and excluded from the 2017 SMFP need determination methodology.

UWSC began providing services in October 2011, initially offering cataract surgery. It has operated continuously since its opening, and now provides surgical services in general surgery, gynecology, ophthalmology, orthopedic surgery, otolaryngology, podiatry and urology.

Therefore, with regard to operating history, UWSC is the more effective alternative.

Geographic Accessibility

The 2017 State Medical Facilities Plan identifies the need for one additional operating room to be located in Union County.

NHMOS proposes to add one new OR and one procedure room to an existing licensed but unutilized ASC for a total of two ORs and one procedure room in Monroe, Union County. According to MapQuest®, Monroe is located in the central part of Union County, approximately 15 miles and 25 minutes driving time from the NH Matthews facilities, where the applicant states it currently serves Union County patients who seek outpatient surgical services from NH providers.

UWSC proposes to add one OR and one procedure room to its existing ASC, for a total of three ORs and one procedure room in Indian Trail, Union County. According to MapQuest®, Indian Trail is located in the northwestern part of Union County, approximately 10 miles and 20 minutes driving time from Monroe, and approximately 4.8 miles and 10 minutes driving time to Matthews; thus it is located in relatively close proximity to the northwestern border of the county. In Section III.1, pages 36 – 37, the applicant states the western portion of Union County is projected to grow at a faster rate than central or eastern portions of the county [2.2% growth projected for the next five year in western Union County; 1.3% in central Union County and 1.2% in eastern Union County]. Furthermore, the applicant states the western portion of Union County also represents 80% of the total population of the county. Therefore, the applicant proposes to add one OR to an existing facility in the portion of the county that is more populous and is projected to grow faster than the central and eastern portions of the county.

Both applicants propose to develop one additional Union County OR in an ASC in Union County. Both towns are in Union County. However, UWSC proposes to add one OR to a facility located in the portion of the county that is more populous and is projected to grow faster than the central and eastern portions of the county. Therefore, with regard to geographic accessibility to the proposed OR, the proposal submitted by UWSC is the more effective alternative.

Demonstration of Physician Support

NHMOS In Exhibit 4, the applicant provides support letters from 19 surgeons in six specialties who the applicant states are expected to utilize the proposed ASC.

UWSC In Section III.1(b), pages 42 - 43, the applicants provide a list of 27 surgeons in seven specialties who have privileges at UWSC and project to perform a total of 4,389 cases annually at the facility. Exhibit 16 contains support letters from the surgeons listed on pages 42 – 43, six

additional surgeons who support the proposal, and 16 other surgeons whose letters will not be considered¹.

Both applications document physician support of their proposed projects. Therefore, with regard to demonstration of physician support, the two proposals are comparable.

Patient Access to Surgical Specialties

Currently, Union County has one hospital that provides surgical services and one operational ASC. The county has 11 ORs: two inpatient, six shared and three outpatient, one of which is not operational. Two of the 11 ORs are dedicated C-section ORs. A review of the surgical data reported in the 2017 Hospital LRAs submitted by CMHA, the only provider of surgical service in Union County, shows that 84% of all surgeries (excluding C-Sections) performed in Union County in FFY 2016 were ambulatory surgeries. The following table shows the percentages of the ambulatory surgeries performed in Union County by specialty:

SURGICAL SPECIALTY	CHS UNION IP	CHS UNION OP	UWSC
General	460	913	26
OB/GYN*	88	400	34
Ophthalmology	0	1376	1717
Oral	1	76	0
Orthopedic	707	1183	127
Otolaryngology	28	198	723
Plastic	5	1	0
Urology	117	774	12
Vascular	0	36	0
Other	47	30	105
Total	1,453	4,987	2,744
Grand Total			9,184
Total OP			7,731
OP % of Total Surgeries (7,731 / 9,184)			0.84179

*Non C-section ORs

The approval of either applicant will add one ambulatory OR and one procedure room in Union County.

NHMOS proposes to offer the following ambulatory surgical services, as indicated by the 19 letters signed by surgeons in Exhibit 4: otolaryngology, OB/GYN, ophthalmology, orthopedics, general surgery and GI endoscopy.

UWSC performed surgeries in the following specialties in FFY 2016: general surgery, OB/GYN, ophthalmology, orthopedic, otolaryngology, urology and vascular surgery. Furthermore, the 33 support letters signed by surgeons in Exhibit 16 reflect those surgeons' intentions to perform surgery in the specialties listed and also in podiatry.

¹ As discussed under Criterion (3) in these Findings, the applicants provide a total of 49 letters of support in Exhibit 16; however, 16 of those letters provide support for CHS Huntersville, which was previously approved. Thus, 33 of the 49 support letters in this application will be considered.

Therefore, based on the expected surgical specialties that will utilize the proposed additional OR, the applications are comparable.

Patient Access to a New Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

NHMOS is 100% owned by Novant Health, Inc., and was formerly known as Presbyterian SameDay Surgery Center Monroe. NHMOS previously operated one OR in its ASC on Wellness Boulevard in Monroe from 2009 to 2013, when it closed. It has remained licensed, though it has not served any patients since January 2013. Thus, although the applicant has continually renewed the annual license on the ambulatory surgical facility in Union County, the facility has not served patients since January 2013. Therefore, it would not be a new provider in Union County. NH is currently providing ambulatory surgical services to Union County residents in its Mecklenburg County facilities, and could serve those Union County residents in its existing facility in Union County. However, it has chosen not to serve patients in its Union County facility since January 2013.

UWSC currently provides ambulatory surgical services to Union County patients in its shared ORs in the hospital and in the two ORs in its existing ASC in Union County. The development of a third OR at its existing ASC will increase its existing operating capacity; whereas the development of an additional OR at NHMOS will effectively add another provider of outpatient surgical services in Union County by a provider that currently serves Union County residents who seek ambulatory surgical services. The proposal submitted by NHMOS will allow its existing Union County patients to receive their care from their NH physicians in their home county.

Therefore, with respect to access to a new provider of surgical services in Union County, the proposals are comparable.

Access by Underserved Groups

The following table illustrates each applicant’s projected Charity Care for the second operating year following project completion. Each applicant has a different OY: NHMOS defines its OY as April 1 to March 30; and UWSC defines its OY as a calendar year. The difference is not material to this review or comparative factor, but is clarified for understanding.

**Surgical Charity Care of Each Applicant
Operating Year Two**

APPLICANT	PROJECTED CHARITY CARE	PROJECTED % OF TOTAL NET REVENUE
NHMOS	\$317,451	4.4%
UWSC	\$85,137	1.1%

Source: Section VI.8 and Pro Forma Form B of each application.
Each applicant lists Charity Care separate from Bad Debt.

As shown in the table above, NHMOS projects the highest charity care as a percent of net revenue to be provided to its patients.

Therefore, with regard to the provision of charity care, the application submitted by **NHMOS** is the more effective alternative.

The following tables illustrate each applicant’s projected number of surgical cases and the percentage of those cases that are projected to be provided to Medicare and Medicaid recipients in the third full OY following project completion:

**Outpatient Surgical Medicaid Cases
Operating Years 2 and 3**

	NHMOS		UWSC	
	OY 2	OY 3	OY 2	OY 3
Total OP Surgical Cases	2,157	2,263	3,644	3,894
# Surgical Cases Provided to Medicaid Recipients	386	405	430	459
% of Total OP Surgical Cases Provided to Medicaid Recipients	17.9%	17.9%	11.8%	11.8%

Source: Form D of each application

**Outpatient Surgical Medicare Cases
Operating Years 2 and 3**

	NHMOS		UWSC	
	OY 2	OY 3	OY 2	OY 3
Total OP Surgical Cases	2,157	2,263	3,644	3,894
# Surgical Cases Provided to Medicare Recipients	783	821	1,665	1,779
% of Total OP Surgical Cases Provided to Medicare Recipients	36.3%	36.3%	45.7%	45.7%

Source: Form D of each application

As illustrated in the tables above, **NHMOS** projects to serve a greater percentage of Medicaid recipients in OYs two and three, but **UWSC** projects to serve a larger number of Medicaid recipients. **UWSC** projects to serve a greater percentage of Medicare recipients in OYs two and three, as well as a larger number of Medicare recipients. Therefore, with respect to provision of outpatient surgical services to Medicaid and Medicare recipients, the application submitted by **UWSC** is the more effective alternative.

Projected Surgical Revenue per Surgical Case

The following table shows the projected average gross and net surgical revenue per case in the second and third years of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements. Generally, the application proposing the lowest average gross and net revenue per case is the more effective alternative with regard to this comparative factor.

Revenue per Surgical Case, Operating Years Two and Three

	NHMOS		UWSC	
	OY 2	OY 3	OY 2	OY 3
# Cases	2,157	2,263	3,644	3,894
Gross Surgical Revenue	\$17,866,166	\$20,289,272	\$21,266,851	\$23,406,382
Gross Revenue per Case	\$8,283	\$8,966	\$5,836	\$6,011
Net Surgical Revenue	\$7,075,160	\$8,034,731	\$7,303,778	\$8,038,567
Net Revenue per Case	\$3,280	\$3,550	\$2,004	\$2,064

Source: Forms D and E in each application

As shown in the table above, UWSC projects the lower average gross and net revenue per surgical case. Both applicants propose to perform a variety of surgical procedures in the ASC, as evidenced by the information provided in Section III of each application and the exhibits with support letters from surgeons provided in each application.

Therefore, with respect to projected revenue per surgical case, the application submitted by UWSC is the more effective alternative.

Projected Average Operating Expense per Surgical Case

The following table shows the projected operating expense in the second and third years of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form B) in each application. Generally, the application proposing the lowest average operating expense is the more effective alternative with regard to this comparative factor.

Each of the applicants provided Form B, an income and expense statement, for ORs and the procedure rooms combined; therefore, a comparison of surgical operating expenses alone is not possible as it was for gross and net revenue projections. Therefore, the table compares operating expenses for the total facility:

Average Operating Expense Operating Years Two and Three

	NHMOS		UWSC	
	OY 2	OY 3	OY 2	OY 3
Total Operating Expenses	\$6,351,416	\$6,564,999	\$7,030,926	\$7,400,921
# Cases/Procedures	2,797	2,925	3,987	4,260
Operating Expense / Case / Procedure	\$2,271	\$2,244	\$1,763	\$1,737

Source: Form B in each application

As shown in the table above, UWSC projects the lower operating expense per case/procedure for the facility, including surgical cases performed in the ORs and procedures performed in the procedure room. Both applicants propose to perform a variety of surgical procedures in the ASC, as evidenced by the information provided in Section III of each application and the exhibits with support letters from surgeons provided in each application.

Therefore, with respect to projected revenue for the facility, the application submitted by UWSC is the more effective alternative.

SUMMARY

The following is a summary of the reasons the proposal submitted by UWSC is determined to be the most effective alternative in this review:

- UWSC is more effective with regard to operating history in Union County.
- UWSC proposes to offer ambulatory surgical services in an area of Union County that is the most populous, representing 80% of the total population of the county, and that is projected to grow at a faster rate than the rest of the county; thus providing more effective geographical access to ambulatory surgical services. See the Comparative Analysis for discussion.
- UWSC proposes to add one OR and offer ambulatory surgical services in a facility that is and has been operational since it opened. See the Comparative Analysis for discussion.
- UWSC projects to serve a larger number of Medicare and Medicaid recipients. See the Comparative Analysis for discussion.
- UWSC projects a lower revenue per surgical case than NHMOS. See the Comparative Analysis for discussion.
- UWSC projects a lower operating cost per case/procedure than NHMOS. See the Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by NHMOS is determined to be a less effective alternative in this review than the approved applicant.

- NHMOS is less effective with regard to operating history in Union County.
- NHMOS does not propose to offer more effective geographical access to ambulatory surgical services. See the Comparative Analysis for discussion.
- NHMOS proposes to add one OR and offer ambulatory surgical services in a facility that has not served patients since January 2013. See the Comparative Analysis for discussion.
- NHMOS projects to serve a smaller number of Medicare and Medicaid recipients. See the Comparative Analysis for discussion.
- NHMOS projects a higher revenue per surgical case than USCW. See the Comparative Analysis for discussion.
- NHMOS projects a higher operating cost per case/procedure than USCW. See the Comparative Analysis for discussion.

CONCLUSION

The Agency determined that the application submitted by Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority, Project ID #F-11348-17, is the most effective alternative proposed in this review for the additional OR in Union County, and is approved. The approval of the application submitted by Novant Health Monroe Outpatient Surgery, LLC would result in the number of ORs in Union County in excess of the need determination as reported in the 2017 SMFP. Consequently, the application submitted by Novant Health Monroe Outpatient Surgery, LLC is denied.

The application submitted by Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority is approved subject to the following conditions.

- 1. Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall materially comply with all representations made in the certificate of need application.**
- 2. Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall develop no more than one operating room for a total of no more than three operating rooms and one procedure room in its ambulatory surgical facility upon completion of this project.**
- 3. Upon completion of this project, Union West Surgery Center shall be licensed for no more than three operating rooms and one procedure room.**
- 4. Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Union West Surgery Center shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 7. Union Health Services, LLC and The Charlotte-Mecklenburg Hospital Authority shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- 8. For the first three years of operation following completion of the project, Union West Surgery Center shall not increase charges more than 5% of the charges projected in Section XI of the application without first obtaining a determination**

from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.

- 9. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 10. Procedures performed in the procedure room 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.**