Competitive Comments on 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-11513-18, Triad Center for Surgery (Compass-OrthoCarolina)

G-11517-18, Novant Health Forsyth Medical Center (NHFMC)

G-11518-18, Novant Health Clemmons Outpatient Surgery (NHCOS)

G-11519-18, North Carolina Baptist Hospital (NC Baptist)

GENERAL COMMENTS

All five applications propose to develop operating rooms in Forsyth County. Like Triad Surgery Center, Compass-OrthoCarolina and NHCOS each propose to develop operating rooms in a freestanding ambulatory surgery center (ASC). By comparison, NHFMC and NC Baptist propose to develop two and four operating rooms, respectively, at their existing hospitals. 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 Multiple Needs

Each of these factors is discussed in turn below.

Geographic Accessibility

Triad Surgery Center proposes to develop a freestanding ASC in Kernersville. NHCOS proposes to develop its proposed operating rooms in Clemmons. Compass-OrthoCarolina, NHFMC, and NC Baptist each 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 <u>less</u> than two-thirds of Kernersville's, yet Clemmons has two-thirds <u>more</u> operating room capacity than Kernersville. The Clemmons population also has convenient access to Davie Medical Center, part of Wake Forest Baptist Health, 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 2018 SMFP has determined that Forsyth County has a total need for four additional operating rooms beyond its existing inventory of 95 operating rooms for a total operating room need of 99 operating rooms. As demonstrated in Section C.4 of Triad Surgery Center's application, if Forsyth County's total need of 99 operating rooms were distributed among the three regions based on 2017 population and compared to the location of the existing/approved 95 operating rooms, the Kernersville region has the largest operating room deficit in the county at more than 10 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 demonstrated 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 100,000 covered lives in Alamance, Guilford, Rockingham, Randolph, and part of Forsyth counties through contracts with Medicare, United Healthcare, Humana, UMR, Cigna, and HealthTeam Advantage. The network encompasses Cone Health's employed physicians as well as the broader independent provider community. Currently more than half of affiliated physicians in THN are in private practice. All participants agree to balance the specific interests of their own organizations and specialties so as to work together to provide coordinated, patient-centered, exceptional care across the healthcare continuum.

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 a result of its efforts, THN was able to save over \$25 million in healthcare costs as part of the Medicare Shared Savings Program through the Centers for Medicare and Medicaid Services (CMS). As of January 1, 2016, THN was selected to participate in CMS's Next Generation ACO, to assume higher levels of financial accountability. In 2016 alone, THN saved \$10.9 million in healthcare costs as part of the Next Generation ACO program. This savings represented the second highest dollar value saved nationally by a Next Generation ACO in 2016. In concert with this financial performance, THN was named by CMS as the 5th ranked ACO in the nation (out of over 400) for

measurable quality. 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. Neither Cone Health nor THN owns or operates any freestanding ASC capacity in Forsyth County, and Cone Health maintains an ownership interest of less than 50 percent in Greensboro Specialty Surgery Center, a three-OR freestanding ASC in Guilford County. 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, Triad Surgery Center's 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 ASC 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 ASCs in the county:

- Novant Health (Two freestanding ASCs: NHKOS and NHCOS)
- Wake Forest Baptist Health (Joint venture freestanding ASC with Surgical Care Affiliates: Clemmons Baptist-SCA ASC)
- Surgical Care Affiliates (Joint venture freestanding ASC with Wake Forest Baptist Health: Clemmons Baptist-SCA ASC)
- Piedmont Ear, Nose & Throat Associates (one freestanding ASC: POSC)

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

Opportunity to Meet Multiple Needs

Because Triad Surgery Center's proposal seeks to develop only two of the four operating rooms identified in the need determination in the *2018 SMFP*, its proposed project enables the development of the two remaining operating rooms for other providers to meet other identified needs should the Agency find multiple applicants conforming with all applicable statutory and regulatory review criteria.

However, 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

Triad Center for Surgery (Compass-OrthoCarolina)

Compass-OrthoCarolina's application to develop a new freestanding ASC with two operating rooms and three procedure rooms in Winston-Salem should not be approved as proposed. Triad Surgery Center identified the following specific issues, each of which contributes to Compass-OrthoCarolina's non-conformity:

- (1) Failure to demonstrate the project will not result in unnecessary duplication of existing or approved health service facilities and that the project is needed
- (2) Failure to demonstrate financial feasibility

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 the non-conformity.

<u>Failure to demonstrate the project will not result in unnecessary duplication of existing or approved health</u> service facilities and that the project is needed

Compass-OrthoCarolina's projected surgical volumes are based on the letters of support from physicians that have previously committed, based on signed letters of support, to practice at NHCOS, an approved but not yet developed ASC. Compass-OrthoCarolina's application does not address this duplication.

In 2017, NHCOS submitted an application develop a new freestanding ASC in Clemmons (Project ID # G-11300-17) by relocating two ORs from the Novant Health Winston-Salem campus and developing a new procedure room. As described in its 2017 application (and in its currently proposed application), NHCOS states that the need for its ASC is based on the need to serve orthopedic volumes to be shifted from Novant Health Winston-Salem, and in particular, cases performed at Novant Health Orthopedic Outpatient Surgery (NHOOS). Of note, NHOOS is co-located with an OrthoCarolina practice location at 170 Kimel Drive, Winston-Salem, and Triad Surgery Center understands that OrthoCarolina comprises the vast majority of surgeons that currently practice at NHOOS. Further, Triad Surgery Center believes that OrthoCarolina owned the building that houses NHOOS. These factors indicate the importance of OrthoCarolina surgeons to NHOOS' volume and to Novant Health's orthopedic surgery volume overall in Forsyth County.

The Agency approved NHCOS's 2017 application and found that it had demonstrated conformity with Criterion 3 for the proposed project based on a number of factors including that NHCOS "states that it expects the growth of surgical staff [at Novant Health Clemmons Medical Center (NHCMC)] and increase in outpatient surgeries to continue with the opening of inpatient surgical services, supporting the need for the relocation of two ORs from NHFMC to Clemmons. Exhibit 4 contains surgeon support letters stating intent to seek privileges at NHCOS upon its development" (see page 7 of Agency Findings for Project ID # G-11300-17 in Attachment 1). Further, the Agency repeatedly cites "the level of support from surgeons who currently perform outpatient surgeries in the NHCMC and NHFMC ORs, as reflected in the letters in Exhibit 4" as supportive of the projected operating room and procedure room volumes for the facility (see pages 10, 11, and 14 of the Agency Findings in Attachment 1).

The Agency found that NHCOS demonstrated conformity with Criterion 7, stating that "Exhibit 4 contains physician support letters, stating intent to seek privileges at the facility upon project development. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services" (see page 25 of the Agency Findings in Attachment 1). Finally, the Agency found that NHCOS demonstrated conformity with Criterion 8, stating "the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 4 of the application contains copies of letters from area physicians and surgeons expressing support for the proposed project (see page 25 of the Agency Findings in Attachment 1).

The above referenced Exhibit 4 (included in Attachment 2) from the NHCOS application includes signed letters of support from a total of 14 orthopedic surgeons stating their intent to "seek privileges to practice at Novant Health Clemmons Outpatient Surgery, once it has been developed" including the following members of OrthoCarolina:

- Daniel Biggerstaff, MD
- William Craig, III, MD
- David V. Janeway, MD
- Mike Laffenburger, MD

These same four OrthoCarolina surgeons provided letters of support for the Compass-OrthoCarolina application documenting their intent to seek medical staff privileges at Compass-OrthoCarolina and their expectation that they would perform 565 to 970 orthopedic cases in total at the proposed facility, as shown below. Of note, William Craig, III, MD also signed a letter of support for Novant Health Kernersville Outpatient Surgery documenting his intent to practice at that facility.

	Low Estimate	High Estimate
Daniel Biggerstaff, MD	125	185
William Craig, III, MD	215	345
David V. Janeway, MD	75	115
Mike Laffenburger, MD	150	325
Total	565	970

Source: Compass-OrthoCarolina application page 35 and Exhibit C.4.

In the third year of operation, the 970 cases expected to be performed by these surgeons represents more than 43 percent of Compass-OrthoCarolina's total projected orthopedic cases (48 percent = $970 \div 2,021$ total orthopedic operating room cases) and 28 percent of Compass-OrthoCarolina's total operating room cases (28 percent = $970 \div 3,522$ total operating room cases).

Neither Compass-OrthoCarolina's application nor NHCOS's current application addresses the duplication of these surgeons' cases and the resulting duplicated need demonstrated at each facility. Moreover, the failure to address this duplication casts doubt on the reasonableness of Compass-OrthoCarolina's projections. In fact, Compass-OrthoCarolina states on page 58 of its application that "there is the concern that some physicians could chose [sic] to withdraw their letters of support after the CON application is submitted." Clearly, the withdrawal of support from the surgeons upon whom its projections are based would result in a failure to demonstrate the reasonableness of Compass-OrthoCarolina's projected utilization and a failure to demonstrate the need for the project.

Based on the issues identified above, Triad Surgery Center believes that the Compass-OrthoCarolina application is non-conforming with Criteria 3 and 6.

Failure to demonstrate financial feasibility

As shown below, Compass-OrthoCarolina's pro forma financial statements include multiple errors and understate expenses throughout the projection period. The following analyses present these issues, in turn.

• Failure to demonstrate the reasonableness of revenue assumptions

In the Notes section below its Form F.3 statement, Compass-OrthoCarolina states that "1 Gross patient revenues are from Form F.4 Gross Revenue for OR Cases and PR Cases with no projected increases in rates for Years 1, 2, and 3" and "3 Net patient revenues are based on Form F.5 with no projected increases in reimbursement rates" (page 111 of the application). There is no other discussion in the application regarding Compass-OrthoCarolina's projected gross and net revenue assumptions. As the Certificate of Need Application form in Section F.4(a) states "For projected revenues and operating expenses, provide the assumptions and methodology used for each line item. Example: Medical supplies (Line 35) averaged \$5.50 per procedure during the last full fiscal year and it is assumed that this amount will increase 2.5% per year. The inflation rate is based on ... As Compass-OrthoCarolina has not provided any discussion of its revenue assumptions, there is no way to determine if its assumptions are reasonable. As shown in the comparative analysis below, Compass-OrthoCarolina's projected net revenue per operating room case is more than 40 percent lower than the other freestanding ASC projects, Triad Surgery Center and NHCOS, which seems unreasonable particularly without any discussion of Compass-OrthoCarolina's assumptions. It is particularly surprising given Compass-OrthoCarolina's high percentage of orthopedics cases and procedures (over 50 percent of projected volume per page 36 of the application) because orthopedics cases generate higher charges and reimbursement than many other specialties. For example, OrthoCarolina's has reported much higher revenue at its existing Mallard Creek Surgery Center. As shown in Attachment 3, OrthoCarolina reported that its net patient revenue per surgical case was \$2,857 from June 2015 to May 2016 and that it grew 9.3 percent in one year to \$3,122 per case.

	6/1/15 to 5/31/16	6/1/16 to 5/31/17	Growth
# of Surgical Cases	2,309	2,352	1.9%
Total Net Patient Revenue	\$6,597,533	\$7,343,231	11.3%
Net Revenue per Case	\$2,857	\$3,122	9.3%

Source: Mallard Creek Surgery Center (OrthoCarolina) 2017 Annual Report to Healthcare Planning and Certificate of Need Section. See Attachment 3.

Compass-OrthoCarolina states that net patient revenue per surgical case will be \$2,149 in 2023, its third year of operation, or nearly \$1,000 fewer than Mallard Creek Surgery Center and that Compass-OrthoCarolina's net patient revenue per case will experience zero annual inflation despite the 9.3 percent inflation experienced by Mallard Creek. Of note, Mallard Creek Surgery Center was required as a condition of its CON to provide a specific level of indigent, Medicaid, and

Self-pay cases and revenue, which suggests that the net revenue per case is lower than other facilities, such as the proposed Compass-OrthoCarolina, would have without such a condition.

Both Triad Surgery Center and NHCOS provide assumptions for projected revenue which discuss the use of their historical experience as a basis for projections. There is no way to determine if Compass-OrthoCarolina had a reasonable basis for its projections, and a comparison with other heavy-orthopedic ASCs suggests not. All of the applicants in this review, except Compass-OrthoCarolina, project annual inflation of revenues per case/procedure. Again, Compass-OrthoCarolina provides no basis for its assumed lack of annual inflation. Given these factors, Compass-OrthoCarolina's projected revenues are unreasonable.

Failure to include Manager's Development Fee of \$225,000

According to its application, Compass-OrthoCarolina will be managed by Compass Surgical Partners of Winston-Salem, LLC. Compass-OrthoCarolina included a copy of its draft management agreement in Exhibit A.9(a). Please note that the manager is not the same entity as the co-owner, Compass Surgical Partners Holdings of Triad, LLC as identified in Section A.1.(e). The management agreement states in the Compensation and Reimbursement section on page 9 that:

6. COMPENSATION AND REIMBURSEMENT.

6.1 Development Fees. As compensation for the development services to be performed hereunder, Owner shall pay Manager a development fee of Two Hundred Twenty-Five Thousand Dollars (\$225,000) to be paid in twelve (12) monthly installments of Eighteen Thousand Seven Hundred Fifty Dollars (\$18,750) with any remaining amount paid upon completion of the first surgical case at the Center ("Center Opening") ("Development Fee"). Manager shall also be entitled to reimbursement of expenses under Section 6.4.

Compass-OrthoCarolina's application fails to include this \$225,000 development fee in its start-up expenses, initial operating expenses, project year expenses, or alternatively in its capital costs. As the management agreement indicates that this development fee is to be paid in full by the opening of the center, it would have been reasonable to include the development fee as a start-up expense. However, Compass-OrthoCarolina states that its start-up expenses will only total \$150,000 (which is insufficient to include the \$225,000 development fee) and that they are "projected based on a six week initial period when the facility administrator hires the primary staff and begins training and orientation. Salary expenses are projected to be approximately 50 percent of the start-up cost. Supplies, rent and utilities comprise the balance of the \$150,000" (page 62). The \$225,000 development fee is not included in Form F.1 Capital Cost, nor is it included as a project year operating expense in Form F.3.

Of note, the management agreement states that the management fee will be 5.5 percent of net patient revenue/net collections. While the Notes section below its Form F.3 states incorrectly that "15 Management services expenses are based on 5% of total net revenue", Compass-OrthoCarolina appears to have correctly calculated projected "Management Service" expenses in the project years as equal to 5.5 percent of net patient revenue. Thus, it is clear from both its statements in the application and its projected financial statements that Compass-OrthoCarolina will have a management agreement with Compass Surgical Partners of Winston-Salem, LLC and would incur the \$225,000 development fee; however, it has failed to include that expense in its

financial statements. Given these factors, Compass-OrthoCarolina's projected expenses are unreasonable. Moreover, as the development fee was not included in its start-up expenses, Compass-OrthoCarolina has understated its start-up expenses. Compass-OrthoCarolina's application provides documentation of its ability to fund its projected working capital amount equal to \$700,000. However, this \$700,000 amount does not include the \$225,000 development fee. As such, Compass-OrthoCarolina has failed to demonstrate the availability of funds for the proposed project.

• Understatement of interest expense and liabilities

As noted above, Compass-OrthoCarolina states that its total working capital needs are \$700,000 and provides documentation that it will fund that amount through a commercial loan. The Notes section below Compass-OrthoCarolina's Form F.3 states that "17 Interest expenses are based on loan amortization of the capital cost and start-up/working capital loans." On page 118 of the application, Compass-OrthoCarolina provides its assumed amortization schedules for the capital cost and start-up/working capital loans. However, the amortization schedule for the start-up/working capital loan erroneously assumes that the loan is only for \$100,000 as shown in the excerpt below.

Working Capital and Start Up		
Loan Amount	\$100,000	
Rate	5.50%	
Amortization	20 years	

As its projected interest expense is based on an amortization schedule for a much smaller assumed loan, Compass-OrthoCarolina's projected interest expense is understated significantly. Moreover, Compass-OrthoCarolina notes on its Form F.2 balance sheet that its Current Portion of Long-Term Debt and Long-term Debt amounts are "Based on Loan Amortization worksheets" which are incorrect. As such, Compass-OrthoCarolina's Form F.2 balance sheet is also incorrect. Therefore, Compass-OrthoCarolina has understated its interest expense and liabilities.

Given the above errors and unreasonable assumptions in its financial projections, Compass-OrthoCarolina's application fails to demonstrate the availability of funds for the capital and operating needs or that the financial feasibility of the project is based on reasonable projections of costs and charges and should be found non-conforming with Criterion 5.

Novant Health Forsyth Medical Center (NHFMC)

NHFMC's application to develop two additional operating rooms in its first floor operating suite at its main campus in Winston-Salem should not be approved as proposed. Triad Surgery Center identified the following specific issues, each of which contributes to NHFMC's non-conformity:

- (1) Failure to demonstrate the reasonableness of its utilization projections
- (2) Failure to demonstrate the need for the proposed project
- (3) Failure to demonstrate the reasonableness of utilization projections for NHCOS

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 demonstrate the reasonableness of its utilization projections

On pages 19-20 of its application, NHFMC provides a discussion of its historical growth in operating room cases and notes that "[t]he Novant Health CAGR for all surgical services is 3.4 percent." This historical growth rate of 3.4 percent is used as the central assumption for all projected operating room cases within the Novant Health system in Forsyth County. As NHFMC states on page 21, "[w]e use this 3.4 percent CAGR to project both inpatient and outpatient future growth in surgical cases." NHFMC's application states that its growth is "due to Novant Health's recruitment of new surgeons to meet the needs of Forsyth County residents" (page 20). However, this 3.4 percent CAGR has not been experienced equally across Novant Health's Forsyth County facilities or services. In particular, the historical growth has been primarily driven by an increase in ophthalmology cases performed at Novant Health Hawthorne Outpatient Surgery (NHHOS) and as such does not appear related to the recruitment of new surgeons that NHFMC cites. NHFMC's application appears to hide that its growth has been driven primarily by increasing utilization at NHHOS, and not by surgical recruitment or volume growth at NHFMC's main campus, as shown in the analysis below.

Figure 1 in NHFMC's Form C Assumptions and Methodology in Section Q, reproduced below, shows Novant Health's historical operating room utilization in Forsyth County.

Figure 1: NH Health System LRA Historical Data for Surgical Locations

FFY 2015	FFY 2016	FFY 2017
	,	
8,665	8.209	9,171
854		1,114
0	0	198
9.519	9 262	10,483
		943
		11,426
		11,420
5,552	5 342	5,320
		2,778
		1,352
		7,329
		2,013
		18,792
		8,782
		0,702
26.058	26 371	27,574
1 20,050		27,574
· · · · ·	2.576	-
36,474	36,504	39,000
1		55,000
	8,665 854 0 9,519 897 10,416	8,665 8,209 854 1,053 0 0 9,519 9,262 897 871 10,416 10,133 4,7% 5,552 5,342 2,347 2,666 1,019 1,108 6,036 6,399 2,491 2,191 17,445 17,706 8,613 8,665 26,058 26,371 2,9%

Source: NC Hospital License Renewal Applications

The table below demonstrates the change in surgical cases at each physical location within the Novant Health system.

Novant Health System Historical Operating Room Utilization

	FFY15	FFY17	CAGR 2015-2017	Change 2015-2017	% of Total Change 2015-2017
NHFMC Main Campus IP	8,665	9,171	2.9%	506	20.0%
NHFMC Main Campus OP	5,552	5,320	-2.1%	-232	-9.2%
NHFMC Main Campus Total	14,217	14,491	1.0%	274	10.8%
NHMPH IP	897	943	2.5%	46	1.8%
NHMPH OP	8,613	8,782	1.0%	169	6.7%
NHMPH Total	9,510	9,725	1.1%	215	8.5%
NHHOS OP	6,036	7,329	10.2%	1,293	51.2%
NHOOS OP	2,491	2,013	-10.1%	-478	-18.9%
NHKMC IP	854	1,114	14.2%	260	10.3%
NHKMC OP	2,347	2,778	8.8%	431	17.1%
NHKMC Total	3,201	3,892	10.3%	691	27.4%

⁽¹⁾ Excludes C-Sections done in a dedicated C-Section OR

⁽²⁾ CON Project ID# G-11150-16, Scheduled to open June 2018

⁽³⁾ CON Project ID# G-11300-17. Scheduled to open July 2019

	FFY15	FFY17	CAGR 2015-2017	Change 2015-2017	% of Total Change 2015-2017
NHCMC IP	0	198	NA	198	7.8%
NHCMC OP	1,019	1,352	15.2%	333	13.2%
NHCMC Total	1,019	1,550	23.3%	531	21.0%
Novant Health Total	36,474	39,000	3.4%	2,526	100.0%

Source: Figure 1 NHFMC Form C Assumptions and Methodology.

As shown above, NHFMC's main campus operating room utilization increased by 274 cases from FFY 2015 to 2017, or 1.0 percent annually. By contrast, NHHOS's operating room utilization increased by 1,293 cases, or 10.2 percent annually. In total, Novant Health's Forsyth County operating rooms performed 2,526 more surgical cases in FFY 2017 than in 2015 and NHHOS's growth accounted for more than 51 percent of that growth. By comparison, NHFMC's main campus operating rooms accounted for less than 11 percent of the growth. In fact, NHFMC's main campus growth was also below that of NHKMC (growth of 691 cases) and NHCMC (growth of 531 cases). The only Novant Health locations that had lower growth than NHFMC main campus were NHMPH and NHOOS.

Of note, NHHOS's operating room growth has been driven almost exclusively by ophthalmology or eye cases. According to NHFMC's License Renewal Applications, NHHOS performed the following surgical cases by specialty in FFY 2015 and 2017.

Novant Health Hawthorne Outpatient Surgery Historical Operating Room Utilization

	FFY15	FFY17	Change 2015-2017	% of Total Change 2015-2017
General Surgery	0	43	43	3.3%
Eye	4,797	5,985	1,188	91.9%
Oral	666	729	63	4.9%
ENT	317	194	-123	-9.5%
Plastic	34	0	-34	-2.6%
Podiatry	222	231	9	0.7%
Vascular	0	95	95	7.3%
Pain	0	52	52	4.0%
Total	6,036	7,329	1,293	100.0%

Source: 2016 and 2018 NHFMC License Renewal Applications.

In 2017, NHHOS performed nearly 1,200 more eye surgery cases than in 2015. That increase accounted for nearly 92 percent of the growth in cases at NHHOS and 47 percent of the total growth in operating room cases across the Novant Health system in Forsyth County (47 percent = 1,188 growth in eye cases at NHHOS \div 2,526 growth in total cases).

As shown, while Novant Health's operating room cases have grown historically, that growth has not been experienced consistently across its locations. The primary source of Novant Health's growth has been outpatient eye surgery cases at NHHOS, not the result of surgeon recruitment as NHFMC suggests. NHFMC's utilization methodology unreasonably assumes that both inpatient and outpatient cases at <u>all</u>

of its locations will grow 3.4 percent annually in the future. As justification for this assumption, NHFMC states that "[r]ecruitment of surgical specialists to meet the needs of the population is an ongoing effort at Novant Health and will continue to increase surgical volume at NHFMC in the coming years" (page 20). NHFMC unreasonably assumes that all of its cases and locations will grow equally when its historical experience clearly suggests that will not be the case and states that this assumption is supported by surgeon recruitment when that has not been the primary driver of its historical growth.

Based on the above issues, Triad Surgery Center believes that NHFMC 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 the need for the proposed project

In Section C.4, NHFMC states that the limitations of the SMFP methodology's calculation of need "overstates Novant Health's OR capacity and understates the number of surgeries and surgery hours Novant Health must accommodate to meet the needs of its patients" (page 19). These statements are false and unsupported and NHFMC's purported analysis reveals that its proposed projects are not needed, as shown below.

On page 23-24 of its application, NHFMC provides its analysis to support its contention that the *SMFP* overstates Novant Health's existing surgical capacity. Simply put, NHFMC illogically argues it has a need for more operating room capacity because it chooses to provide fewer hours per day than statewide standards. NHFMC provides the following chart which demonstrates that all of its operating rooms provide fewer than ten hours per day for fewer than 260 days per year, which are statewide standards.

OR Capacity at Novant Facilities, Using Surgical Location Actual Capacity

			Operating	Hours/Days	from 2018 LR	A
Licénse	Surgical Location	Avg Hours Per Day	Avg Days Per Year	Adjusted Planning ORs	Actual Hours Per OR = Capacity x 75%	Total Capacity Hours
	Forsyth Main (NHFMC)	9.21	253	18	1,765	31,457
	Kernersville (NHKMC)	8.9	253	4	1,613	6,778
H0209	Clemmons (NHCMC)	8.4	253	. 5	1,471	7,941
	Hawthorne (NHHOS)	7.75	253	4	1,518	5,882
	Orthopedic (NHOOS)(1)	7.5	253	0	1,471	0
H0229	Medical Park (NHMPH)	8.7	253	10	1,651	16,508
*	Kernersville ASC (NHKOS)	100	Since the	2	1,312.5	2,625
*	Clemmons ASC (NHCOS)	Capping.	1	2	1,312.5	2,625
Novant I	Forsyth Total			45		73,816

Source: 2018 North Carolina License Renewal Applications, 2018 SMFP

(1) NHOOS will close and ORs will be relocated to NHCOS in July 2019

NHFMC does not provide any discussion of why it is unable to provide scheduled hours per day and days per year consistent with other hospitals across the state, particularly given the size and scope of services at NHFMC. It is clear that Novant Health could increase its operating room capacity without adding any additional operating rooms by extending its hours of operation and days per year. Moreover, NHFMC failed to discuss why extended hours of operation would not be the most effective alternative and in order to demonstrate its conformity with Criterion 4. It seems clear that if Novant Health really needed additional operating room capacity it would operate at or above statewide standards. Given its current hours of operation, it is clear that Novant's need for additional capacity is unfounded.

Based on the above evidence, Triad Surgery Center believes that NHFMC should be found non-conforming with Criteria 3 and 4.

Failure to demonstrate the reasonableness of utilization projections for NHCOS

As noted above in the discussion of Compass-OrthoCarolina's application, several surgeons who previously supported the development of NHCOS provided letters of support for Compass-OrthoCarolina's application documenting their intent to perform cases there. Additionally, the utilization methodology for NHCOS relies heavily on a shift of historical volume from NHOOS. As shown in the table below, NHOOS has experienced a 10.1 percent annual decrease in utilization from 2015 to 2017.

Novant Health System Historical Operating Room Utilization

Novant Health System Historical Operating Room Othization						
	FFY15	FFY17	CAGR 2015-2017			
NHFMC Main Campus IP	8,665	9,171	2.9%			
NHFMC Main Campus OP	5,552	5,320	-2.1%			
NHFMC Main Campus Total	14,217	14,491	1.0%			
NHMPH IP	897	943	2.5%			
NHMPH OP	8,613	8,782	1.0%			
NHMPH Total	9,510	9,725	1.1%			
NHHOS OP	6,036	7,329	10.2%			
NHOOS OP	2,491	2,013	-10.1%			
NHKMC IP	854	1,114	14.2%			
NHKMC OP	2,347	2,778	8.8%			
NHKMC Total	3,201	3,892	10.3%			
NHCMC IP	0	198	NA			
NHCMC OP	1,019	1,352	15.2%			
NHCMC Total	1,019	1,550	23.3%			
Novant Health Total	36,474	39,000	3.4%			

Source: Figure 1 NHFMC Form C Assumptions and Methodology.

NHFMC's application does not address this loss in supporting physicians for NHCOS or the substantial decline in volume at NHOOS. Rather, NHFMC assumes that NHOOS's baseline surgical cases will grow 3.4 percent annually through 2024. As noted above, NHFMC's assumed 3.4 percent growth is attributable primarily to a growth in outpatient eye cases, not outpatient orthopedic cases as currently performed at NHOOS. As such, the utilization projections for NHCOS are unreasonable and unsupported.

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

Novant Health Clemmons Outpatient Surgery (NHCOS)

NHCOS's application to develop two additional operating rooms in its previously approved, but not yet developed, freestanding ASC should not be approved as proposed. As the utilization methodology and demonstration of need with the NHFMC and NHCOS applications are identical, certain specific issues identified above for NHFMC's application are also issues for NHCOS, each of which contributes to NHCOS's non-conformity:

- (1) Failure to demonstrate the reasonableness of its utilization projections
- (2) Failure to demonstrate the need for the proposed project

The discussion regarding these two issues found in the NHFMC comments above is incorporated herein by reference. Additionally, NHCOS has the following specific issue:

(3) Failure to demonstrate the reasonableness of NHCOS utilization projections

This last issue is discussed 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 demonstrate the reasonableness of NHCOS utilization projections

As noted above in the discussion of Compass-OrthoCarolina's and NHFMC's application, several surgeons who previously supported the development of NHCOS provided letters of support for Compass-OrthoCarolina's application documenting their intent to perform cases there. Additionally, the utilization methodology for NHCOS relies heavily on a shift of historical volume from NHOOS, which has experienced a 10.1 percent annual decrease in utilization from 2015 to 2017. NHCOS's application does not address this loss in supporting physicians or the substantial decline in volume at NHOOS. Rather, NHCOS assumes that NHOOS's baseline surgical cases will grow 3.4 percent annually through 2024. As noted above, Novant Health's assumed 3.4 percent annual growth is attributable primarily to a growth in outpatient eye cases, not outpatient orthopedic cases as currently performed at NHOOS.

Beginning in 2019, it is assumed that 100 percent of NHOOS's surgical cases will shift to NHCOS. NHCOS fails to demonstrate that this shift of cases is reasonable or supported. The letters of support from orthopedic surgeons and other physicians do not mention any shift of patients from NHOOS to NHCOS. Rather, the letters reference these surgeons' intention to seek privileges to practice at NHCOS and the increase in <u>local</u> geographic access. Surgical cases historically served at NHOOS includes patients from all areas of Forsyth County and beyond. For example, the patient pool includes all NHOOS patients from Winston-Salem. NHCOS fails to demonstrate that that increase in local access sought by these surgeons supports the assumption that Winston-Salem or Guilford County patients who have historically been served by NHOOS, would travel further to Clemmons for care. This shift of an entire service line is not supported by NHCOS's application.

Similarly to unreasonable shift from NHOOS, beginning in 2019, it is assumed that a portion of NHMPH's outpatient surgical cases will shift to NHCOS. NHFMC does state that its analysis of this potential shift is based on the percentage of low acuity outpatient surgical cases from the Clemmons market that are assumed to be appropriate to shift. In the footnote to Figure 5 describing this analysis, NHFMC states that the percentage appropriate to shift from NHMPH to NHCOS is 12.7 percent.

Figure 5: Potentially Appropriate Volume to Shift from NH Medical Park to NHCOS

Surgical Location	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020 ·	CY 2021	CY 2022	CY 2023	CY 2024
Outpatient Surgical Cases							in the second		
NHMPH Total	8,782	8,857	9,158	9,469	9,791	10,124	10,468	10,824	11,192
Percent of NHMPH Cases Shifted to NHCOS (1)	21%	21%	21%	21%	21%	21%	21%	21%	21%
Potential NHCOS Cases Shifted from NHMPH	1,844	1,860	1,923	1,989	2,056	2,126	2,198	2,273	2,350
Adjustments			· · · · · · · · · · · · · · · · · · ·				,		
ORs 1 & 2 Open: Add 50% of Potential (2)				497	1,028	1,063	1,099	1,137	1,175
ORs 3 & 4 Open: Add Remainder of Potential (3)			T		771	1,063	1,099	1,137	1,175
Subtract OP Cases from NHMPH				497	1,799	2,126	2,198	2,273	2,350

Source: Figure 2, Internal Trendstar FFY 2016 and FFY 2017

(1) 12.7% = (1) HMPH Low Acuity OP Surgical Cases from Clemmons market assumed appropriate to shift)/ NHMPH Total Surgical Cases. Average of FFY 2016 and FFY 2017.

Clemmons market = Low acuity cases from the 12 zip codes that represent 47.7% of historical NHCMC (and projected NHCOS) surgical cases

(2) NHCOS ORs 1 & 2 will open July 2019. Shift only 6 months of 2019 to NHCOS

(3) NHCOS ORs 3 & 4 will open April 2020. Shift only 9 months of CY 2020 (Potential Cases Shifted / 12 * 9)

Yet, NHFMC assumes that 21 percent of NHMPH surgical cases will shift to NHCOS. Assuming that only 12.7 percent of NHMPH's outpatient cases will shift to NHCOS, NHCOS fails to demonstrate the need for the proposed two additional operating rooms. As shown in the table below, based on a 12.7 percent shift and no other changes to its utilization methodology, NHCOS demonstrates a deficit of only 1.4 operating rooms in CY 2023, its third project year.

Novant Health Clemmons Outpatient Surgery CY 2024 Utilization

	As Provided in CON	Assuming 12.7 Percent Shift		
NHMPH Total	10,824	10,824		
Percent of NHMPH Cases Shifted to NHCOS	21.0%	12.7%		
Potential NHCOS Cases Shifted from NHMPH	2,273	1,375		
Shift from NHOOS	2,481	2,481		
Total NHCOS Outpatient Surgery	4,754	3,856		
Average Case Time	68.6	68.6		
Total Surgical Hours	5,435	4,408		
Standard Hours per OR per Year	1,312.5	1,312.5		
Total Surgical Hours / Standard Hours per OR per Year	4.1	3.4		
Previously Approved ORs	2	2		
OR Deficit	2.1	1.4		

Notably, outpatient cases historically served at NHCMC are not projected to be impacted by NHCOS's opening or additional operating rooms. NHCOS does not explain why these patients who have historically sought outpatient surgical care in Clemmons at a hospital-based facility would not be better served at a freestanding facility on the same site, particularly since the hospital was not providing inpatient care during the time period of the historical data utilized by NHCOS (FFY 2017).

More significantly, the proposed shifts are not supported by NHCMC's historical ability to shift surgical cases from other Novant Health facilities. In the 2008 application to develop NHCMC (Project ID # G-8165-08), Novant Health assumed that 55 to 58 percent of outpatient surgical cases historically served by Novant Health for patients originating from four ZIP codes in Davie and Forsyth counties would shift to NHCMC (see page 127 of Project ID # G-8165-08 included in Attachment 4). This shift of cases was

expected to ramp up over time and result in more than 3,000 outpatient surgical cases by the third year of operation. As noted above, NHCMC has operated since 2013 or more than three full years and performs only ~1,350 outpatient surgical cases or 45 percent of the volume projected in the original application. NHCOS fails to demonstrate that the currently proposed shifts from other Novant Health facilities will be successful given its historic inability to shift cases between the same facilities/locations. In fact, it is unclear whether Novant Health has the ability to shift any additional cases to Clemmons facilities beyond what is currently served at NHCMC. NHCMC currently has more than sufficient capacity in the two existing ORs to serve its patients. As shown below, NHCMC's current surgical cases indicates a utilization rate of 28.6 percent. Moreover, even if NHCMC's operating rooms were assumed to have standard hours of operation consistent with a Group 4 facility (eight hours per day and 250 days per year), its current surgical cases indicates a utilization rate of only 46 percent.

Novant Health Clemmons Medical Center Operating Room Utilization

	FFY17	FFY17
NHCMC IP Cases	198	198
NHCMC OP Cases	1,352	1,352
NHCMC IP Case Time	152.2	152.2
NHCMC OP Case Time	142.5	142.5
NHCMC IP Surgical Hours	502	502
NHCMC OP Surgical Hours	3,211	3,211
NHCMC Total Surgical Hours	3,713	3,713
Hours per Day	10	8
Days per Year	260	250
Hours per OR per Year	2,600	2,000
ORs	5	4
- · · · ·		
Total OR Hours	13,000	8,000
	13,000	8,000

Even if all of the 1,352 outpatient cases historically served by NHCMC were shifted to NHCOS where they would be served by a lower cost freestanding ASC at the same location, NHCOS, on that volume alone, would not demonstrate the need for its previously approved two operating rooms and would also fail to demonstrate the need for its currently proposed two additional operating rooms.

Based on the above issues, Triad Surgery Center believes that NHCOS 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).

North Carolina Baptist Hospital (NC Baptist)

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

- (1) Failure to demonstrate the need for the proposed project
- (2) Failure to provide evidence of quality care

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 creating the 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, stating that this need will continue to persist until NC Baptist is awarded additional operating rooms. While this statement may be valid 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 ASC. As this shift occurs, the need for additional capacity at NC Baptist will wane.

Moreover, NC Baptist's own planned shifting of surgical cases to other settings will drive lower utilization of its operating rooms, obviating the need for the proposed four additional operating rooms. The application states on page 26 that "the surgical case capacity of the NCBH ORs is in the 34,000 case range." In its utilization methodology, the application states on page 48, "[t]he result of these planned shifts [to WFBH-OSC and DMC] combined with the conservative annual growth of 1.0% results in a slight decrease of NCBH surgical volume by Project Year 3." Indeed, the utilization projections found in Table C.9.5 on page 49 demonstrate this fact, as FY 2017 is the highest year of utilization in the NCBH operating rooms, with 34,853 cases, and with a Project Year 3 (FY 2027, 10 years later) projection of 34,834 cases. The application fails to demonstrate why NC Baptist needs the four proposed additional operating rooms, when it has successfully performed more cases in its existing operating rooms than it projects to perform at any point between now and 2027. Apart from stating that it can meet the performance standards for new operating rooms, the applicant provides no rationale for needing to increase the number of operating rooms at NC Baptist. It provides no evidence that patients will have difficulty accessing the surgical services they need, particularly since there will be fewer of them in the future than there were in 2017. Since the performance standards are only one component of the review, even if the application is found conforming with them, that alone does not meet the standard of need under Statutory Review Criterion 3.

NC Baptist also failed to consider developing fewer than all four of the operating rooms it proposes. In Section D, the application outlines the alternatives that were considered; however, none of them includes developing fewer than four operating rooms. As discussed below, NC Baptist has been approved for seven additional operating rooms since 2013 that it will not develop until 2024. Given the discussion above regarding the projected decline in surgical cases performed in the operating rooms at NC Baptist, and its

numerous approved but inchoate operating rooms, it would have been reasonable to consider proposing fewer operating rooms.

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, since the applicant will not develop the ORs until 2024. As noted above, 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 to be developed. Based on its application and a material compliance request approved by the Agency, these seven additional operating rooms are not scheduled to be developed until July 2024, more than 11 years after receiving the CON. 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 any of the four operating rooms to NC Baptist, particularly since the need in the SMFP is based on the estimated number of operating rooms needed in the service area by 2020.

Based on the above issues, Triad Surgery Center believes that NC Baptist should be found non-conforming with Criteria 3, 4 and 6.

Failure to provide evidence of quality care

NC Baptist has failed to demonstrate that it has provided quality care in the past. Although the applicant responded to questions in Section O, Triad Surgery Center believes that NC Baptist is non-conforming with Criterion 20 based on a lack of sufficient information and documentation provided to allow the Agency to make a determination regarding conformity.

In February 2018, NCBH was deemed noncompliant with conditions of participation in CMS due to deficiencies in pathology related to cancer misdiagnoses. Despite these serious quality failures, NC Baptist fails to mention them when responding to questions in Section B regarding quality and safety relating to Policy GEN-3 in the *SMFP*. Without clear and detailed explanation of how it is addressing these patient safety events, especially with regard to the unnecessary harmful surgeries performed at NC Baptist, the applicant has failed to demonstrate how its proposal will foster safety and quality in healthcare delivery, one of the central tenets of the *SMFP*. Hence, NC Baptist has not provided sufficient documentation to allow the Agency to make a determination regarding conformity with Criterion 20.

Based on the above issues, Triad Surgery Center believes that NC Baptist should be found non-conforming with Criteria 1 and 20.

COMPARATIVE COMMENTS

Given that a total of five applicants propose to meet all or part of the need for the four 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 2017 New Hanover County OR review, the 2017 Union County OR review, and the 2017 Brunswick County OR review. 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 Alternative Providers
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Average Revenue per Case
- Projected Average 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 Compass-OrthoCarolina, NHFMC, NHCOS, 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 2018 SMFP identifies a need for four additional operating rooms in the Forsyth County OR Service Area. Triad Surgery Center proposes to develop two operating rooms in a freestanding ASC in Kernersville. NHCOS proposes to develop two operating rooms in a freestanding ASC in Clemmons. Compass-OrthoCarolina proposes to develop two operating rooms in a freestanding ASC in Winston-Salem. NHFMC proposes to develop two hospital-based based operating rooms in Winston-Salem. NC Baptist proposes to develop four hospital-based operating rooms in Winston-Salem. Triad Surgery Center is the only applicant to propose to develop operating rooms in Kernersville. As discussed in the general comments above and in Section C.4 of Triad Surgery Center's application, the Kernersville region has the greatest need within Forsyth County for additional operating room capacity based on analyses of the number of operating rooms per 10,000 population as well as population distribution in the county. Therefore, with regard to geographic accessibility, Triad Surgery Center is the most effective alternative.

Documentation of Physician Support

Triad Surgery Center provides support letters from 29 surgeons/proceduralists in nine specialties as well as 19 primary care physicians. NHFMC provides support letters from 31 surgeons/proceduralists in five specialties. NHCOS provides support letters from 21 surgeons/proceduralists in six specialties. Compass-OrthoCarolina provides support letters from 25 surgeons/proceduralists in six specialties. NC Baptist

provides support letters from 109 surgeons/proceduralists in multiple specialties and more than 30 other physicians. All five applicants have a comparable demonstration of physician support. However, Triad Surgery Center is the only applicant that is conforming with statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to physician support.

Patient Access to Alternative Providers

NHFMC, NHCOS, and NC Baptist are all existing providers of surgical services in Forsyth County. Triad Surgery Center and Compass-OrthoCarolina both represent new providers of surgical services in the county. However, Triad Surgery Center is the only applicant that is conforming with statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to providing Forsyth County patients with access to an alternative provider of surgical services.

Patient Access to Low Cost Outpatient Surgical Services

As noted in the 2017 New Hanover County Operating Review (see Attachment 5), "many, but not all outpatient surgical services can either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room (ASC) however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely much less expensive if received in a non-hospital licensed operating room." NHFMC and NC Baptist are existing hospitals that offer hospital licensed operating rooms. Triad Surgery Center, Compass-OrthoCarolina, and NHCOS would offer non-hospital licensed operating rooms. However, Triad Surgery Center is the only applicant that is conforming with statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to patient access to low cost outpatient surgical services

Patient Access to Surgical Specialties

Each of the five applicants proposes to provide surgical services representing multiple specialties. However, Triad Surgery Center is the only applicant that is conforming with 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

The following tables show each applicant's projected operating room cases to be provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in the applicants' pro forma financial statements (Forms D and E).

Self Pay/Indigent/Charity, Medicare, and Medicaid Surgical Cases – Project Year 3

Applicant	Self Pay/ Indigent/Charity as % of Total	Medicare % of Total	Medicaid % of Total
Triad Surgery Center	0.3%	31.1%	1.0%
Compass-OrthoCarolina	1.8%	46.5%	3.8%
NHFMC	4.1%	49.2%	9.3%
NHCOS	1.5%	44.2%	5.3%

NC Baptist	5.4%	33.8%	19.8%
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Source: Each applicant's Forms D and E

As shown in the table above, NC Baptist projects the highest percentage of Self Pay/Indigent/Charity and the highest percentage of Medicaid patients. NHFMC projects the highest percentage of Medicare patients. However, Triad Surgery Center is the only applicant that is conforming with statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to access by underserved groups.

Projected Average Revenue per Case

The following tables show the projected gross revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms D and E).

Gross Revenue per Operating Room Case - Project Year 3

	1		
Applicant	Gross Revenue	Cases	Gross Revenue per Case
Triad Surgery Center	\$16,981,623	2,247	\$7,557
Compass-OrthoCarolina	\$15,167,293	3,527	\$4,300
NHFMC	\$931,850,030	17,299	\$53,867
NHCOS	\$54,596,887	4,754	\$11,484
NC Baptist	\$3,612,931,253	34,834	\$103,719

Source: Each applicant's Forms D and E

As shown above, Compass-OrthoCarolina projects the lowest average gross revenue per operating room case in the third project year. Triad Surgery Center projects the second lowest average gross revenue per operating room case. However, as noted in the application-specific comments above, Compass-OrthoCarolina's projected revenues are unsupported and unreasonable, with the next lowest comparable recent applicant projecting charges per case of more than 45 percent higher.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form B).

Net Revenue per Operating Room Case – Project Year 3

Applicant	Net Revenue	Cases	Net Revenue per Case
Triad Surgery Center	\$8,584,313	2,247	\$3,820
Compass-OrthoCarolina	\$7,579,791	3,527	\$2,149
NHFMC	\$305,938,556	17,299	\$17,685
NHCOS	\$20,311,735	4,754	\$4,273
NC Baptist	\$881,585,974	34,834	\$25,308

Source: Each applicant's Form B

As shown above, Compass-OrthoCarolina projects the lowest average gross revenue per operating room case in the third project year. Triad Surgery Center projects the second lowest average net revenue per operating room case. As noted above, Compass-OrthoCarolina's projected revenues are unsupported and

unreasonable. Furthermore, Triad Surgery Center is the only applicant that is conforming with statutory and regulatory review criteria. Therefore, Triad Surgery Center is the most effective alternative with regard to patient revenue.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case/procedure in the third year of operating for each of the applicants, based on the information provided in applicants' pro forma financial statements (Form B).

Operating Expenses per Case – Project Year 3

Applicant	Total Operating Cases Expenses		Operating Expense per Case
Triad Surgery Center	\$7,062,615	2,247	\$1,456
Compass-OrthoCarolina	\$6,756,586	3,527	\$1,481
NHFMC	\$123,812,155	17,299	\$7,157
NHCOS	\$17,861,106	4,754	\$2,565
NC Baptist	\$585,209,070	34,834	\$17,834

Source: Each applicant's Financials Form B & C

As shown in the table above, Triad Surgery Center projects the lowest average operating expense per case in the third project year. Therefore, with regard to operating expenses, Triad Surgery Center is the most effective alternative.

Further, Triad Surgery Center is the only applicant that projected an expense for CRNA services. As such, to provide a consistent comparison between applicants, an adjusted analysis of operating expenses per case that excludes CRNA expenses is shown in the table below.

Operating Expenses (Adjusted for CRNA Expenses) per Case – Project Year 3

Applicant	Total Operating Expenses Excluding CRNA	Cases	Operating Expense per Case Excluding CRNA
Triad Surgery Center	\$6,410,662	2,247	\$1,322
Compass-OrthoCarolina	\$6,756,586	3,527	\$1,481
NHFMC	\$123,812,155	17,299	\$7,157
NHCOS	\$17,861,106	4,754	\$2,565
NC Baptist	\$585,209,070	34,834	\$17,834

As shown in the table above, after excluding CRNA expenses, Triad Surgery remains the most effective alternative with regard to operating expenses.

History of Project Development/Operating History

Both NHFMC and NHCOS are part of the Novant Health system. As noted in the Agency findings for the 2016 Brunswick County OR review (see Attachment 6), 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 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 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% 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 CONapproved 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 ASCs has denied New Hanover and Franklin counties access to ambulatory surgery services.

Additionally, Novant Health owns a now-closed and chronically underutilized ASC 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 ASC 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 7).

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 its application and a material compliance request approved by the Agency, these seven additional operating rooms are not scheduled to be developed until July 2024, more than 11 years after receiving the CON. Similarly, NC Baptist was awarded a CON in January 2012 to develop a three operating room ASC 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. In the instant application, NC Baptist is proposing a development schedule that would postpone development of the additional operating rooms until 2024, and that is before any unscheduled delays occur as they have with other recent operating room projects.

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

SUMMARY

In summary, Triad Surgery Center believes that it is clearly the most effective alternative for additional operating rooms in Forsyth County. It is the only applicant that conforms to all the statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, Triad Surgery Center believes its proposal should be approved.



ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 11, 2017 Findings Date: May 11, 2017

Project Analyst: Celia C. Inman Team Leader: Fatimah Wilson

Project ID #: G-11300-17

Facility: Novant Health Clemmons Outpatient Surgery

FID #: 170068 County: Forsyth

Applicant: Novant Health Clemmons Outpatient Surgery, LLC

Project: Develop a multispecialty ambulatory surgical facility on the Novant Health

Clemmons Medical Center campus by relocating two ORs from the Novant Health-

Winston-Salem campus and developing a new 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

The applicant, Novant Health Clemmons Outpatient Surgery, LLC [NHCOS] proposes to develop a new ambulatory surgery center (ASC) by relocating two existing operating rooms (ORs) from Novant Health Forsyth Medical Center (NHFMC) in Winston-Salem to a new separately licensed ASC to be developed on the campus of Novant Health Clemmons Medical Center (NHCMC) in Clemmons. Both facilities are located in Forsyth County. In addition to the two outpatient surgical ORs, the proposed surgery center will also include one minor procedure room.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2017 SMFP which is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

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."

The proposed capital expenditure for this project is greater than \$5 million. In Section XI.8, page 104, the applicant states:

"The applicant will use modern energy controls and the most energy efficient material when implementing the proposed construction and upfit for the surgery center.

In addition, the Novant Health Clemmons Outpatient Surgery, LLC has been designed using Novant Health's prototypical surgery center model to maximize efficient and effective care in the surgery center space.

The surgery center project will be designed in compliance with all applicable state, local, and federal requirements for energy efficiency and consumption. The applicant

will use and enforce engineering standards that mandate the use of state-of-the art components and systems. The applicant will strive to ensure that energy efficient systems are part of the project. When the surgery center becomes operational, the applicant will include it as part of Novant Health's Utility Management and Reporting System, pursuant to Novant Health's Sustainable Energy Management Plan and Utilities Management Plan (see Exhibit 15), which are currently in place across the Novant Health facilities footprint."

Exhibit 15 of the application contains a copy of Novant Health's "Sustainable Energy Management Plan" for 2017, which the applicant states will include 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 and conforming to this criterion subject to Condition (5) in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion, subject to Condition (5) in Criterion (4).

- (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

The applicant proposes to develop, a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new facility to be developed on the campus of NHCMC in Clemmons. Both facilities are located in Forsyth County. In addition to the two outpatient surgical ORs, the proposed facility will also include one minor procedure room. In Section I.1, page 1, the applicant states that NHCOS is a new limited liability company with 100% of membership interests owned by Novant Health, Inc. (NH). In Section III.1, pages 22-23, the applicant describes the project as follows:

"Novant Health Clemmons Outpatient Surgery (NHCOS) is seeking approval to relocate two licensed surgical operating rooms from the Novant Health Forsyth Medical Center (NHFMC) in Winston Salem to a new separately licensed freestanding ambulatory surgery center on the campus of Novant Health Clemmons Medical Center (NHCMC) in Clemmons to serve Novant Health patients. Upon completion of the project, Novant Health will have two licensed freestanding ambulatory surgical operating rooms at NHCOS and five shared inpatient/outpatient operating rooms at NHCMC in Clemmons.

Upon completion of the proposed project Novant Health will utilize its 47 Forsyth County operating rooms as reflected in the following table."

The Project Analyst summarizes the table as follows:

Novant Health Forsyth County Operating Rooms Current and Proposed Distribution

			ved Proposed inges	CON Approved	Proposed NHCOS	
Facility	2017 LRA	Project ID #G-8165-08 Shift	Project ID #G-11150-16 Shift	Future Licensed Inventory	Project Under Review	Proposed Future Inventory
Proposed NHCOS	0			0	+2	2
NHCMC	2	+3		5		5
NHKOS (#G-11150-16, not operational)	0		+2	2		2
NHKMC	4			4		4
NHFMC*	29	-1	-2	26	-2	24
NHMPH	12	-2		10		10
Total NH OR Inventory	47	0	0	47	0	47

^{*}Novant Health Forsyth Medical Center inventory includes five Open Heart or C-Section ORs, and six hospital-based dedicated outpatient ORs: four at NH Hawthorne Surgical Center and two at NH Orthopedic Outpatient Surgery at Kimel Park Source: LRAs and ongoing CON Projects; Exhibit 3, Table 8.

Patient Origin

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." In Figure 6.1, page 60 of the 2017 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

In Section III.6, page 49, the applicant provides the projected patient origin for ambulatory surgical services at the proposed NHCOS facility for the first three project years (PY), as summarized in the table below.

Novant Health Clemmons Outpatient Surgery Projected Patient Origin

		PY 1 PY 2		PY3
County	Percent	7/1/19-6/30/20	7/1/20-6/30/21	7/1/21-6/30/22
Davie	12.6%	237	268	300
Forsyth	54.2%	1,022	1,155	1,291
Yadkin	9.4%	177	200	223
Other*	23.9%	450	509	569
TOTAL	100.0%	1,885	2,133	2,382

Sums may not total due to rounding

Source: Table on page 49 of the application.

In Sections III.5 and III.6, pages 49-50, and Exhibit 3, Table 10, the applicant describes the historical patient origin for ambulatory surgical services for NHCMC. The applicant's projected patient origin for the proposed ambulatory surgical facility is consistent with the historical patient origin for ambulatory surgical services provided at NHCMC, based on the patient origin data reported in the applicant's 2017 Hospital License Renewal Application, and the patient origin data reported by the applicant in Exhibit 3, Table 10, of the application. 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, starting with the increased demand for outpatient surgery due to medical technology advances and cost containment (page 22) and including:

- The historical utilization of surgical services at NHCMC from April 2013 to through December 2016 (pages 25-27).
- Changes in outpatient surgery reimbursement that encourage the development of ambulatory surgery centers to provide quality care at lower costs (pages 27-28).
- The increasing number of surgeons on NHCMC medical staff (pages 28-29).
- NHCMC's increasing outpatient market share of the targeted market (pages 29-30).
- The projected population growth in the municipalities within the targeted market area (pages 30-31).

Medical Technology Advances and Cost Containment (page 22)

The applicant states that outpatient surgery continues to increase in the United States for two major reasons: continued advances in medical technology and increasing emphasis on cost containment initiatives. The medical advances mentioned by the applicant include

^{*}The applicant states the counties included in the "Other" category are Stokes, Surry and "all other counties and locations identified on the NHCMC outpatient surgery patient origin in the 2017 NHFMC LRA." The 2017 License Renewal Application (LRA) for Novant Health Forsyth Medical Center includes a listing of the North Carolina counties and other states from which NHCMC ambulatory surgical patients originated in FY2016, including Alleghany, Ashe, Caldwell, Carteret, Caswell, Catawba, Chatham, Davidson, Davie, Forsyth, Guilford, Henderson, Iredell, Orange, Pamlico, Randolph, Rockingham, Rowan, Stokes, Surry, Watauga, Wilkes, Yadkin, and other states.

improvements in anesthesia and the increasing use of minimally invasive procedures, which make outpatient surgery less complex, less risky and shorten the patient's recovery time.

The applicant further states that concern over rising health care costs and changes resulting from the Affordable Care Act have changed reimbursement for outpatient surgery and resulted in payors and patients demanding a shift of less complex surgery to outpatient settings. The applicant also states that Medicare and Medicaid are approving more procedures for reimbursement in a freestanding outpatient setting, such that many types of surgeries previously performed in hospitals and requiring overnight stays increasingly are performed during outpatient visits. As a result, improved access is needed to freestanding ambulatory surgery centers.

Historical Utilization of Surgical Services (pages 25-27)

The applicant states that it reviewed, analyzed, and compared NHCMC historical LRA fiscal data and the most current internal Trendstar data to determine growth in outpatient surgical cases. The applicant states that as illustrated in the comparison table provided on page 25,

"the difference between surgical data reflected in the Novant Health Trendstar Financial Data System and the data reported on the annual License Renewal Application is not statistically significant. As a result, NHCOS determined that the use of internal data results in a realistic and timelier estimate of need using the most current data available at the time this CON application was filed."

The applicant provides the following table on page 26 of the application, showing NHCMC's total surgical services utilization, based on internal Trendstar data.

Novant Health Clemmons Medical Center Surgical Services Utilization April 2013 - December 2016

	2013	2014	2015	2016*	CAGR 2013-2016	CAGR 2014-2016	AGR 2015-2016
Outpatient	418	923	1,049	1,083	37.4%	8.3%	3.3%
Average Annual Growth		120.8%	13.7%	3.2%			

^{*}January-November Annualized

Percentages may not calculate due to rounding

The applicant states that NHCMC opened its outpatient services in April 2013 and inpatient services will not be operational until August 2017, per the settlement of Project ID #G-8165-08. NH has determined that a significant volume of inpatient surgical cases as well as additional outpatient cases will shift to NHCMC once the inpatient beds are operational. As a result of physician involvement and market planning, a significant portion of the inpatient volume at NHCMC is expected to be orthopedic, both surgical and medical. Surgeons currently cannot provide both inpatient and outpatient care at NHCMC, therefore, many have not yet shifted outpatient volume to the two currently operational ORs. NHCMC is anticipating that all five of the operating rooms at NHCMC will be operating at practical capacity within the first few years of operation as additional surgeons shift inpatient and

outpatient surgical volume to NHCMC from NHFMC. The applicant states that the expected shift in outpatient surgical volume, including significant orthopedic volumes, results in the need for the additional freestanding operating rooms proposed at NHCOS. The applicant further states that the proposed NHCOS will allow surgeons to provide lower cost surgical services to acuity appropriate patients in a safe, high quality environment.

Changes in Outpatient Surgery Reimbursement (pages 27-28)

The applicant states that according to The Medicare Payment Advisory Commission (MedPAC), the Centers for Medicare and Medicaid Services (CMS) believes that ambulatory surgery centers offer advantages compared to hospital outpatient departments providing outpatient services. For example, patients may experience the flexibility to schedule medical procedures with shorter waiting times, expediency to source of care, and lower cost sharing requirements.¹ The applicant further states that as a result of constraints put on providers by CMS moving toward value-based purchasing, increased deductibles and higher out-of-pocket costs for consumers, NH is developing health care service opportunities, like the proposed project, to provide high quality care to the populations they serve at lower costs.

Increasing Number of Surgeons on NHCMC Medical Staff (pages 28-29)

The applicant states that NHCMC opened in April 2013 with a medical staff of 179 physicians, including 68 surgeons. Since that time the medical staff has increased to 222 and the surgical complement has grown to include 86 surgeons in January 2017, an annual increase of 8.0%. The applicant further states that it expects the growth of surgical staff and increase in outpatient surgeries to continue with the opening of inpatient surgical services, supporting the need for the relocation of two ORs from NHFMC to Clemmons. Exhibit 4 contains surgeon support letters stating intent to seek privileges at NHCOS upon its development.

Novant Health and NHCMC Outpatient Surgical Market Share (pages 29-30)

On page 29, the applicant provides a table showing NHCMC's market share of outpatient surgery from 2012 through 2015 in its defined market area of 12 ZIP codes adjacent to the proposed facility. The increase exceeded 5% in six of the 12 ZIP codes and the total market share growth was 1.4%. The table shows that the surgical market share in the Forsyth and Yadkin county ZIP codes adjacent to Clemmons increased. The market share in one Davie County service area ZIP code also increased, while two other Davie County service area ZIP codes decreased. The applicant states that the decrease in the two Davie County ZIP codes is due to the opening of the replacement Davie County Hospital in Bermuda Run, near Advance, which began offering outpatient surgery in two ORs in 2013. The applicant states that the patients from its defined ZIP code market area are choosing to seek outpatient surgical care at NHCMC and Novant Health today and are likely to seek care in the future at NHCOS which will be located on the NHCMC campus.

¹ Medicare Payment Advisory Commission. Medicare Payment Policy: Report to Congress. March 2016. Report is available at http://medpac.gov/docs/default-source/reports/march-2106-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0

Population Growth in the NHCOS Market Area (pages 30-31)

The applicant states that based on data from the North Carolina Office of State Budget and Management (NC OSBM), Clemmons and the surrounding areas represent some of the fastest growing population bases in Forsyth, Davie and Yadkin counties; Clemmons population increased 5.09% from 2010 to 2015. Forsyth County is projected to grow 1.0% annually over the next five years, while Yadkin and Davie are expected to have minimal growth. The applicant further states:

"This population growth will result in an increased demand for ambulatory surgical services in the market area and supports the need for the relocation of two operating rooms from NHFMC's licensed OR capacity to the proposed surgery center in Clemmons on the NHCMC campus."

In conclusion, on pages 31-32, the applicant states:

"The impetus driving the proposed relocation of two operating rooms from NHFMC to NHCOS is to achieve the best utilization of existing Novant Health surgical resources, and to meet the demand for expanded surgical services in Clemmons in a low cost, high quality setting. The proposed project responds to one of the central purposes of the CON Law: to promote efficient, cost-effective solutions which maximize existing resources rather than unnecessarily duplicating existing services. Those CON statutory premises are reflected in N.C.G.S. 131E-183(a)(6) and (18a)."

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

Projected Utilization

In Section IV.1, page 54, the applicant provides projected utilization for the proposed ambulatory surgery facility through the first three years of operation following completion of the project (July 2019 – June 2022), which is summarized below.

Novant Health Clemmons Outpatient Surgery Projected Utilization, July 1, 2019 – June 30, 2022

	PY 1 7/1/19–6/30/20	PY 2 7/1/20-6/30/21	PY 3 7/1/21-6/30/22
Outpatient Surgical Operating Rooms	2	2	2
Outpatient Surgical Cases	1,885	2,133	2,382

As shown in the above table, the applicant projects it will perform 2,382 outpatient surgical cases in the two outpatient surgical operating rooms at the proposed facility in the third operating year of the project. Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be two $(2,382 \times 1.5 \text{ hours} = 3,573 \text{ hours}; 3,573 \text{ hours}/1,872 \text{ hours} = 1.9 \text{ operating rooms}).$

In Section III.1(b), pages 32-41, the applicant describes its assumptions and methodology, in ten steps, for projecting utilization of the five existing shared operating rooms at NHCMC and two proposed outpatient surgical ORs at NHCOS, as summarized below.

Step 1: Determine Baseline Volume for Use in Surgical Projections

On page 33, the applicant states it reviewed the historical surgical data for Novant Health's Forsyth County inpatient and outpatient surgical utilization from both Trendstar data and data submitted on Novant Health's hospital LRAs. After reviewing data from Novant Health's Trendstar Data (Exhibit 3, Tables 6 and 7), as well as data reported on the hospital LRAs, the applicant determined that internal (Trendstar) data on surgical utilization during the most recent full calendar year (CY2016) was the most reasonable baseline from which to project future utilization. The applicant adequately documents that using the Trendstar data is reasonable.

Step 2: Determine NHFMC Inpatient and Outpatient Volume Appropriate to Shift to Clemmons Market

On pages 33-34, the applicant states that it reviewed the historical inpatient (Exhibit 3, Table 6) and outpatient surgical volume (Exhibit 3, Table 7) at NHFMC from 2012 – 2016, resulting in a four-year inpatient CAGR of 0.0% and an outpatient CAGR of 0.54%. The applicant states that NH leadership has determined that certain orthopedic inpatient and outpatient surgical procedures (in particular, joint cases) at NHFMC will shift to NHCMC when the inpatient unit opens in August 2017. In addition, the applicant reviewed historical inpatient and outpatient surgical volume at NHFMC for residents of the Clemmons ZIP code subset. The applicant then combined the Clemmons ZIP code subset and the orthopedic subset to determine the potential inpatient pool available to be shifted to NHCMC (Exhibit 3, Table 3) and the potential outpatient pool available to be shifted to NHCOS (Exhibit 3, Table 4) and projected the total potential pool of surgical cases that could shift forward by calendar year, as shown in the table on page 34 of the application and summarized below.

NHFMC Potential Pool of Surgical Cases Which Could Shift to Clemmons

	CY	4-Yr	2017	2017		2019	2019	CY	CY	CY
	2016	CAGR	Jan- Jul	Aug -Dec	2018	Jan- July	July- Dec	2020	2021	2022
			Jui	-Dec		July	Dec			
NHFMC Potential Inpatient										
Pool to Shift to Clemmons	4,627	0.00%	3,100	1,527	4,627	2,314	2,314	4,627	4,627	4,627
NHFMC Potential Outpatient										
Pool to Shift to Clemmons	5,782	0.54%	3,895	1,918	5,844	2,938	2,938	5,908	5,940	5,972

Step 3: Determine Percentage of Outpatient Cases that are Acuity Appropriate for NHCOS

As the table above shows, the applicant analyzed the total surgical cases that could potentially shift to Clemmons by inpatient and outpatient designation. The applicant then assumed an estimated 40% (based on acuity) of the projected NHFMC potential pool of outpatient surgical cases will shift to the proposed ambulatory surgery center, NHCOS. The applicant states that

the projected percentage assumption is based on an analysis of outpatient surgical volume at NHFMC completed by Novant Health Planning and Development working with NHFMC administration; the level of support from surgeons who currently perform outpatient surgeries in the NHCMC and NHFMC ORs, as reflected in the letters in Exhibit 4; and on expert input from the Novant Health surgical and leadership teams.

Step 4: Project Outpatient Surgical Cases at NHCOS

The applicant then applies the 40% assumption to the potential pool of outpatient surgical cases available to shift from NHFMC to NHCOS, as shown on page 35 of the application and summarized below.

NHFMC Shift of Outpatient Surgical Cases to NHCOS

	2019 Jan- July	2019 July- Dec	CY2020	CY2021	CY2022
NHFMC Potential Outpatient Pool to Shift to Clemmons	2,938	2,938	5,908	5,940	5,972
Percent Projected to Shift to NHCOS		40%	40%	40%	40%
NHFMC Outpatient Volume Appropriate to Shift to NHCOS		1,175	2,363	2,376	2,389

The applicant then converts the calendar year projections above to project years, and applies a ramp-up rate, as shown on page 35 and below. Project years run from July 2019 through June 2022.

NHFMC Shift of Outpatient Surgical Cases to NHCOS

	CY2020	CY2021	CY2022	
CY Outpatient Volume Shift to NHCOS	2,363	2,376	2,389	
	PY1 Jul2019-Jun2020	PY2 Jul2020-Jun2021	PY3 Jul2021-Jun2022	
Converted to Project Years	2,357	2,370	2,382	
Projected Ramp Up	80%	90%	100%	
Projected Outpatient Volume	1,885	2,133	2,382	

Note: methodology for conversion from calendar to project year (PY1 = $\frac{1}{2}$ CY2019 + $\frac{1}{2}$ CY2020)

The applicant then weights the ambulatory surgical cases by 1.5 hours per case, resulting in the following number of weighted hours and OR need.

NHCOS Projected Surgical Volume

	PY1	PY2	PY3	
	Jul2019-Jun2020	Jul2020-Jun2021	Jul2021-Jun2022	
Projected Outpatient Volume	1,885	2,133	2,382	
Weighted Outpatient Hours of Surgery	2,828	3,200	3,573	
Outpatient OR Need	1.5	1.7	1.9	
OR Need Rounded per SMFP	2.0	2.0	2.0	

Source: Exhibit 3, Tables 1, 4, and 5

The applicant states that the projected utilization at NHCOS is sufficient to justify the two operating rooms in the third year of the proposed project, as shown in the table above and on page 35 of the application.

Step 5: Determine Percentage of Inpatient Surgical Cases Appropriate for NHCMC

The applicant estimates that up to 45% of the potential inpatient pool will shift to NHCMC in August of 2017. The applicant states that the projected percentage assumption is based on an analysis of surgical volume at NHFMC completed by Novant Health Planning and Development working with NHFMC administration; the level of support from surgeons who currently perform inpatient and outpatient surgeries in the NHFMC ORs, as reflected in the letters in Exhibit 4; and on expert input from the Novant Health surgical and leadership teams.

Step 6: Project Inpatient Surgical Cases at NHCMC

On page 36, the applicant states that to be conservative in projecting the utilization of inpatient surgical services at NHCMC, it uses the 0.0% growth rate and a ramp up in 2017 and 2018 to assure a smooth transition to the new facility. The applicant projects the following inpatient volume shift to NHCMC.

NHFMC Inpatient Surgical Cases Projected to Shift to Clemmons

		4-Yr	2017	2017	-				
	CY2016	CAGR	Jan- Jul	Aug -Dec	CY2018	CY2019	CY2020	CY2021	CY2022
NHFMC Potential Inpatient									
Pool to Shift to Clemmons	4,627	0.00%	3,100	1,527	4,627	4,627	4,627	4,627	4,627
Percent of Patients to Shift				25%	35%	45%	45%	45%	45%
Inpatient Volume Shifted to									
NHCMC				382	1,619	2,082	2,082	2,082	2,082

Source: Exhibit 3, Table 2

Step 7: Determine Percentage of Outpatient Surgical Cases Appropriate to Shift to NHCMC

On page 37, the applicant states that using the same analysis of surgical volume and leadership input as discussed with the previous assumptions for percentage of surgical volumes to shift, it estimated that 10% of the NHFMC total potential pool of outpatient surgical services will shift to NHCMC (based on acuity) when inpatient services open in August 2017.

Step 8: Project Outpatient Surgical Utilization at NHCMC

On page 37, the applicant provides data showing a three-year 8.3% Compound Annual Growth Rate (CAGR) in NHCMC outpatient surgical volume. The annual growth rate (AGR) for outpatient surgical volume at NHCMC from 2015 to 2016 was 3.3%. The applicant states that it uses the AGR of 3.3%, the more conservative rate, to grow NHCMC outpatient surgical volume from 2017 to 2022 as shown below.

NHCMC Projected Outpatient Surgical Case Growth

	CY2016	AGR	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY2022
Outpatient Surgical Cases	1,083	3.30%	1,119	1,155	1,193	1,232	1,272	1,314

The applicant then determines the additional outpatient volume that will shift from NHFMC to NHCMC, as shown in the following table.

NHFMC Shift of Outpatient Surgical Cases to NHCMC

Title since of outputted surgicult surges to Title ite								
	2017 Aug-Dec	CY2018	CY2019	CY2020	CY2021	CY2022		
NHFMC Potential								
Outpatient Pool to Shift to								
Clemmons	1,918	5,844	5,876	5,908	5,940	5,972		
Percent Projected to Shift	10%	10%	10%	10%	10%	10%		
NHFMC Outpatient Volume								
Appropriate to Shift to								
NHCMC	192	584	588	591	594	597		

As the table above shows, the applicant utilized the NHFMC 0.54% outpatient surgery annual growth rate to project the potential pool of NHFMC outpatient surgeries which could be shifted to NHCMC (Step 2). The applicant then applied the 10% acuity appropriate assumption in Step 7, to the total projected NHFMC potential pool of outpatient surgical cases calculated in Step 2, which results in the outpatient volume shift from NHFMC to NHCMC, as shown above and on page 38.

The applicant then added the 10% shift of acuity appropriate outpatient surgical cases from the NHFMC potential outpatient surgical case pool (Step 7) to the projected utilization of NHCMC existing outpatient surgery cases grown at an annual 3.3% growth, per the table above, resulting in the table on page 39, as summarized below.

NHCMC Projected Outpatient Surgical Cases 2017-2022

	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022
NHCMC Existing Outpatient						
Surgical Case Growth	1,119	1,155	1,193	1,232	1,272	1,314
NHFMC Outpatient Cases						
Appropriate to Shift to						
NHCMC	192	584	588	591	594	597
Total Adjusted Outpatient Volume at NHCMC	1,310	1,740	1,781	1,823	1,866	1,911

Step 9: Project Operating Room Need for NHCMC

The applicant projects future inpatient and outpatient surgical volume at NHCMC (Steps 6 through 8) and converts the calendar year projections to the applicant's project years to project operating room need at NHCMC, as shown on page 39. As shown in the table on page 39, the applicant calculates total weighted surgical hours as 9,773, 9,875, and 9,980 for PY1, PY2 and PY3, respectively. This results in an OR Need of 5.2, 5.3 and 5.3 in PY1, PY2, and PY3, respectively. However, the applicant incorrectly calculates the total weighted surgical hours. The Project Analyst calculates the total weighted surgical hours as shown in the table below, which results in an OR Need of 4.8, 4.8 and 4.9 in PY1, PY2, and PY3, respectively. Regardless of the incorrect calculation, the result rounds to a need for five ORs in each year when rounded according to the methodology in the 2017 SMFP.

NHCMC Projected Operating Room Need

When I rojected Operating Room Need								
	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022		
Inpatient Volume at NHCMC (Step 6)	382	1,619	2,082	2,082	2,082	2,082		
Outpatient Volume at NHCMC (Step 8)	1,310	1,740	1,781	1,823	1,866	1,911		
Conversion to Project Year				PY1 Jul2019- Jun2020	PY2 Jul2020- Jun2021	PY3 Jul2021- Jun2022		
Inpatient Cases at NHC	МC			2,082	2,082	2,082		
Outpatient Cases at NHO	CMC			1,802	1,844	1,889		
Weighted Inpatient Surg	gical Hours	(Cases x 3	hours)	6,246	6,246	6,246		
Weighted Outpatient Surgical Hours (Cases x 1.5 hours)				2,703	2,766	2,834		
Total Weighted Surgical	8,949	9,012	9,080					
ORs Needed at 1,872 Hours per OR				4.8	4.8	4.9		
Rounded OR Need per S	SMFP			5	5	5		

Note: methodology for conversion from calendar to project year (PY1 = ½ CY2019 + ½ CY2020)

Step 10: Project Operating Room Need for NHCOS and NHCMC

The applicant provides a table on page 40, as summarized below, which the applicant states "shows the combined projections for both facilities."

NHCOS and NHCMC Projected OR Need

	PY1 Jul2019- Jun2020	PY2 Jul2020- Jun2021	PY3 Jul2021- Jun2022
NHCOS OR Need (rounded per SMFP)	2	2	2
NHCMC OR Need (rounded per SMFP)	5	5	5
Total Combined OR Need	7	7	7

Minor Procedure Room

The applicant proposes to develop one minor procedure room as part of the project. On pages 40-41, the applicant states,

"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 NHCOS.

Non-surgical minor procedure volume at the proposed NHCOS is estimated based upon discussion with NHCMC/NHFMC surgical management staff and a review of other multi-specialty ambulatory surgical facilities with procedure rooms in North Carolina. Estimated volumes reflect a percentage of projected total cases (surgical cases + non-surgical cases) as calculated in Exhibit 3, Table 19."

Exhibit 3, Table 18 and page 41 of the application, show the applicant's projected number of non-surgical procedures as 544, 614, and 689 in PY1, PY2, and PY3, respectively, based on the assumption that procedure room volume will equal 22.4% of total surgical and non-surgical volume.

Exhibit 4 contains letters from surgeons expressing support for the proposed project to develop an ASC with two relocated ORs and a minor procedure room; and their intent to seek privileges at the proposed ASC, upon development. Projected utilization of the relocated ORs and the minor procedure room at NHCOS is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to develop two relocated ORs and one new minor procedure room at the proposed ambulatory surgical facility.

Access

In Section VI.2, pages 67-69, the applicant states its commitment to provide services to all patients who need the services regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay. In Section VI.13, page 76, the applicant reports that 55.6% of

outpatient surgical cases at NHFMC was provided to Medicare or Medicaid recipients in FY2016. The same data reported for NHFMC less the surgical programs at NHKMC and NHCMC was 59.2%. In Section VI.14, page 77, the applicant projects that 36.9% of surgical cases will be provided to Medicare or Medicaid recipients at the proposed facility. The applicant states that the payor mix for NHCOS is based upon an average of historical outpatient surgical payor mix for patients from the Clemmons ZIP code market at NHFMC; orthopedic outpatients at NHFMC; and outpatients currently at NHCMC.

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 adequately 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.

 \mathbf{C}

The applicant, NHCOS, proposes to develop a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new freestanding outpatient facility to be developed on the campus of NHCMC in Clemmons. In addition to the two ORs, the proposed surgery center will also include one minor procedure room.

NHFMC (Winston-Salem campus only) reported a total of 23 licensed operating rooms in its 2017 Hospital License Renewal Application form, as shown in the following table:

Novant Health Forsyth Medical Center Operating Rooms by Type

Operating Room Type	Number of Operating Rooms
Dedicated Open Heart Surgery	3
Dedicate C-Section	2
Shared Inpatient/Ambulatory Surgery	18
Total Surgical Operating Rooms	23

Source: 2017 Hospital License Renewal Application.

In Project ID #G-8165-08, and as modified by a September 11, 2015 Material Compliance Approval letter, Novant was approved to relocate one shared OR from NHFMC to NHCMC.

In Project ID #G-11150-16, Novant was approved to relocate two shared ORs from NHFMC to NHKOS. Therefore, upon completion of Project ID #G-8165-08, Project ID #G-11150-16, and this project, NHFMC will operate a total of 18 licensed operating rooms, including 13 shared operating rooms (18-1-2-2=13), two dedicated C-section surgical operating rooms, and three dedicated open heart surgery operating rooms. This does not include Novant's six ambulatory ORs: four at Hawthorne Surgical Center and two at NH Orthopedic Outpatient Surgery.

In Section III.3(c), pages 43-44, the applicant states:

"As reflected in the following table [sic] inpatient surgical utilization has declined slightly and outpatient surgical utilization has increases [sic] slighted [sic] at NHFMC in the last five years. When new Novant Health surgical programs opened in Kernersville and Clemmons, patients appropriate for the services and the market choose to seek care at these new facilities.

Novant Health Forsyth Medical Center Historical Surgical Volumes

Surgical	CY	CY	CY	CY	CY	CAGR
Facility	2012	<i>2013</i>	2014	2015	2016	2012-2016
Inpatient	7,627	7,837	7,629	7,368	7,615	-0.04%
Annual Growth		2.8%	-2.7%	-3.4%	3.3%	
Outpatient	14,132	14,545	14,016	14,568	14,440	0.5%
Annual Growth		2.9%	-3.6%	3.9%	-0.9%	

Source: Exhibit 3, Tables 6, 7

As previously discussed, the opening of inpatient surgical services at NHCMC in August 2017 and NHCOS in July 2019 also will result in additional volume shifting from NHFMC. When the three additional operating rooms at NHCMC become operational August 2017, there will be a shift of patients living in Clemmons and surrounding areas to NHCMC. In addition, several orthopedic surgeons will relocate from the Winston-Salem campus to the Clemmons campus. These surgeons performed around 1,500 inpatient joint cases and 250 outpatient joint cases in 2016. This volume of surgical cases is expected to shift to NHCMC when the 36 new inpatient beds and 3 additional ORs become operational allowing inpatient surgical cases as well as outpatient surgical cases to be performed at NHCMC.

The opening of NHCOS in July 2019 will result in an additional shift in multi-specialty outpatient surgical patients living in the Clemmons and surrounding areas and outpatient orthopedic cases from NHFMC to a lower cost alternative. The following table shows that sufficient surgical capacity remains at NHFMC to meet the needs of the patients currently being seen and projected for the future even with shifting NHFMC's operating rooms to NHCOS."

On page 44, the applicant provides a table showing the projected calendar year utilization of the operating rooms at NHFMC based on a 0.0% annual increase for inpatient volume and a 0.54% increase for outpatient surgical volume. After the proposed shift of inpatient and outpatient surgical volume from NHFMC to NHCMC and NHCOS, the applicant shows

NHFMC's projected utilization in weighted surgical hours of 34,300, 34,395, and 34,492 for CY2020 through CY2022, respectively. The applicant then converts the calendar year utilization to project years for the first three operating years of the project and calculates NHFMC's OR need and surplus, as summarized below:

Projected Surgical Utilization Novant Health Forsyth Medical Center

	PY1	PY2	PY3
	Jul2019-Jun2020	Jul2020-Jun2021	Jul2021-Jun2022
Total Weighted Surgical Hours	35,133	34,347	34,444
Total OR Need @ 1,872 Hours	18.8	18.3	18.4
OR Inventory (2017 LRA less 5 OH and C-Section ORs, 1 OR relocated to NHCMC and 2 relocated to NHKOS (Ex 3, Table 8)	21.0	21.0	21.0
OR Surplus	2.2	2.7	2.6
ORs Shifted to NHCOS	2.0	2.0	2.0
Remaining Surplus at NHFMC	0.2	0.7	0.6
OR Surplus Rounded per SMFP	0	1	1

Based on the applicant's utilization projections, NHFMC would have adequate capacity to meet the need for surgical services for the population presently served following relocation of the two shared surgical operating rooms from NHFMC to the proposed ambulatory surgical facility.

In Section III.3(d), page 45, the applicant states:

"The proposed project will result in meeting the need for surgical services in the Clemmons market area as discussed in response to Question III.3(b) without having an impact on surgical services at NHFMC as discussed in the response to Question III.3(c). As a result, there will be no changes in services, costs, charges, or level of access by medically underserved populations.

It is the policy of all Novant Health facilities to provide necessary services to all individuals without regard to race, creed, color, or handicap. Novant Health surgical providers do not discriminate against medically underserved persons regardless of their ability to pay.

• • •

Therefore, the relocation of the two operating rooms from NHFMC to NHCOS will not impact the ability of the medically underserved to receive health care services as NHFMC will continue to provide the same services currently provided."

In Section VI.13, page 76, the applicant reports the following payor mix for outpatient surgical services at NHFMC (including NHCMC and NHKMC) for FFY2016:

Payor Category	Percent of Total
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	46.7%
Medicaid	8.9%
Commercial Insurance	0.4%
Managed Care	39.0%
Other	3.0%
Total	100.0%

Totals may not sum due to rounding

In Section VI.14, page 77, the applicant projects the following payor mix for surgical services at NHCOS in the second operating year of the project.

Payor Category	Percent of Total Cases
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	31.1%
Medicaid	5.8%
Commercial Insurance / Managed Care	53.3%
Managed Care	Included Above
Other	7.7%
Total	100.0%

The applicant does not specify what makes up other in either of the above tables.

On page 77, the applicant states:

"Payor mix for Novant Health Clemmons Outpatient Surgery is based upon an average of historical outpatient surgical payor mix for patients from the Clemmons zip code market at NHFMC; orthopedic outpatients at NHFMC; and outpatients currently at NHCMC. NHCOS reviewed outpatient surgical payor mix for calendar years 2014, 2015 and year to date in 2016 for these surgical subsets. Slight changes in payor mix occurred during this timeframe. Therefore, NHCOS used the most current average payor mix for NHCOS."

As shown in the table above, the applicant projects that 36.9 percent of its surgical cases will be for patients who will have some or all of their care paid for by Medicare or Medicaid. The applicant adequately demonstrates that the needs of the population presently served will be met adequately after the proposed relocation of the ORs and the relocation of the two shared surgical operating rooms from NHFMC 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 NHFMC will be adequately met following the proposed relocation of two operating rooms from NHFMC to NHCOS. 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.

CA

In Section III.8, pages 50-51, the applicant describes the other 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 the existing operating rooms at NHCMC have experienced robust growth in surgical volume and the three additional ORs being added in August 2017, along with the additional surgical service line, will not add adequate capacity to meet the growing need for surgical services at NHCMC.
- 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 in a separately licensed ambulatory surgery center.
- Develop a Freestanding Separately Licensed Surgery Center in Another Location The
 applicant states that developing an ambulatory surgery center in another location is not
 an effective alternative because the NHKMC development of NHKOS on the eastern
 side of Forsyth County makes the demand for ambulatory surgical services greater in
 the Clemmons area on the western side of the county. The applicant also states that the
 development of the center on NHCMC campus allows for operational and cost
 efficiency.

After considering the alternatives listed above, the applicant states that the alternative represented in the application, develop a freestanding, separately licensed multispecialty surgery center on the NHCMC campus by "relocating two operating rooms from NHFMC allows Novant Health to put its OR resources to their best and most productive uses." Therefore, the applicant states the project as proposed is the most effective alternative to meet the identified need.

Furthermore, the application is conforming or conditionally 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 and approved subject to the following conditions.

- 1. Novant Health Clemmons Outpatient Surgery, LLC shall materially comply with all representations made in the certificate of need application.
- 2. Novant Health Clemmons Outpatient Surgery, LLC shall develop an ambulatory surgery center with no more than two ambulatory surgical operating rooms and one minor procedure room.

- 3. Novant Health Forsyth Medical Center shall de-license two shared operating rooms. Following completion of this project and Project I.D. #G-8165-08, and Project I.D. #G-11150-16, Novant Health Forsyth Medical Center shall be licensed for no more than 18 operating rooms, including 13 shared operating rooms, three dedicated open heart surgery operating rooms, and two dedicated C-section operating rooms.
- 4. Novant Health Clemmons Outpatient Surgery, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.
- 5. Novant Health Clemmons Outpatient Surgery, LLC 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.
- 6. Novant Health Clemmons Outpatient Surgery, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

 \mathbf{C}

The applicant proposes to develop a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new facility to be developed on the campus of NHCMC in Clemmons. In addition to the two ORs, the proposed surgery center will also include one minor 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:

NHCOS Project Capital Cost

	_
Site Costs	\$796,654
Construction Costs	\$6,514,461
Miscellaneous Project Costs	\$5,859,777
TOTAL CAPITAL COST	\$13,170,892

Source: Table on page 89 of the application.

In Section IX.1, page 97, the applicant states there will be \$129,747 in start-up expenses and \$391,952 in initial operating expenses associated with the project, for total working capital

required of \$403,587. However, the total working capital required, based on the stated start-up and initial operating expenses, is \$521,699 (\$129,747 + \$391,952 = \$521,699). A difference of \$118,112.

Availability of Funds

In Section VIII.3, page 93, the applicant states that the total project capital costs will be funded with accumulated reserves of Novant Health, Inc., the sole member of NHCOS. Also, in Section IX.3, page 90, the applicant states that the working capital costs will be funded with accumulated reserves of Novant Health, Inc. In Exhibit 7, the applicant provides a letter dated February 15, 2017, from the Senior Vice President, Finance for Novant Health, Inc., documenting its intention to fund the proposed project's capital costs in the amount of \$13,170,892 and "the Working Capital for the NHCOS project as defined in the application Section IX" from accumulated reserves. As discussed above, the applicant incorrectly calculates the total working capital, based on the listed start-up and initial operating expenses; however, in its funding letter, Novant Health agrees to fund the working capital and does not set a limit.

The funding letter reserves Novant Health's right to seek tax-exempt financing, based on market conditions at that time. Exhibit 7 also contains a copy of the December 31, 2015 and 2014 Consolidated Financial Statements for Novant Health, Inc. and Affiliates that indicates it had \$354 million in cash and cash equivalents, \$990 million in current assets (net of receivables and limited use assets), and \$1.8 billion in long-term assets available for capital projects, 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 NHCOS's surgical services (Form B), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

Projected NHCOS Revenue and Expenses

rrojecteu NHCOS Revenue and Expenses										
	PY1 Jul2019-June2020		PY2 Jul2020-June2021			PY3 1-June2022				
Projected # of Surgical Cases		1,885		2,133		2,382				
Projected Average Charge (Gross Patient Revenue / Projected # of Cases)	\$	8,374	\$	8,539	\$	8,713				
Gross Patient Revenue	\$	15,784,384	\$	18,214,734	\$	20,755,532				
Deductions from Gross Patient Revenue	\$	10,345,772	\$	11,938,670	\$	13,604,140				
Net Patient Revenue	\$	5,438,611	\$	6,276,064	\$	7,151,392				
Total Expenses	\$	5,168,541	\$	5,614,930	\$	6,087,023				
Net Income	\$	270,070	\$	661,134	\$	1,064,369				

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q 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 that sufficient funds will be available for the capital and working capital 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.

 \mathbf{C}

The applicant, NHCOS, proposes to develop a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new, separately licensed outpatient surgery facility to be developed on the campus of NHCMC. In addition to the two ORs, the proposed surgery center will also include one minor procedure room.

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." In Figure 6.1, page 60 of the 2017 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth 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 Forsyth County, and the outpatient and inpatient case volumes for each provider. Surgical case volumes are from Table 6A of the 2017 SMFP.

Forsyth County Operating Room Inventory

	OP	IP OF	Shared	OP	IP ~
	ORs	ORs	ORs	Surgery Cases	Surgery Cases
Clemmons Medical Park Ambulatory Surgery Center (1)	3	0	0	0	0
Plastic Surgery Center of North Carolina (1)	-3	0	0	171	0
Piedmont Outpatient Surgery Center (2)	2	0	0	2,224	0
North Carolina Baptist Hospital (3)	0	4	36	19,549	14,214
Novant Health Forsyth Medical Center (4)	6	5	24	9,519	17,445
Novant Health Medical Park Hospital (5)	0	0	12	8,613	897

Source: 2017 SMFP, Table 6A.

Notes

- (1) In Project I.D. # G-8608-10, approved January 19, 2012, Wake Forest Ambulatory Venture, LLC was approved to relocate the three operating rooms at Plastic Surgery Center of North Carolina from Winston-Salem to a new ambulatory surgery facility in Clemmons. The project has yet to be developed.
- (2) Piedmont Outpatient Surgery Center is a single-specialty ambulatory surgery demonstration project. These operating rooms are not counted in the inventory for the calculation of need (Table 6B) in the 2017 SMFP.
- (3) North Carolina Baptist Hospital was approved on April 2, 2013 (Project I.D. # G-8460-10) to develop a new ambulatory surgery building with 7 new outpatient operating rooms pursuant to Policy AC-3. These operating rooms are not shown above or counted in the inventory for the calculation of need (Table 6B) in the 2017 SMFP. This hospital-based ambulatory project has yet to be developed.
- (4) The operating room total for NHFMC includes all hospitals and outpatient surgery centers on the NHFMC license, including Novant Health Kernersville Medical Center, Novant Health Clemmons Medical Center, Novant Health Hawthorne Outpatient Surgery, and Novant Health Orthopedic Outpatient Surgery. Also includes one shared operating room that will be relocated to NHCMC upon completion of Project I.D. # G-8165-08 and two shared operating rooms that will be relocated to NHKMC upon completion of Project ID #G-11150-16.
- (5) The operating room total for NHMPH includes five operating rooms that will be relocated to NHCMC upon completion of Project I.D. # G-8165-08.

As the table above shows, Forsyth County residents do not currently have access to any freestanding ambulatory surgery services. Wake Forest Ambulatory Venture, LLC, a Wake Forest Baptist Health affiliate, received CON approval in 2012 to develop a freestanding ambulatory surgery facility, Clemmons Medical Park Ambulatory Surgery Center, in Forsyth County. To date, the project has not been developed. Forsyth County has no operational freestanding ambulatory surgery centers.

In addition, North Carolina Baptist Hospital, a Wake Forest Baptist Health affiliate, received CON approval in 2013 to develop a hospital-based ambulatory surgery building on its campus with seven new ORs and one relocated OR. To date, this ambulatory surgery project has not been developed.

The data listed in the 2017 SMFP and in the above table for Novant Health Forsyth Medical Center includes all hospitals and outpatient surgery centers listed on NHFMC's license. For a clearer understanding of the current operating room status and surgical case volumes for NHFMC, the following table shows the consolidated NHFMC ORs and case volume and the individual hospitals and surgery centers' ORs and case volume, as reported separately on the NHFMC 2016 LRA.

Novant Health Forsyth Medical Center ORs FFY2015

	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP Surgery Cases
Novant Health Forsyth Medical Center (1)	6	5	24	17,445	11,338
NHFMC Winston-Salem Campus (2)	0	5	18	5,552	10,484
NHFMC Kernersville Campus (2)	0	0	4	2,347	854
NHFMC Clemmons Campus (2)	0	0	2	1,019	0
Novant Health Hawthorne Outpatient Surgery (2)	4	0	0	6,036	0
Novant Health Orthopedic Outpatient Surgery (2)	2	0	0	2,491	0

Source: 2016 Hospital License Renewal Application for NHFMC.

- (1) Reported on NHFMC 2016 LRA as "Cumulative: Includes Winston-Salem, Kernersville & Clemmons Hospital Campuses" and Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery.
- (2) Reported on NHFMC 2016 LRA as "Winston-Salem Campus Only, Kernersville Hospital Only & Clemmons Hospital Campus Only, Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery."

The following table shows the consolidated NHFMC ORs and case volume and the individual hospitals and surgery centers' ORs and case volumes, as reported separately on the NHFMC 2017 LRA.

Novant Health Forsyth Medical Center ORs FFY2016

	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP Surgery Cases
Novant Health Forsyth Medical Center (1)	6	5	24	17,706	11,006
NHFMC Winston-Salem Campus (2)	0	5	18	5,342	9,953
NHFMC Kernersville Campus (2)	0	0	4	2,666	1,053
NHFMC Clemmons Campus (2)	0	0	2	1,108	0
Novant Health Hawthorne Outpatient Surgery (2)	4	0	0	6,399	0
Novant Health Orthopedic Outpatient Surgery (2)	2	0	0	2,191	0

Source: 2017 Hospital License Renewal Application for NHFMC. Notes:

- (1) Reported on NHFMC 2017 LRA as "Cumulative: Includes Winston-Salem, Kernersville & Clemmons Hospital Campuses" and Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery.
- (2) Reported on NHFMC 2017 LRA as "Winston-Salem Campus Only, Kernersville Hospital Only & Clemmons Hospital Campus Only, Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery."

The applicant proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from Novant Health Forsyth Medical Center in Winston-Salem to a new facility to be developed on the campus of Novant Health Clemmons Medical Center in Clemmons. Therefore, the applicant does not propose to increase the inventory of operating rooms in the service area. The applicant adequately demonstrates the need to relocate the existing operating rooms, and adequately demonstrates 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 Forsyth 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

In Section VII.2, page 79, the applicant provides the proposed staffing for the facility in project year 2 (July 2020– June 2021), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Clinical Coordinator (RN)	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	18.0

In Section VII.3, page 79-81, and Section VII.7, pages 84-85, the applicant describes parent company, NH's experience and process for recruiting and retaining staff. Exhibit 5 contains a copy of a letter from John Mann, M.D., expressing his interest in serving as the Medical Director for the facility. Exhibit 4 contains physician support letters, stating intent to seek privileges at the facility upon project development. 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

In Sections II.1 and II.2, pages 9-10, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 4 of the application contains copies of letters from area physicians and surgeons expressing support for the proposed project. Exhibit 5 contains letters documenting availability of anesthesiology, pathology and radiology services. Exhibit 9 contains a transfer agreement with NHCMC. 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.

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The applicant proposes to develop a new, separately licensed ambulatory surgery center in 15,454 square feet of space in a medical office building to be constructed on the campus of Novant Health Clemmons Medical Center. Exhibit 14 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. Line drawings and a site plan are also provided in Exhibit 14. In Section XI.8, pages 104-105, 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;

 \mathbf{C}

In Section VI.13, page 76, the applicant reports the following FFY2016 payor mix for all surgical services for NHFMC License # H0209:

Payor Category	Surgical Cases as Percent of Total
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	46.7%
Medicaid	8.9%
Commercial Insurance	0.4%
Managed Care	39.0%
Other (not specified)	3.0%
Total	100.00%

Totals may not sum due to rounding

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 service area of Forsyth County, and statewide.

Percent of Population							
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**	
Forsyth	14%	53%	42%	20%	7%	17%	
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"

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

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

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

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

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, pages 74-75, the applicant states:

"Novant Health's hospitals (NHFMC and NHPMC [sic]) fulfilled their Hill-Burton obligations long ago. ... FMC, PMC [sic] and all 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, page 74, the applicant states that no civil rights access complaints have been filed against any Novant Health facility or surgery center 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

In Section VI.14, page 77, the applicant projects the following payor mix for NHCOS's proposed surgical services during the second project year (July2020 – June2021):

Payor Category	Outpatient Surgical Cases as Percent of Total
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	31.1%
Medicaid	5.8%
Commercial Insurance/ Managed Care	53.3%
Other (not specified)	7.7%
Total	100.00%

On page 77, the applicant states:

"Payor mix for Novant Health Clemmons Outpatient Surgery is based upon an average of historical outpatient surgical payor mix for patients from the Clemmons ZIP code market at NHFMC; orthopedic outpatients at NHFMC; and outpatients currently at NHCMC. NHCOS reviewed outpatient surgical payor mix for calendar years 2014, 2015 and year to date in 2016 for these surgical subsets. Slight changes in payor mix occurred during this timeframe. Therefore, NHCOS used the most current average payor mix for NHCOS."

The applicant demonstrates that medically underserved populations will have adequate 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.

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In Section VI.9, page 73, the applicant describes the range of means by which a person will have access to NHCOS's 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.

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

 \mathbf{C}

In Section V.1, page 55, the applicant states that Novant Health has extensive relationships with health professional training programs which will be extended to NHCOS. Exhibit 9 contains a list of educational institutions with which Novant Health has training arrangements, including Forsyth Technical Community College, Duke University, Davison County Community College, Elon University, High Point University, and UNC-Charlotte, among others. The information provided is reasonable 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.

 \mathbf{C}

The applicant proposes to develop a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new facility to be developed on the campus of NHCMC.

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." In Figure 6.1, page 60 of the 2017 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth 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 Forsyth County, and the outpatient and inpatient case volumes for each provider. Surgical case volumes are from Table 6A of the 2017 SMFP.

Forsyth County Operating Room Inventory

				OP	IP
	OP	IP	Shared	Surgery	Surgery
	ORs	ORs	ORs	Cases	Cases
Clemmons Medical Park Ambulatory Surgery Center (1)	3	0	0	0	0
Plastic Surgery Center of North Carolina (1)	-3	0	0	171	0
Piedmont Outpatient Surgery Center (2)	2	0	0	2,224	0
North Carolina Baptist Hospital (3)	0	4	36	19,549	14,214
Novant Health Forsyth Medical Center (4)	6	5	24	9,519	17,445
Novant Health Medical Park Hospital(5)	0	0	12	8,613	897

Notes:

- (1) In Project I.D. # G-8608-10, approved January 19, 2012, the applicant was approved to relocate the three operating rooms at Plastic Surgery Center of North Carolina from Winston-Salem to a new ambulatory surgery facility in Clemmons. The project is currently under development.
- (2) Piedmont Outpatient Surgery Center is a single-specialty ambulatory surgery demonstration project. These operating rooms are not counted in the inventory for the calculation of need (Table 6B) in the 2017 SMFP.
- (3) North Carolina Baptist Hospital was approved on April 2, 2013 (Project I.D. # G-8460-10) to develop 7 outpatient operating rooms pursuant to Policy AC-3. These operating rooms are not shown above or counted in the inventory for the calculation of need (Table 6B) in the 2017 SMFP.
- (4) The operating room total for NHFMC includes all hospitals and outpatient surgery centers on the NHFMC license, including Novant Health Kernersville Medical Center, Novant Health Clemmons Medical Center, Novant Health Hawthorne Outpatient Surgery, and Novant Health Orthopedic Outpatient Surgery. Also includes one shared operating room that will be relocated to NHCMC upon completion of Project I.D. # G-8165-08 and two shared operating rooms that will be relocated to NHKMC upon completion of Project ID #G-11150-16.
- (5) The operating room total for NHMPH includes five operating rooms that will be relocated to NHCMC upon completion of Project I.D. # G-8165-08.

As the table above shows, Forsyth County residents do not currently have access to any freestanding ambulatory surgery services. Wake Forest Ambulatory Venture, LLC, a Wake Forest Baptist Health affiliate, received CON approval in 2012 to develop a freestanding ambulatory surgery facility, Clemmons Medical Park Ambulatory Surgery Center, in Forsyth County. To date, the project has not been developed. Forsyth County has no operational freestanding ambulatory surgery centers.

In addition, North Carolina Baptist Hospital, a Wake Forest Baptist Health affiliate, received CON approval in 2013 to develop a hospital-based ambulatory surgery building on its campus with seven new ORs and one relocated OR. To date, this ambulatory surgery project has not been developed.

The applicant, NHCOS, is a new limited liability company with 100% of its LLC membership interests owned by Novant Health. Novant Health formed two similar LLCs, applied for, and received 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. A progress report dated March 30, 2017, acknowledged a Letter of Intent was executed, but did not add details on development of the project. 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.

NHCOS's proposed 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 could make its proposed project a less effective alternative with regard to history of project development in a competitive review. However, this review is not competitive. In fact, the applicant proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from NHFMC to a new facility to be developed on the campus of NHCMC. Therefore, the applicant does not propose to increase the inventory of operating rooms in the service area; the applicant states that it proposes to better utilize NH's existing OR inventory in Forsyth County.

The data listed in the 2017 SMFP and above for Novant Health Forsyth Medical Center includes all hospitals and outpatient surgery centers listed on NHFMC's license. For a clearer understanding of the current operating room status and surgical case volumes for NHFMC, the following table shows the consolidated NHFMC ORs and case volume and the individual hospitals and surgery centers' ORs and case volume, as reported separately on the NHFMC 2016 LRA.

Novant Health Forsyth Medical Center ORs FFY2015

				OP	IP
	OP	IP	Shared	Surgery	Surgery
	ORs	ORs	ORs	Cases	Cases
Novant Health Forsyth Medical Center (1)	6	5	24	17,445	11,338
NHFMC Winston-Salem Campus (2)	0	5	18	5,552	10,484
NHFMC Kernersville Campus (2)	0	0	4	2,347	854
NHFMC Clemmons Campus (2)	0	0	2	1,019	0
Novant Health Hawthorne Outpatient Surgery (2)	4	0	0	6,036	0
Novant Health Orthopedic Outpatient Surgery (2)	2	0	0	2,491	0

Notes:

- (1) Reported on NHFMC 2016 LRA as "Cumulative: Includes Winston-Salem, Kernersville & Clemmons Hospital Campuses" and Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery.
- (2) Reported on NHFMC 2016 LRA as "Winston-Salem Campus Only, Kernersville Hospital Only & Clemmons Hospital Campus Only, Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery."

The following table shows the consolidated NHFMC ORs and case volume and the individual hospitals and surgery centers' ORs and case volumes, as reported separately on the NHFMC 2017 LRA.

Novant Health Forsyth Medical Center ORs FFY2016

	OP	ΙP	Shared	OP Surgery	IP Surgery
	ORs	ORs	ORs	Cases	Cases
Novant Health Forsyth Medical Center (1)	6	5	24	17,706	11,006
NHFMC Winston-Salem Campus (2)	0	5	18	5,342	9,953
NHFMC Kernersville Campus (2)	0	0	4	2,666	1,053
NHFMC Clemmons Campus (2)	0	0	2	1,108	0
Novant Health Hawthorne Outpatient Surgery (2)	4	0	0	6,399	0
Novant Health Orthopedic Outpatient Surgery (2)	2	0	0	2,191	0

Notes:

- (1) Reported on NHFMC 2017 LRA as "Cumulative: Includes Winston-Salem, Kernersville & Clemmons Hospital Campuses" and Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery.
- (2) Reported on NHFMC 2017 LRA as "Winston-Salem Campus Only, Kernersville Hospital Only & Clemmons Hospital Campus Only, Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery."

The applicant proposes to develop a new ambulatory surgery center by relocating two existing ORs from NHFMC in Winston-Salem to a new facility to be developed on the campus of NHCMC in Clemmons. Therefore, the applicant does not propose to increase the inventory of operating rooms in the service area.

In Section V.7, pages 60-66, 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, NHCOS will have the opportunity to offer outpatient surgeries at a lower price point than a hospital-based outpatient surgery

program. Traditionally, patient co-pays and charges have been lower at licensed outpatient surgery centers, than at hospital-based outpatient surgery programs. This approach will offer a new, more cost effective option for local access to outpatient surgical care in the Clemmons market area. As a result, NHCOS 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."

The applicant continues its discussion on the proposed surgery center's cost effectiveness, the quality the applicant intends to provide, and the access patients will have to the services throughout Section V.7.

See also Sections II, III, 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 (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3), (3a), 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.

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According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no Novant Health facilities are currently out of compliance with a CMS Condition of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any other facility owned and operated by Novant Health in North Carolina. 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.

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

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

- (a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.
- -C- In Section II.10, page 17, the applicant states that NHCOS is projected to be open five days per week and 52 weeks a year.
- (b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:
 - (1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(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) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled

"Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

- (2) The number of rooms needed is determined as follows:
 - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;
 - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and
 - (C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.
- -C- The Forsyth County operating room service area has more than 10 operating rooms. In Section II.10, page 18, the applicant provides a table showing the projected utilization for the proposed facility for the first three operating years, as summarized below:

Novant Health Clemmons Outpatient Surgery Projected Volume								
	PY1	PY2	PY3					
	Jul2019-June2020	Jul2020-June2021	Jul2021-June2022					
Projected NHCOS Cases	1,885	2,133	2,382					
Weighted Outpatient Surgical Hours (1.5 hours per case)	2,828	3,199	3,574					
ORs needed at 1,872 Hours per OR	1.51	1.71	1.91					
Total Operating Rooms Needed (Rounded per SMFP)	2	2	2					

Source: Table on page 18 of the application.

Projected utilization, which is based on reasonable and adequately supported assumptions, supports the need for two operating rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:
 - (1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected

outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

- (2) The number of rooms needed is determined as follows:
 - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;
 - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and
 - in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.
- -NA- The applicant does not propose to increase the number of operating rooms in the service area.
- (d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.
- -NA- The applicant does not propose to develop an additional dedicated C-section operating room.
- (e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:
 - (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

- (2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.
- **-NA-** The applicant does 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.
- (f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.
- -C- The applicant provides documentation of its assumptions and provides data supporting its methodology in Section III.1 (b), pages 32-42, and Exhibit 3 of the application.



Orthopedic Surgeon Support Letters

Martha Frisone, Assistant Chief,
Certificate of Need
Healthcare Planning & Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, specializing in foot and ankle surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called OrthoCarolina with offices in Clemmons, Winston-Salem, King, Kernersville, Boone, and Ashe County. I practice primarily in the OrthoCarolina offices in Winston-Salem and Kernersville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

I plan to seek privileges to practice at Novant Health Clemmons Outpatient Surgery, once it has been developed. The proposed surgery center will give patients, families, payors, and surgeons more choices in selecting the venue for their outpatient surgeries.

Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely.

Daniel S. Biggerstaff, MD

OrthoCarolina

File: ClemmonsASCOrthoSuppLtrBiggerstaff.docx

Martha Frisone, Assistant Chief,
Certificate of Need
Healthcare Planning & Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, specializing in sports medicine and knee and shoulder arthroscopy. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called OrthoCarolina with offices in Clemmons, Winston-Salem, King, Kernersville, Boone, and Ashe County. I practice primarily in the OrthoCarolina offices in Clemmons and Winston-Salem.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

I plan to seek privileges to practice at Novant Health Clemmons Outpatient Surgery, once it has been developed. The proposed surgery center will give patients, families, payors, and surgeons more choices in selecting the venue for their outpatient surgeries.

Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

William L. Craig, III, MD

OrthoCarolina

11 Marie

Fellow American Academy of Orthopaedic Surgeons

File: ClemmonsASCOrthoSuppLtrCraig.docx

Martha Frisone, Assistant Chief,
Certificate of Need
Healthcare Planning & Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, specializing in sports medicine, and arthroscopic and reconstructive surgery of the shoulder and knee. I am an active member of the medical staffs at Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called OrthoCarolina with offices in Clemmons, Winston-Salem, King, Kernersville, Boone, and Ashe County. I practice primarily in the OrthoCarolina office in Winston-Salem.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

I plan to seek privileges to practice at Novant Health Clemmons Outpatient Surgery, once it has been developed. The proposed surgery center will give patients, families, payors, and surgeons more choices in selecting the venue for their outpatient surgeries.

Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

David V Janeway, MD

Ortho Carolina

File: ClemmonsASCOrthoSuppLtrJaneway.docx

Martha Frisone, Assistant Chief,
Certificate of Need
Healthcare Planning & Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, specializing in sports medicine, shoulder and knee arthroscopy, and elbow surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called OrthoCarolina with offices in Clemmons, Winston-Salem, King, Kernersville, Boone, and Ashe County. I practice primarily in the OrthoCarolina offices in Winston-Salem and Clemmons.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Michael P. Lauffenburger, MD

OrthoCarolina

File: ClemmonsASCSuppLtrLauffenburger.docx

Martha Frisone, Assistant Chief,
Certificate of Need
Healthcare Planning & Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, specializing in sports medicine and shoulder and knee arthroscopy. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called OrthoCarolina with offices in Clemmons, Winston-Salem, King, Kernersville, Boone, and Ashe County. I practice primarily in the OrthoCarolina offices in Clemmons and Winston-Salem.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

John E. Ritchie, MD

OrthoCatolina

File: ClemmonsASCOrthoSuppLtrRitchie.docx



Orthopedics & Sports Medicine – Winston Salem 200 Robinhood Medical Plaza Winston Salem, NC 27106

February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, with a specialty in limb preservation. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County, Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Snow B. Daws, MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthoSuppLtrDaws.02.2017.docx



Orthopedics & Sports Medicine – Clemmons 7138 Village Medical Circle Clemmons, NC 27012

February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified Orthopedic Surgeon, specializing in hand surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center and Novant Health Forsyth Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, High Point, Mocksville, Salisbury, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

T. A. Ginn, MD

Novant Health Orthopedic & Sports Medicine



Orthopedics & Sports Medicine – Clemmons 7138 Village Medical Center Clemmons, NC 27012

February 7, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-eligible orthopedic surgeon, with a specialty sports medicine. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, Kernersville, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely

Richard E. Haigler, MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthoSuppLtrHaigler.02.2017.docx



Orthopedics and Sports Medicine 200 Robinhood Medical Plaza Winston-Salem, NC 27106

February 6, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am an orthopedic surgeon, with a specialty in pediatric orthopedic surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Phillip R. Mason, MD

Novant Health Orthopedics & Sports Medicine

File: Clemmons ASCP odiatry Supp Ltr Vogler. 02.2017. docx



Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, with a specialty in foot and ankle surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, and Thomasville.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Stuart M. Saunders, MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthSuppLtrSaunders.02.2017.docx



February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, with a focus in sports medicine and orthopedic adult reconstruction. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely.

Mark L. Schweppe, MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthoSuppLtrSchweppe.02.2017.docx



February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, with a focus in orthopedic trauma and orthopedic surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, Kernersville, and Thomasville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Joseph A Veneziano, Jr., MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthoSuppLtrVeneziano.02.2017.docx



February 7, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr.

Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Kernersville, Thomasville, and Mocksville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing FMC ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

William Ward Sr. MD

Novant Health Orthopedics & Sports Medicine

File: ClemmonsASCOrthoSuppLtrWard.02.2017.docx



February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified orthopedic surgeon, with a specialty in hand surgery. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of orthopedic surgeons called Novant Health Orthopedics & Sports Medicine with offices in Clemmons, Winston-Salem, Mocksville, Salisbury, Kernersville, and Thomasville.

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Sincerely,

Walter H. Wray, III, MD

Novant Health Orthopedics and Sports Medicine

File: ClemmonsASCOrthoSuppLtrWray.02.2017.docx

Podiatrist Support Letters



Mothershed Foot & Ankle 3057 Trenwest Drive Winston Salem, NC 27103

February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified in podiatric medicine. I am an active member of the medical staffs at Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center, where I practice surgery. I practice with a group of podiatrists called Novant Health Mothershed Foot & Ankle with offices in Clemmons, Winston-Salem and Kernersville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Thomas J. Ame, DPM

Novant Health Mothershed Foot & Ankle

File: Clemmons ASCP odiatry SuppLtr Arne. 02.2017. docx

Thomas/Chim, oon



Mothershed Foot & Ankle 3057 Trenwest Drive Winston Salem, NC 27103

February 2, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified in podiatric medicine. I am an active member of the medical staffs at Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center, where I practice surgery. I practice with a group of podiatrists called Novant Health Mothershed Foot & Ankle with offices in Clemmons, Winston-Salem and Kernersville.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Robb A. Mothershed, DPM

Novant Health Mothershed Foot & Ankle

File: Clemmons ASCP odiatry SuppLtrR Mothershed. 02.2017. docx



Limb Preservation 2825 Lyndhurst Ave Suite 105 Winston-Salem ,NC 27103

February 6, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am board-certified in foot and ankle surgery, and wound care. I am an active member of the medical staffs at Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center, where I practice surgery. I practice with a group of surgeons (vascular and orthopedic) called Novant Health Limb Preservation with an office in Winston-Salem.

I am aware that Novant Health Clemmons Outpatient Surgery, LLC is seeking the state's Certificate of Need approval to develop a freestanding, multi-specialty, licensed ambulatory surgery center with two operating rooms and one non-surgical procedure room on the campus of Novant Health Clemmons Medical Center in western Forsyth County. Novant Health plans to relocate two of its existing Forsyth County ORs to NHCOS. A separately licensed ambulatory surgery center on the grounds of Novant Health Clemmons Medical Center will increase local geographic access and affordability to outpatient surgery services in a surgical program that is not hospital-based, which often triggers higher charges for an outpatient surgical case.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Timothy A. Vogler, DPM

Novant Health Limb Preservation

File: ClemmonsASCPodiatrySuppLtrVogler.02.2017.docx

Obstetrician/Gynecologist Support Letters



January 18, 2017

114 Chariois Boulevard Winston-Salem, NC 27103

280 Broad Street, Suite D Kernersville, NC 27284

nhwomancare.org

WomanCare

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

RE: Surgeon Support Letter for Novant Health Clemmons Outpatient Surgery, LLC ("NHCOS") CON Application filed 2/15/2017; a new multi-specialty, licensed 2-OR ambulatory surgery center on the campus of Novant Health Clemmons Medical Center; (Forsyth County/Health Service Area II)

Dear Ms. Frisone:

I am a board-certified Obstetrician/Gynecologist. I am an active member of the medical staffs at Novant Health Clemmons Medical Center, and Novant Health Forsyth Medical Center. I practice with a group of Obstetricians/Gynecologists called Novant Health WomanCare with offices in Clemmons, Kernersville, and Winston-Salem.

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Please give this ambulatory surgery center for your full and fair consideration so that we can expand the options for delivering high quality, affordable and accessible outpatient surgical services in the Clemmons market area.

Sincerely,

Melissa A. Helman, MD, FACOG

Novant Health WomanCare



WomanCare

114 Charlois Boulevard Winston-Salem, NC 27103 280 Broad Street, Suite D Kernersville, NC 27284

nhwomancare.org

January 18, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

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Sincerely,

Pamela A. Oliver, MD Novant Health WomanCare

File: Clemmons ASCObGynSuppLtrOliver.02.2017.docx



January 18, 2017

114 Charlois Boulevard Winston-Salem, NC 27103 280 Broad Street, Suite D

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Sincerely,

Laura B. Ramsay, MD, FACOG Novant Health WomanCare



January 18, 2017

WomanCare

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Kernersville, NC 27284 nhwomancare.org

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Sincerely,

Jaleema N. Speaks, MD, FACOG

Novant Health WomanCare

Jaleema Greaks MD

Urologist Support Letters



Urology Partners

2010 Baldwin Lane Winston Salem, NC 27103

T 336-277-1717 F 336-277-1718

nhurologypartners.org

a department of Novant Health Forsyth Medical Center

February 10, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

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Dear Ms. Frisone:

I am a board-certified Urological Surgeon. I am also an active member of the medical staffs at Clemmons Medical Center, Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical Center. I practice with a group of urologists called Novant Health Urology Partners with offices in Winston-Salem and Kernersville.

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Sincerely.

John H. Wilson, MD

Novant Health Urology Partners

File: ClemmonsASCUrologySuppLtrWilson.02.2017.docx



Urology Partners

2010 Baldwin Lane Winston Salem, NC 27103

T 336-277-1717 F 336-277-1718

nhurologypartners.org

a department of Novant Health Forsyth Medical Center

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Sincerely.

John Joseph Smith III, MD Novant Health Urology Partners

File: ClemmonsASCUrologySuppLtrSmith.02.2017.docx

(min

General Surgeon Support Letters



Salem Surgical Associates

2915 Lyndhurst Avenue Winston-Salem, NC 27103

nhsalemsurgicalassociates.org

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

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Sincerely,

Lori G. Kellam, MD

Novant Health Salem Surgical Associates

David R. Carr, MD
John W. F. Mann, MD
W. Scott Berger, MD
Julio H. Reyes, MD
Jennifer A. Christman, MD
S. Pat Stuart, MD
Thomas P. Mutton, MD
Lori G. Keilam, MD
Christopher T. Hunter, MD
Beth Talent, PA-C
W. Dave Thompson, PA-C
Lisa Darby-OBar, PA-C
Matthew Tucker, PA-C
Kevin Spainhour, NP

T: 336-765-5221 F: 336-765-0430



Salem Surgical Associates

2915 Lyndhurst Avenue Winston-Salem, NC 27103

nhsalemsurgicalassociates.org

February 1, 2017

Martha Frisone, Assistant Chief, Certificate of Need Section Healthcare Planning & Certificate of Need Section NC Division of Health Service Regulation 809 Ruggles Dr. Raleigh, NC 27603

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Sincerely,

S. Patrick Stuart, Jr., MD

Novant Health Salem Surgical Associates

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Single-Specialty Ambulatory Surgery Facility Demonstration Project Annual Evaluation Report Summary Mallard Creek Surgery Center Year 3 (5/7/2016 – 5/6/2017)

Mallard Creek Surgery Center received a license in May of 2014 to operate as an ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan (Plan).

The facility is required to submit an annual report to the Agency showing its compliance with the demonstration project criteria in Table 6D in the 2010 Plan. The Agency received the third annual report on August 2, 2017 for the time period May 7, 2016 to May 6, 2017. Financial data is provided for 6/1/2016-5/31/2017.

The facility reported that of the 55 physicians practicing at the facility, 19 are non-owners of the practice. All physicians maintained privileges at area hospitals. Of the 29 orthopedic surgeons at Mallard Creek, 19 took ER call at local hospitals. The report lists the hospitals at which each physician has privileges and/or took ER call and the number of night of ER call taken.

Based on the facility's information regarding the number of and payor source of the patients served, the Agency was able to verify that the facility's total revenue attributed to self-pay and Medicaid was at least seven percent in its third year of operation. In the facility's first full year of operation, its total revenue attributed to self-pay and Medicaid was 4.4%. The facility explained that it experienced a delay in receiving authorization from CMS, such that it was only able to begin accepting Medicare patients on December 8, 2014 and Medicaid patients on February 23, 2015. To reflect revenue after receiving authorization to accept Medicare patients, its total revenue attributed to Medicaid and self-pay was 5.9% from January 1, 2015 through May 31 2015. To reflect revenue after receiving authorization to accept Medicaid patients, Mallard Creek submitted total revenue attributed to self-pay and Medicaid 8.4% from March 1, 2015 through May 31, 2015. From June 1, 2015 through May 31, 2016 total revenue attributed to self-pay and Medicaid was 7.3%. From May 8, 2015 through May 7, 2016, (the second full year of licensure), the percentage was 7.0%. From June 1, 2016 through May 31, 2017, the percentage was 7.8%. (Attachment A)

Mallard Creek Surgery Center uses a manual surgical safety checklist adapted from the World Health Organization. The facility reported 99.85% completion. (Attachment B)

The facility established several policies and procedures related to quality assurance, along with a clinical quality measures dashboard. In accordance with Condition 8 on the certificate of need, the facility tracks the required measures (wound infection rate, post-operative infections, post-procedure complications, readmissions, and medication errors) and also tracks 12 additional quality indicators. The report contained information showing negative results on the required measures in less than 0.5% of cases. Issues were noted in the areas of readmissions and post-procedure complications. (Attachment C)

Mallard Creek Surgery Center does not have electronic health records (EHR). It does, however, use an electronic scheduling system, and scans chart audits to an electronic system daily to back up health records. The facility is in the process of developing an EHR system, but no target date is available.

The facility documented that it reported utilization and payment data to the statewide data processor, as required by G.S. 131E-214.2 and the demonstration project criteria in Table 6D of the 2010 Plan. (Attachment D)

Based on the review of the annual report, the Agency determined that Mallard Creek Surgery Center materially complies with the demonstration project criteria in Table 6D in the 2010 Plan and the conditions on the certificate of need.

Attachment A

Total Comment of the state of t				
Wallard Creek Suigey Cellici		B. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	Colf.Day	Total
(34)46 6134146)	Indigent	Medicald	Jell-I ay	
70/ Morkshoet (Approx. CON YR2 - 6/1/13 - 3/31/19)			176	698
/ Mariana (April 1997)		10/1		
30300 100,000			017 140	61 749
A # of Surgical Cases	81 749	\$1,749	01, 0	
First And Son Allowable Amount ner Surgical Case			0001000	\$615 408
B Average Medicale Allowable Allowable	\$20 738	\$307.880	\$307,880	0110
	001,030		300 V C#	\$164 296
C Kevenue (A x b)	00	\$129.471	670,400	007,400
Call of the traversity of the payor category)			100 CTCE	6181 202
D Kevenue Collected (Het levellue by payor caregory)	\$20 738	\$178.409	\$273,055	4401,202
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E Difference (C - D)	¢6 507 531	\$6.597.531	1.55,785,93	
- The state of the	00,100,00		/07 7	
F Otal Net Revenue (all payors company)	%¥ U	2.7%	4.1%	
	0.0.0			
G Percentage (= / r)				

			Colf Day	2
(Lated a control of the control of t	Indiant	Medicaid	Sell-Lay	1000
79, Morkshoot (Approx CON YR3 - 6/1/16 - 5/31/17)	III GIBCIII		400	360
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A # of Curcinal Cases		* * C * C	64 044	\$1 944
Condition of the control of the cont	\$1 944	41,944	10,-0	
Terror Medicare Allowable Amount per Surdical Case				\$699 955
D Average Medical C Microsoft	\$77 773	\$311,091		
				£120 713
C IRevenue (A x b)	CO	\$120 765 I		017,0014
() CO	200	201,0210		
bayor of		9700 208		
	\$////3	026,0814		
		700 070		\$7.343.231
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FETTATING POYON (all navors combined)			70 / /	7 8%
ר ו סומו ואפן ואפארוותכ (מון המלכו	1 1%	7.6%	4.1.70	The second secon
	0/			
G Percentage (E / r)				

Attachment A

Revenue and Evners Co.	Attac	hme	ent A
Revenue and Expense Statement Attachment A	From <u>6/1/</u> To <u>5/31</u> /		From <u>6/1/16</u> To <u>5/31/17</u>
# of Surgical Cases			
REVENUE	2	,309	2,532
Net Patient Revenue			
Other Revenue	\$6,597,		\$7,343,231
Total Revenue		\$0	\$0
EXPENSES	\$6,597,	533	\$7,343,231
Direct Expenses			
Total Salaries			
Payroll Taxes and Benefits	\$1,396,		\$1,418,739
Medical Supplies	\$324,		\$372,703
Other Supplies	\$1,655,0		\$1,858,505
Raw Food	\$60,8		\$67,165
Other Direct Expenses (specify)		\$0	\$0
Total Direct Expenses	00.10=	\$0	\$0
Indirect Expenses	\$3,437,2	276	\$3,717,112
Housekeeping/Laundry	000	_	990
Equipment Maintenance	\$38,1		\$40,478
Building & Grounds Maintenance	\$16,6		\$18,600
Utilities	\$17,3		\$32,701
Insurance	\$60,2		\$73,677
Professional Fees	\$14,4		\$20,958
Interest Expense	\$25,0		\$32,539
Rental Expense	\$205,3		\$145,635
Property and other Taxes (except Income)	\$451,8		\$459,658
Depreciation - Buildings	\$172,32		\$187,386
Depreciation - Equipment	\$382,48		\$354,283
Other Indirect Expenses (specify)	\$483,53		\$306,702
Total Indirect Expenses	\$1,137,4		\$1,255,414
Total Expenses	\$3,004,82		\$2,928,031
let Income	\$6,442,09	18	\$6,645,143
ederal & State Income Taxes	\$155,43	5	\$698,088
	\$	0	\$0

SURGICAL SAFETY CHECKLIST

Surgical Safety Checklist #____

1	Before Patient is Transferre	ed to OR	
	☐ Report received from pre-op nurse: TIME:	□ Clippers	
8	☐ Report received from pro-op ☐ RN Circulator verified consent signed and H&P update	☐ SCD's	
h	a Surgical site marked by surgeon	□ Sage wipes	
	☐ RN Circulator has confirmed all necessary equipment/implants are	☐ Antibiotics	prepared
F	ready in OR		· ·
翼	RN Circulator has confirmed rep is available	Pre-op RN:	
	□ OR ready for patient Time: Out Pause		Time:
		800100000000000000000000000000000000000	
	All team members pause to verify:		DRN
86	© correct patient (name and DOB)		
	correct procedure		D CST
	□ correct site	,	- AAT
-35	☐ correct position		□ MD
	□ all implants are available		☐ Fellow
	□ allergies		
	 all necessary images are displayed all sterility indicators have been confirmed 		ΠPA
		es	
M.	 antibiotic prophylaxis has been given within the last of minute any safety concerns are addressed 		□ Private Scrub Tech
	☐ fire risk assessment		
			Anesthesia
P(2			
織	Before Patient is Transferre	d to PACI	
ŀ	☐ RN confirms with surgeon the name of procedure ☐ Sponge and sharp counts are completed and correct		
	Specimens have been correctly labeled to include:		
щ	patient name and DOB		
#Carer	name of specimen including site		
	Any equipment or instrument issues to be addressed?	***************************************	
T	☐ Surgeon, Anesthesia, and RN review key concerns for recovery of	patient	
9	By signing below I agree that this process was con	mpleted:	
	RN Circulator: Da	ate/Time:	
		-1- FE:	
	1	ate/Time:	•
	(if relieved)		•
			·
	·		
	Malland Caroli		
ić.	' Mallard Creek	1	PATIENT LABEL
	**************************************	,	LELEVANA AND A PARTIE A STATE OF STATE

Attachment B

Mallard Creek Surgery Center 2016-2017 Attachment J

	710000000000000000000000000000000000000	
		ASC-7 Volume (total
	ASC-6 Surgical	# of cases performed
Month	Safety Checklist	for the month)
16-May	84.6%	191.00
16-Jun	92.9%	185.00
16-Jul	100.0%	189.00
16-Aug	100.0%	227.00
16-Sep	100.0%	165.00
16-Oct	100.0%	197.00
16-Nov	100.0%	220.00
16-Dec	100.0%	249.00
17-Jan	100.0%	180.00
17-Feb	100.0%	198.00
17-Mar	100.0%	221.00
17-Apr	100.0%	194.00
Average	98.1%	2416.00

Average

Attachment C

DHSR Requirements								the passes were productive the	Control of the Contro	AND CONTRACTOR OF THE PROPERTY			
Complications	0	1	1	1	2	0	2	0	1	0	0	3	11
% by volume	%0.0	0.5%	0.5%	0.4%	1.2%	%0.0	%6.0	%0.0	%9.0	%0:0	%0:0	1.5%	0.46%
ReAdmissions	0	0	0	1	2	0	1	1	0	1	0	2	∞
% by volume	%0.0	%0.0	%0.0	0.4%	1.2%	%0.0	0.5%	0.4%	%0.0	0.5%	%0:0	1.0%	0.33%

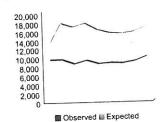
4 CARE COMPARISON

Facility Performance Dashboard

Mallard Creek Surgery Center

Year-to-date: October - December, FY 2017 Data Current as of Q1, 2017

Charges



Charge opportunities

Current	-\$4,608,428
Previous year	-\$7,572,432
2 years prior	-\$3.505.908

Top 10 service lines

		Ranking	Previous year	2 years prior
Service Line	YTD Encounters	Raiking	1 teness y	1
ORTHOPEDIC SURGERY	626	1		
The second secon	24	2	2	3
NEUROSURGERY		3	3	2
PODIATRY				4
GENERAL SURGERY	4	4		
EMERGENCY MEDICINE	1	5	- 0	5
EMERGENCY WEDICINE		5	6	0
OTHER	The same of the sa			

Primary service area market share

0%	Previous year	0%	0% 🔺
U /0	2 years prior	0%	0%

Average events per month

226 Previous year 355 123% Δ
2 years prior 159 894% Δ

Payer mix



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FMC/Clemmons Medical Center

New Community Hospital
CON Application
Filed July 15, 2008
(Forsyth County)
Volume 1 of 4

Clemmons Medical Center (CLMC) Summary Utilization Statistics

The following table shows summary utilization statistics for all inpatient, surgical, outpatient, emergency, observation, and ancillary services during the first three years of operation of the proposed Clemmons Medical Center (CLMC).

Clemmons Medical Center: Summary Utilization Statistics

CLMC Projected Utilization First Three Projec	t Years: 4/1/20	12-3/31/2015	
	PY 1	PY 2	PY 3
Discharges	4,737	4,820	4,904
Days (Including ICU)	11,438	12,696	13,994
ALOS	4.39	4.39	4.39
ADC	31.3	34.8	38.3
Proposed Med-Surg and ICU Bed Capacity	50	50	50
Med-Surg Occupancy	62.7%	69.6%	76.7%
Acute Days (no ICU)	10,473	11,624	12,813
Acute Beds (no ICU)	46	46	46
Acute Care Occupancy	62.4%	69.2%	76.3%
ICU Days	965	1,071	1,181
Proposed ICU Bed Capacity	4	4	4
ICU Occupancy	66.1%	73.4%	80.9%
CLMC Projected Outpatient and Ancillary Services	Utilization: 4/	1/2012-3/31/2	2015
Total Discharges/Visits	PY 1	PY 2	PY 3
Inpatient Discharges	4,737	4,820	4,904
Outpatient Visits	13,645	16,629	19,715
Outpatient Visits w.o. Outpt Surg	11,067	13,678	16,379
ED Visits	11,020	13,616	16,300
Proposed ED Timt Bays/Areas	8	10	12
Observation Days	PY1	PY 2	PY 3
Total Days	1,167	1,295	1,428
Proposed Observation Bed Capacity	6	6	6
Surgery	PY 1	PY 2	PY 3
Inpatient	885	1,012	1,144
Outpatient - MPH Clemmons	2,578	2,951	3,336
Total Surgery	3,462	3,963	4,480
Proposed Shared OR Capacity	5	5	5
GI Endoscopy	PY 1	PY 2	PY 3
Total	1,279	1,464	1,655
Ancillary Procedures	PY-1	PY 2	PY 3
MRI (mobile)-By Contract with 3 rd Party Vendor	1,670	1,945	2,230
CT	8,299	9,647	11,041
Nuclear Medicine	2,023	2,305	2,597
Mammogram	1,982	2,431	2,894
Ultrasound	3,120	3,638	4,173
Other Radiology	15,738	18,067	20,474
Pharmacy Units	450,514	474,025	498,233
Lab Tests	115,880	124,905	134,214

Source: Note: Project Year 1 = 4/1/2012 - 3/30/2013

Methodologies Used to Project Future Need

CLMC used two basic methodologies to project future utilization for the proposed project.

1. A Use Rate Methodology

Projected Utilization = (Defined Service Area Population x Use Rate x Market Share) + Other Inmigration was used to project:

- Acute care inpatient discharges, days, and bed need;
- ICU days and ICU bed need;
- Observation bed days and observation bed need;
- Inpatient and outpatient surgical procedures and shared operating room need;
- GI endoscopy procedures and GI endoscopy procedure room need;
- Outpatient visits; and
- Emergency Department visits and emergency treatment rooms need.

This methodology has been substantiated as a reasonable methodology for projecting future beds, operating rooms, emergency services, outpatient and other hospital services as it was utilized in recently approved CON applications for Brunswick Community Hospital (Project I.D. #O-7767-06), Presbyterian Hospital Mint Hill (Project I.D. #F-7448-06) and FMC-Kernersville (Project I.D. #G-7604-06).

2. Ancillary utilization projections were calculated based upon existing ancillary utilization patterns at existing Novant Health community hospitals. Data from other similarly sized Novant community hospitals at Thomasville Medical Center (TMC), Brunswick Community Hospital (BCH), Presbyterian Hospital Matthews (PHM) and Presbyterian Hospital Huntersville (PHH) were averaged to determine rates and ratios for ancillary services. CLMC assumes that projected ancillary utilization at CLMC will imitate current ancillary utilization patterns at these facilities.

This methodology has been substantiated as a reasonable methodology for projecting future beds, operating rooms, emergency services, outpatient and other hospital services as it was utilized in recently approved CON applications for Brunswick Community Hospital (Project I.D. #O-7767-06), Presbyterian Hospital Mint Hill (Project I.D. #F-7448-06) and FMC-Kernersville (Project I.D. #G-7604-06).

Assumptions Consistent Throughout Projections

CLMC utilized the following assumptions throughout the projections.

Zip Code Population Projections

The proposed Clemmons service area consists of two zip codes in Forsyth County and three zip codes in Davie County. Population growth in the defined service area is expected to continue into the next decade. Therefore, population is expected to grow at the same rate through 2015 as reflected in the following table.

Population of Defined Service Area

		MPH (Iemmons S	ervice Area	- Projected	l Population	Growth F	Cate		
Zip Code	Town	2008	2009	2010	2011	2012	2013	2014	2015	CAGR
27006	Advance	13384	13,693	14,010	14,333	14,664	15003	15,350	15,704	1.023
27012	Clemmons	25089	25,478	25,873	26,275	26,682	27096	27.516	27,943	1.016
27023	Lewisville	11039	11,188	11,340	11,494	11,649	11807	11,967	12,129	1.014
27028	Mocksville	27666	28,161	28,665	29,178	29,700	30232	30,773	31,324	1.018
Total		77,178	78,521	79,888	81,280	82,696	84,138	85,606	87,100	1.017

Source: Claritas;

Note: Zip code 2/014 is a PO Box location in Cooleemee which is in Davie County geographically located within the Mocksville zip code, 27028

Other Inmigration Assumption

While not part of the defined service area, CLMC recognizes that patients from other North Carolina counties may choose to travel across service areas to receive services at CLMC, or may end up having to seek hospital services while in the service area for business or pleasure. As a result, 10% of the total projected utilization in each of the project years has been allocated to the category of "Other Inmigration"." Other inmigration is expected to come from surrounding zip codes in Forsyth County and other surrounding counties, such as Iredell and Yadkin. In calendar year 2007 residents of Iredell and Yadkin Counties represented a substantial percentage of both FMC and MPH patient origin as reflected in the 2008 Annual Hospital Licensure Renewal Applications. All inmigration to CLMC is assumed to be a shift of patients to CLMC from FMC and MPH. This estimate of inmigration is consistent with other Novant Health CON Applications for new community hospitals based upon zip code level data approved by the CON Section. See e.g., Agency Findings for Presbyterian flospital Mint Hill (Project I.D. #F-7448-06) (December 2006).

Clemmons Medical Center Utilization Projections

1. Projected Acute Care Inpatient Discharges, Days, and Bed Need

Projected acute care inpatient discharges, days, and bed need were determined as follows:

Three Year Average Acute Care Inpatient Discharge Use Rate

As previously discussed, the proposed CLMC will be a community hospital without obstetric services ⁴⁰; therefore, obstetrics, cardiac surgery and other tertiary level services will not be provided. To determine total medical/surgical discharges and patient days at CLMC, zip code level inpatient cases and inpatient days and zip code level acuity adjusted inpatient cases and inpatient days were determined using the Solucient/Thomson database. The term, "acuity adjusted" as used in this application reflects all exclusions referenced in the following table, made from the Solucient/Thomson database of discharges and patient days from the defined service area.

³⁹ "Other Immigration" reflects utilization of a facility over and above the historically defined "Primary and Secondary Service Area." A facility's primary and secondary service area is customarily defined as the markets from which 80% to 90% of patient days or utilization originate. This also is known as those markets upon which the hospital depends for its success. Therefore, "Other Inmigration" is historically between 10% to 20% of total utilization. Consistent with the approach taken in the (approved) Presbyterian Hospital Mint Hill application and FMC Kernersville Medical Center, CLMC has used 10% inmigration in this application.

FMC and NCBH have a long standing agreement for the provision of jointly-sponsored obstetrical services on the FMC campus. In addition, the new Women's Pavilion at FMC will be open in February 2008. NCBH also offers specialty pediatric services at Brenner Children's Hospital on a dedicated floor(s) in the NCBH hospital facility.

Solucient/Thomson Database Exclusions CY 2003-2006

Medical Surgical Exclusions
Mental Health and Drug Abuse DRGs (424-433 and 521-523)
Rehab (462)
Normal Newborns (391)
Delivery DRGs (370-375)
NICU (385-390)
Diagnostic Cardiac Cath (124,125)
DRGs with FY2005 Relative Weight > - 2.0

Source:

CLMC analyzed FFY 2005 – 2007 (10/1/05-9/30/07) zip code level Solucient/Thomson data to determine the acute care inpatient discharge use rate per 1,000 population. The following table shows the three year average (FFY 2005-2007) acute care inpatient discharge use rate per 1,000 population for total patient days in the combined five zip code service area and acuity adjusted patient days in the combined five zip code service area.

Three Year Average Acute Care Inpatient Discharge Use Rate

	2005	2006	2007
Population	71,602	73,000	74,832
Total Discharges - Combined Service Arca	6,949	6,975	6,938
Use Rates	97.05	95.55	92.71
3 Yr Average			95.10
Population	71,602	73,000	74,832
Total Acuity Adjusted Discharges –			
Combined Service Area	4,555	4,924	4,908
Discharge Use Rate	63.62	67.45	65.59
3 Yr Avcrage			65.55
Percent Acuity Adjusted Discharges of Total	65.5%	70.6%	70.7%
Discharges	7.02.20	1/0.0%	/U./70

Source,

Note: the three year period includes: FFY 2005- FFY 2007

The three year average acute care inpatient discharge use rate, for total discharges, for the combined zip code was used to determine total acute care inpatient discharges for the defined service area for the first three years of the proposed project. The combined service area use rate was used because several zip codes in the service area had limited admissions and using a larger population base results in a more realistic discharge rate with less fluctuation. The previous table also shows that acuity adjusted discharges represented over 70% of total discharges in FFY 2007.

Projected Acute Care Inpatient Market Share in Defined Service Area

Using the Solucient/Thomson FFY 2005 - 2007 inpatient discharge data, CLMC calculated the Novant acute care inpatient market share for each zip code in the defined service area. The following table shows actual Novant acute care inpatient discharges, total acute care inpatient discharges, and Novant acute care inpatient market share for each of the five zip codes in the defined service area and the combined market share for the five zip code service area.

Novant Inpatient Market Share in Defined Service Area FFY 2005 - 2007

	200	5	200	6	20	07
Hospital	Cases	Mkt Share	Cases	Mkt Share	Cases	Mkt Share
77996 - David						
Forsyth Memorial Hospital	847	69.0%	794	64.1%	768	63.8%
Medical Park Hospital	43	3.5%	42	3.4%	27	2.2%
Total 27006	1,228		1,238		1,204	
27012 - horsysta						
Forsyth Memorial Hospital	1,340	68.1%	1,421	70.3%	1,455	69.7%
Medical Park Hospital	74	3.8%	62	3.1%	86	4.1%
Total 27012	1,967		2,022		2,089	
27023 - Forsyth						
Forsyth Memorial Hospital	575	69.9%	553	70.6%	557	68.3%
Medical Park Hospital	39	4.7%	24	3.1%	37	4.5%
Total 27023	823		783		815	
18014 - Davie					AND THE PERSON NAMED OF TH	
Forsyth Memorial Hospital	63	25.4%	49	26.3%	68	29,6%
Medical Park Hospital	1	0.4%	1	0.5%		0.0%
Total 27014	248		186		2.30	
17618 Basse						
Forsyth Memorial Hospital	1,176	43.8%	1,164	42.4%	1,106	42.5%
Medical Park Hospital	67	2.5%	48	1.7%	57	2.2%
Total 27028	2,683		2,746		2,600	
Total Novant	4,225	61%	4,158	60%	4,161	60%
Total All 5 Zip Codes	6,949		6,975		6,938	

Source: Solucient/Thomson; Exhibit 5, Lable

The market share for the combined zip code service area was used to determine acute care inpatient discharges by zip code in the defined service area for the first three years of the proposed project.

Projected Acute Care Inpatient Discharges in Defined Service Area

CLMC projected total acute care inpatient discharges for the first three years of operation for the combined service area using the following methodology:

Projected Acute Care Inpatient Discharges = (Defined Service Area Population x Three Year Average Acute Care Inpatient Discharge Use Rate x Market Share)

The resulting total projected acute care inpatient discharges for the CLMC service area are reflected in the following table.

Total Projected Acute Care Inpatient Discharges

	2012	2013	2014	2015
Total CLMC Service Area Population	82,696	84,138	85,606	87,100
Service Area Non-Acuity Adjusted Inpatient Discharge Use Rate	95.10	95.10	95.10	95.10
Projected Inpatient Cases Total Service Area	7,865	8,002	8,141	8,284
Novant Market Share	60%	60%	60%	60%
Projected Total Novant Service Area Inpatients	4,717	4,799	4,883	4,968

Source: Fakilly 2. Takie 6

CLMC is projected to be operational April, 2012. CLMC converted projected discharges to project years in the following table.

Total Projected Acute Care Inpatient Discharges April 2012 – March 2015

PY 1	PY2	PY3
Apr12-Mar13	Apr13-Mar14	Apr14-Mar15
4,737	4,820	4,904

Source:

Projected CLMC Acuity Adusted Inputient Discharges

CLMC assumed 65 % of total projected acute care inpatient discharges would be appropriate for a proposed community hospital based upon historical Solucient/Thomson data. The following table reflects acuity adjusted discharges for the combined five zip code service area as a percent of total discharges.

Three Year Acute Care Inpatient Discharges

	2005	2006	2007
Total Discharges - Combined Service Area	6,949	6,975	6,938
Total Acuity Adjusted Discharges -			
Combined Service Arca	4,555	4,924	4,908
Percent Acuity Adjusted Discharges of Total			
Discharges	65.5%	70.6%	70.1%

Source:

Note: the three year period includes: FFY 2005- FFY 2007

As shown in the previous table, approximately 70% of total discharges fit the CLMC definition of acuity adjusted discharges without obstetrical services.

CLMC assumed that volume for the new hospital would come from existing Novant market share and that market share would remain constant for the first three years of operation of the new community hospital. CLMC also assumed that the proposed volume shift from FMC and MPH would occur gradually over the first three years of operation, shifting 55% in Project Year 1, 60% in Project Year 2, and 65% in Project Year 3 as reflected in the following table.

CLMC Projected Discharges April 2012 – March 2015

	PY 1 Apr12-Mar13	PY2 Apr13-Mar14	PY3 Apr14-Mar15
Total Projected Service Area Discharges	4,737	4,820	4,904
Percent Shifted from Existing Facilities (70% Acuity Less than 2.0 = Appropriate for Shifting;)	55%	60%	65%
Clemmons Medical Center Inpatient Discharges	2.606	2,892	3,188

Source

Total projected acute care inpatient discharges reflected in the previous table for April 2012 - March 2015 were used to project total acute care inpatient days for CLMC.

Projected Acute Care Inpatient Days and Bed Need in Defined Service Area

FFY 2007 Solucient/Thomson Novant acuity adjusted acute care inpatient discharge and inpatient day data specific to the defined zip code service area was used to determine an acuity adjusted average length of stay

of 4.39 days for the service area. Actual data is included in Example 5. Annual total acute care acuity-adjusted inpatient discharges were multiplied by average length of stay to project acute care bed need in each of the three project years.

Projected Acute Care Inpatient Days and Bed Need

	PY 1 Apr12 - Mar13	PY 2 Apr13 – Mar14	PY 3 Apr14 - Mar15
Total Acute Care Inpatient Discharges	2,606	2,892	3,188
Average Length of Stay	4.39	4.39	4.39
Total Inpatient Days	11,438	12,696	13,994
ADC	31.3	34.8	38.3
Acute Care Bod Need @ 66.7% Occupancy	47.0	52.1	57.5
Proposed Total Acute Care Beds	50.0	50.0	50.0
Occupancy @ 50 Acute Care Beds	62.7%	69.6%	76.7%

Source:

The previous table reflects projected acute care bed need based upon the State Medical Facilities Plan Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients. The application of the state's SMFP new acute bed need method results in an acute care bed need at CLMC of 57 acute care beds in 2015. The proposed 50 acute care bed hospital is projected to achieve an occupancy level of 76.7% in 2015.

2. Projected ICU Days and Bed Need

Projected ICU beds were determined using total projected inpatient days and FFY 2007 ICU utilization data from North Carolina hospitals. CLMC reviewed historical ICU utilization for all hospitals in North Carolina reporting ICU utilization. This data is included in a children in the latter of latter

Based upon the total North Carolina ICU database, CLMC ICU days were projected assuming that 8.4% of total patient days would be ICU days. This percent represents the average ICU days as a percent of total days for North Carolina hospitals in the lower 50% ranking of ICU days as a percent of total days as reflected in the lower 50% ranking of ICU days as a percent of total days as

For community hospitals with total patient days in a range similar to the projected patient days for CLMC, the percent of total days that were ICU days in FFY 2007 was 11.3%. Therefore, the CLMC projected ICU days reflects a conservative estimate of total days. CLMC elected to be conservative as the proposed satellite hospital is projected to offer a full-service suburban community hospital level of care (based on DRG acuity weights of less than 2.0) for residents of the Clemmons service area. The following table shows projected ICU patient days and the resulting ICU bed need for CLMC.

CLMC
Projected ICU Patient Days and Bed Need

	PY 1 Apr12 – Mar13	PY 2 Apr13 – Mar14	PY 3 Apri4 – Mari5
Total Inpatient Days	11,438	12,696	13,994
Projected ICU Days (8.4%)	965	1,071	1,181
Average Daily Census	2.6	2.9	3.2
ICU Bed Need @ 60% Occupancy	4.4	4,9	5.4
Occupancy @ 4 ICU Beds	66.1%	73.4%	80.9%

Source:

The previous table reflects projected ICU patient days and ICU bcd need based upon the CON Criteria And Standards ICU performance standard of 60% for facilities with small ICUs, which results in a need at CLMC of 4 ICU beds in PY 3 (April 2014 – March 2015). The proposed 4 bcd ICU unit is projected to achieve an occupancy level of 80.9% in PY 3.

3. Projected Observation Patient Days and Bed Need

CLMC reviewed historical utilization of observation beds and days for all hospitals in North Carolina reporting observation days in the 2008 Hospital Licensure Renewal Application. This data is included in the latest the latest to be a consistent of the latest to be a consistent of the latest to be a consistent days was varied across hospital sizes and services. However, at hospitals with designated observation units, the mean ratio of acute inpatient days to observation days was 1:14.3, the median ratio was 1:10.3, and the data was bi-modal with modes at 1:9.8 and 1:9.0 acute care days. CLMC used 9.8 acute care days to one observation day to project future observation bed need at CLMC.

Furthermore, the FFY 2007 observation day utilization data from BCH, TMC, PHM and PHH reflect ratio of 9.0 acute care days to one observation day. The average of these four facilities is a reasonable assumption consistent with previously approved CON applications. However, CLCM utilized the more conservative ratio, 9.8 acute care days per 1 observation day based upon the review of 2008 LRAs to project observation bed need at CLMC. The following table shows projected observation patient days and the resulting observation bed need.

CLMC
Projected Observation Patient Days and Bed Need

	PY 1 Apr12 – Mar13	PY 2 Apr13 – Mar14	PY 3 Aprl4 - Marl5
Total Inpatient Days	11,438	12,696	13,994
Projected Observation Patient Days (Ratio = 1:9.8)	1,167	1,295	1,428
Average Daily Census	3.2	3.5	3.9
Observation Bcd Necd @ 66.7% Occupancy	5	5	6

Source:

Note: Observation Bed Need calculation = 3.9 ADC/66.7% target occ rate = 5.8 beds needed

The previous table reflects projected observation patient days and bed need based upon the *State Medical Facilities Plan* Acute Care Bed Need Methodology planning occupancy target of 66.7% for facilities with an average daily census less than 100 patients, which results in a need for 6 observation beds at CLMC in PY 3 (April 2014 – March 2015).

4. Projected Surgical Cases and Shared Operating Room Need

Projected surgical cases and shared operating room need were determined as follows:

2007 Inpatient and Outpatient Surgical Use Rates Forsyth and Davie County

Inpatient and outpatient surgical cases from Forsyth and Davie County were aggregated from the 2008 Hospital Licensure Renewal Applications and the 2008 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2007 were obtained from the North Carolina Office of State Demographics⁴¹. Inpatient and outpatient surgical use rates for 2007 were calculated for Forsyth and Davie Counties, respectively, and are shown in the following table.

2007 Inpatient and Outpatient Surgical Use Rates

Zip Code	City	County	Inpatient Surgical Use Rate	Outpatient Surgical Use Rate
27006	Advance	Davie	32.5	77.73
27012	Clemmons	Forsyth	32.98	67.54
27023	Lewisville	Forsyth	32.98	67.54
27028	Mocksville	Davie	32.5	77.73

Source:

Inpatient Surgical use rate were within a narrow range for the CLMC proposed service area zip codes. However, outpatient surgical use rates for the CLMC proposed service area zip codes varied significantly between Forsyth and Davie County zip codes in 2007. Use rate variations reflect different surgical practice patterns in the two counties and may reflect a lack of local access to the full continuum of outpatient surgical services. The county specific surgical use rate for each zip code was used to determine total inpatient and outpatient surgery in the defined service area for the first three years of the proposed project.

Projected Surgical Market Share in the Defined Service Area

Using FFY 2007 inpatient and outpatient surgical case data from 2008 Hospital Licensure Renewal Application, CLMC calculated the Novant surgical market share for each county. Data is included in The following table shows actual Novant inpatient and outpatient surgical cases, total inpatient and outpatient surgical cases, and Novant market share for each of the five zip codes in the defined service area.

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Novant Surgical Market Share in the Defined Service Area: FFY 2007

Zip Code	County	Novant Surgical Cases	Total Surgical Cases	Novant Market Share
Inpatient				
27006	Advance	243	721	57.6%
27012	Clemmons	536	799	67.1%
27023	Lewisville	230	342	67.1%
27028	Mocksville	511	887	57.6%
Outpatient				
27006	Advance	555	1007	55.2%
27012	Clemmons	944	1636	57.7%
27023	Lewisville	405	701	57.7%
27028	Mocksville	1170	2121	55.2%

Source: Solucient/Thomson;

CLMC also assumed that the proposed market shift from FMC and MPH in Winston-Salem will occur gradually over the first three years of CLMC operation, realizing 70% of projected market share in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3. The proposed market share shift from FMC and MPH to CLMC is reflected in the following table.

Inpatient and Outpatient Market Share Shift From FMC and MPH to CLMC

NHTR Mkt Share	2007	Percent Shift	PY 1 Apr12 – Mar13	PY 2 Apr13—Mar14	PY 3 Apr14 – Mar15
Davic Inpatient	57.6%	59%	80%	90%	100%
Davie Outpatient	55.2%	85%	80%	90%	100%
Forsyth Inpatient	67.1%	59%	80%	90%	100%
Forsyth Outpatient	57.7%	85%	80%	90%	100%

Source: Solucient/Thomson;

The projected market share for each zip code was used to determine projected inpatient and outpatient surgical cases by zip code in the defined service area for the first three years of the proposed project.

Projected Surgical Cases in Defined Service Area

CLMC projected surgical utilization for the first three years of operation using the following methodology:

Projected Inpatient Surgical Cases = (Defined Service Area Population x Inpatient Surgical Use Rate x Market Share) + "Other Inmigration"

AND

Projected Outpatient Surgical Cases = (Defined Service Area Population x Outpatient Surgical Use Rate x Market Share) + "Other Inmigration"

CLMC projected surgical cases by zip code are reflected in the following table. Projected inmigration and total surgical cases also are included.

CLMC Projected Surgical Cases Project Years 1 – 3

Inpatient	Town	County	PY 1 Apr12 - Mar13	PY 2 Apr13 – Mar14	PY 3 Apr14 – Mar15
27006	Advance	Davie	130	150	171
27012	Clemmons	Forsyth	280	320	361
27023	Lewisville	Forsyth	122	139	157
27028	Mocksville	Davie	264	302	342
Inmigration 10%			88	101	114
Total Inpatient			885	1012	1144
Outpatient	Town		PY 1 Apr12 – Mar13	PY 2 Apr13 – Mar14	PY 3 Apr.14 – Mar.15
27006	Advance	Davie	430	495	563
27012	Clemmons	Forsyth	710	811	915
27023	Lewisville	Forsyth	310	353	398
27028	Mocksville	Davie	870	996	1127
Inmigration 10%			258	295	334
Total Outpatient			2578	2951	3336

Source:

Total projected surgical cases reflected in the previous table were used to project shared operating rooms needed for CLMC.

Projected Shared Operating Room Need in the Defined Service Area

Projected inpatient and outpatient surgical cases were used to project shared operating rooms needed at CLMC using the case weighting and operating room capacity assumptions used in the State Medical Facilities Plan Operating Room need methodology. The following table reflects the operating rooms needed.

Projected Shared Operating Room Need at CLMC Project Years 1-2-3

	(1) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	PY 2 Apr13 – Mar14	PY 3 Apr14 – Mar15
Total Inpatient Surgical Cases	885	1,012	1,144
Total Outpatient Surgical Cases	2,578	2,951	3,336
Weighted Procedures	6,521	7,463	8,437
OR Need @ Planning Capacity	3.5	4.0	4.51
OR Need Upon Rounding	4	4	5

Source:

The previous table shows projected inpatient and outpatient surgical cases and the resulting shared operating rooms needed based upon the State Medical Facilities Plan Surgical Operating Room Need Methodology, inpatient surgical case weighting of 3.0 hours per case, outpatient surgical case weighting of 1.5 hours per case, and a planning capacity target of 1,872 operating hours per year, which results in a need at CLMC for 5 shared surgical operating rooms in 2015.

Surgery market volume shift for years one and two were projected slightly less as the facility is new and time is allowed for the volume to grow. The following factors were considered important to the determination of the percent of market volume projected to shift from the zip code service area.

- Surgical scheduling for all NTR surgical facilities is centralized and surgical administration works with physicians and patients to maximize utilization of surgical resources.
- CLMC is closer to all areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in Salan Salan and Map 5;
- There currently are four NMG-Forsyth employed practices in the defined service area: Medical Associates of Davie/Mocksville-27028 & Medical Associates of Davie/Hillsdale-27006 (7 MDs, 5 extenders); Clemmons Family Practice/Clemmons-27012 (3 MDs, 2 extenders), Family Medical Associates of Lewisville/Lewisville-27023 (5 MDs); and West Forsyth Family Medicine/Clemmons-27012 (1 MD, 2 extenders); a total of 28 medical providers with established practices and satisfied patients;
- These established physician practices and other nearby NMG practices combined have existing doctor-patient relationships with 45,200 patients that reside in the CLMC 5-Zip Code service area for the most recent 12-month period (June 1, 2007 May 31, 2008). NMG patient visits during that same time period for the these residents of Clemmons, Lewisville, and Davie County were over 150,000;
- Additional physician offices with easier access will be developed in the future on the CLMC campus;
- Congestion and traffic on I-40 into Winston Salem will increase;
- CLMC offers a choice for surgical services closer to home;
- The proposed location of CLMC adjacent to I-40 and the Harper Rd. interchange, just two miles from the Davic County border, will result in ease of access to the existing population in the defined zip code service area;
- Some patients will continue to seek care at other existing surgical facilities, therefore 100% of the demand for services in the five zip codes will not shift to CLMC;
- Based upon an analysis of both acuity-adjusted inpatient surgery as a percent of total surgery at FMC and MPH and as a percent of total surgery for the service area at FMC and MPH, 65% to 70% of total surgery performed at FMC and MPH is appropriate for the proposed surgical services program at CLMC.

5. Projected GI Endoscopy Procedures and GI Endoscopy Procedure Room Need

Projected GI endoscopy cases, cases per procedure, and GI endoscopy procedure room need were determined as follows:

2007 GI Endoscopy Use Rate Forsyth and Davie County

GI endoscopy cases from Forsyth and Davic County were aggregated from the 2008 Hospital Licensure Renewal Applications and the 2008 Freestanding Ambulatory Surgery Center Annual Licensure Renewal Applications. County population estimates for 2008 were obtained from the North Carolina Office of State Demographics⁴². The GI endoscopy use rate per 1,000 population for 2007 was calculated for Forsyth and Davie County, respectively, and is reflected in the following table.

2007 GI Endoscopy Use Rates: CLMC Service Area

Zip Code	City	County	GI Endoscopy Use Rate
27006	Advance	Davie	59.15
27012	Clemmons	Forsyth	59.52
27023	Lewisville	Forsyth	59.52
27028	Mocksville	Davie	59.15

Source.

GI endoscopy utilization varied slightly between Forsyth and Davic Counties in 2007. Use rate variations reflect different medical practice patterns in the two counties. Also of note is that existing FMC-affiliated gastroenterology practices periodically offer GI endoscopy services in Yadkin & Davie Counties. The county specific GI endoscopy use rate was used to determine total GI endoscopy cases by zip code in the defined service area for the first three years of the proposed project. Total GI endoscopy cases projected in the defined service area are reflected in the following table.

Projected GI Endoscopy Cases

Zip	Town	County	PY 1 Apr12-Mar13	PY2 Apr13-Mar14	PY3 Apr14-Mar15
27006	Advance	Davie	872	893	913
27012	Clemmons	Forsyth	1,594	1,619	1,644
27023	Lewisville	Forsyth	696	705	715
27028	Mocksville	Davic	1,765	1,796	1,828
Total Cases			4,927	5,013	5,100

NOTE: Projected Endoscopy Volume is Based upon County Use Rate and Converted to Project Years Source:

Projected GI Endoscopy Novant Market Share in the Defined Service Area

Using 2007 GI endoscopy case data from the hospital licensure renewal applications, CLMC calculated the Novant market share for both Forsyth and Davic County in the defined CLMC service area. Data is included in a lateral to the lateral to and is reflected in the following table.

Novant Current and Projected GI Endoscopy Market Share

County	2007	Projected Market Share Increase	Projected Market Share
Davie	17.0%	15.0%	32.0%
Forsyth	22.1%	15.0%	37.1%

Source:

CLMC GI endoscopy projections reflect an increase in market share to reflect a percent market share increase as shown in the previous table. Currently the only GI endoscopy procedure room in the service area is located in Mocksville. Projected GI endoscopy volume in the service area can justify 4.4 additional GI endoscopy rooms in the future based population growth and upon 1,500 procedures annually per room, the State required performance standard for additional GI endoscopy rooms, as shown in the following table.

CLMC Service Area Projected GI Endoscopy Procedure Rooms Needed

Zip	Town	County	PY 1 Apr12-Mar13	PY2 Apr13-Mar14	PY3 Apr14-Mar15
27006	Advance	Davie	872	893	913
27012	Clemmons	Forsyth	1,594	1,619	1,644
27023	Lewisville	Forsyth	696	705	715
27028	Mocksville	Davic	1,765	1,796	1,828
Total Cases			4,927	5,013	5,100
Procedures = Cases x 1.29			6,356	6,466	6,579
GI Endoscopy Rooms at					
1500 Procedures Each			4.2	4.3	4.4

Source:

CLMC also assumed that the proposed market shift, 85% of total volume currently at FMC, will occur gradually over the first three years of operation, realizing 80% of projected market share in Project Year 1, 90% in Project Year 2, and 100% in Project Year 3.

Projected GI Endoscopy Cases in Defined Service Area

CLMC projected GI endoscopy cases for the first three years of operation using the following methodology:

Projected GI Endoscopy Cases = (Defined Service Area Population x GI Endoscopy Use Rate x Market Share) + "Other Inmigration"

CLMC projected GI Endoscopy Cases by zip code are reflected in the following table. Projected "Other Inmigration" and total GI endoscopy cases also are included.

CLMC Projected GI Endoscopy Cases Project Years 1 – 3

Zip	Town	County	PY 1 Apr12-Mar13	PY2 Apr13-Mar14	PY3 Apr14-Mar15
27006	Advance	Davie	190	219	248
27012	Clemmons	Forsyth	402	459	518
27023	Lewisville	Forsyth	175	200	225
27028	Mocksville	Davie	384	440	497
lnmigration 10%			128	146	166
Total GI Endo Room					
Cases			1,279	1,464	1,655

Source:

Total projected GI endoscopy cases reflected in the previous table for April 2012 – March 2015 were used to project GI endoscopy procedures and GI endoscopy procedure rooms needed for CLMC.

<u>Projected GI Endoscopy Procedures and GI Endoscopy Procedure Room Need in the Defined Service</u> <u>Area</u>

CLMC reviewed 2008 Hospital Licensure Renewal Application GI endoscopy data, included in to determine that 6.1% of endoscopy cases in GI endoscopy rooms are for bronchoscopy and other non-GI endoscopy procedures and that 1.29 GI endoscopy procedures are performed per endoscopy case at existing Novant Health community hospitals. Projected GI endoscopy cases were adjusted to delete

non-GI endoscopy procedures and were then multiplied by average 1.29 procedures per case to determine projected GI endoscopy procedures and GI endoscopy procedure rooms needed at CLMC as shown in the following table.

Projected GI Endoscopy Cases Project Years 1 – 3

Zip	PY 1 Apr12-Mar13	PY2 Apr13-Mar14	PY3 Apr14-Mar15
Total CLMC Projected GI Endo Room Cases	1,279	1,464	1,655
Total GI Endo Cases – Total Cases minus 6.1 %			
Non GI Endo Cases	1,201	1,375	1,554
Total Procedures - GI Only Procedures x 1.29			
Procedures per Case	1,546	1,770	2,000
GI Endo Rooms Needed @ 1500	1.0	1.2	1.3

Source.

The previous table reflects total GI endoscopy procedures, and GI endoscopy procedure room need based upon CON Criteria and Standards GI Endoscopy planning standard of 1,500 procedures per room, which results in a need at CLMC for 1 GI endoscopy procedure room in 2015.

6. Projected Hospital Outpatient Visits

Projected hospital outpatient visits were determined as follows:

2006 North Carolina Hospital Outpatient Visit Use Rate

CLMC used the North Carolina Hospital Outpatient Visit Use Rate for community hospitals defined by the American Hospital Association (AHA) ⁴³ to project CLMC outpatient visits. Data compiled from the AHA Annual Survey are used to calculate state specific utilization rates. This rate includes emergency visits but not outpatient surgery.

The 2006 North Carolina Hospital Outpatient Visit Use Rate, adjusted to remove emergency visits, was 150.1 visits per 1,000 population as reflected in Extended Latence of This is the most current outpatient visit rate that is publicly available. CLMC used the 2005 North Carolina Hospital Outpatient Visit Use Rate to determine total outpatient visits and NHTR market share by zip code in the defined service area for the first three years of the proposed project. This methodology is the same methodology used to project outpatient visits for Presbyterian Hospital Mint Hill, previously approved by the CON Section.

Current Outpatient Visits and Market Share in the Defined Service Area

Using calendar year outpatient visit data from the NHTR internal Trendstar database, CLMC calculated the NHTR market share for each zip code in the defined service area. Relevant data is included in . The following table shows NHTR outpatient visits, total outpatient visits, and NHTR market share for zip codes in the defined service area.

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Novant Health Hospital Outpatient Market Share in the Defined Service Area April 2012 – March 2015

Zip Code	County	NH Winston Salem Outpatient Visits	Total Outpatient Visits	NH Winston Salem Market Share
27006	Davie	3,396	19,442	17.5%
27012	Forsyth	6,012	36,350	16.5%
27023	Forsyth	2,651	15,580	17.0%
27028 (<u>includes 28014 Volume</u>)	Davie	5,382	40,950	13.1%

Source:

Market Volume Shift and Market Share Assumptions

The following assumptions related to the percent market volume shift from FMC and MPH in Winston-Salem to CLMC in Clemmons and resulting market share for the proposed CLMC are used in the projections. The following percent market volume shift was used to project outpatient visit volume at CLMC.

Percent Market Volume Shift from Existing NHTR Winston Salem Facilities to CLMC

Zip Code	Percent Market Volume Shift
27006	75.0%
27012	75.0%
27023	75.0%
27028 (Includes 28014 Volume)	75.0%

Source:

The proposed facility will be located near the border of these two zip codes; CLMC will be located about 2 miles from the Forsyth-Davie County border. The following factors were considered important in the determination of the projected market share of hospital outpatient visits from each zip code:

- The new hospital will be a community hospital and will have a full range of outpatient services including imaging, laboratory, pharmacy, physical therapy, etc., in addition to surgical services. There is currently no full service community hospital in the proposed service area.
- CLMC will treat a variety of patients as inpatients, emergency patients and patients referred from local physicians with asthma, strokes, orthopedic injuries and other diagnosis which require outpatient therapy services such as physical therapy, speech therapy, occupational therapy, respiratory therapy; utilization of these outpatient are included in these outpatient projections.
- Much of FMC's outpatient imaging volume is referred to other NHTR/Excel Imaging and MedQuest freestanding imaging facilities in Winston-Salem, such as Maplewood Imaging Center, Salem MRI Center, The Breast Clinic, and Piedmont Imaging; therefore, this volume was not included in the calculation of current hospital outpatient visit market share.
- CLMC is closer to areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in a code of the decision;
- New physician offices with easier access will be developed in the future on and near the CLMC campus;
- Congestion and traffic on I-40 into Winston Salem will increase;
- CLMC offers a choice for outpatient services closer to home;

- The proposed location of CLMC adjacent to I-40 at the Harper Rd. interchange will result in ease of access to the existing population in the defined zip code service area;
- Interstate I-40 will result in population growth in the defined zip code service area;
- Some patients will continue to seek care at other NHTR Winston Salem hospitals, therefore 100% of the demand for services in the five zip codes will not shift to CLMC.

CLMC also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3. The projected market share for each zip code was used to determine projected outpatient visits by zip code in the defined service area for the first three years of the proposed project.

Projected Hospital Outpatient Visits in the Defined Service Area

CLMC projected hospital outpatient visits for the first three years of operation using the following methodology:

Projected Hospital Outpatient Visits = (Defined Service Area Population x North Carolina Hospital Outpatient Visit Use Rate x Market Share) + "Other Inmigration"

CLMC projected hospital outpatient visits by zip code in the defined service area are shown in the following table. Projected "Other Inmigration" and total outpatient visits also are included.

MPH Clemmons Projected Hospital Outpatient Visits Project Years 1 – 3

Zip Code 3	PY 1 Jul11-Jun12	PY 2 Jul12-Jun13	P¥3 Jul13-Jun14			
27006	2,687	3,356	4,060			
27012	4,658	5,730	6,829			
27023	2,059	2,519	2,985			
27028 (Includes 28014 PO Box Volume)	4,295	5,316	6,375			
Other Inmigration (10%)	1,522	1,880	2,250			
Total Outpatient Visits	15,221	18,800	22,499			

Source:

The previous table reflects total hospital outpatient visits at CLMC in the defined service area for the first three years of the proposed project.

The need for additional ancillary and outpatient services at CLMC is substantiated by the existing utilization of services at FMC. As reflected in the following table inpatient and emergency department utilization at FMC are at an all time high. Over the last several years, inpatient demands have resulted in FMC shifting outpatient services to other providers. The following table illustrates the decrease in hospital outpatient utilization at FMC. This shift has been the result of direct efforts of FMC to provide outpatient services in settings less complex than a tertiary care hospital. For example, with the consummation of the Excel Imaging outpatient imaging joint venture (between FMC and Forsyth Radiological Associates) in April 2007, there is a single, centralized outpatient imaging scheduling phone number and outpatient with imaging needs can be directed to numerous Excel Imaging freestanding outpatient imaging sites in Forsyth County such as Winston-Salem Health Care's Radiology Department, The Breast Clinic, Greystone Imaging Center, Maplewood Imaging Center, and Salem MRI Center, in addition to the outpatient

^{*&}quot;Other Inmigration represents volume from outside of the proposed zip code service area, surrounding zip codes in surrounding counties as discussed in responses to Question III.1.a.

imaging available in the FMC hospital radiology department, which is often reserved for the more medically complex or higher risk outpatients. The FMC COO concurs that many types of hospital outpatient visits have migrated off the FMC tertiary hospital campus during the past few years. In addition, certain elective outpatient services are subject to getting delayed or re-scheduled if a higher acuity or emergent need intervenes. The FMC COO agrees that hospital outpatient services are needed at CLMC, in the more accessible local community hospital setting, where there are routinely fewer emergent cases such as cardiac catheterizations, high-risk obstetrical cases, or complex trauma cases. Thus, the proposed hospital in Clemmons will provide another location for needed outpatient services in the community setting and away from the higher intensity tertiary campus at FMC. In the future, this will prove to be more satisfying and simple to access for residents of the service area.

Forsyth Medical Center Historical Utilization

FFY	2004	2005	2006	2007	CAGR
Inpatient Days	200,063	206,071	207,044	210,427	
		3.0%	0.5%	1.6%	1.7%
Emergency Visits	77,533	86,118	89,941	97,685	
<u> </u>		11.1%	4.4%	8.6%	8.0%
Outpatient Visits	27,190	29,596	26,876	23,321	<u>.</u>
		8.8%	-9.2%	-13.2%	-4.5%

Source: Annual Hospital LRAs

This position is consistent with the Basic Principles included on page 34 of the 2008 SMFP, regarding goals related to Acute Care Hospitals, which states "To encourage the substitutions of less expensive for more expensive services whenever feasible and appropriate," which includes the use of outpatient diagnostic studies and other elective outpatient services.

The proposed CLMC outpatient services will have a positive impact on existing services at FMC, by relieving the pressure building up at FMC as a result of increasing inpatient utilization.

7. Projected Emergency Department Visits and Emergency Treatment Rooms

Projected emergency department visits and emergency treatment rooms were determined as follows.

2006 North Carolina Emergency Department Visit Use Rate

CLMC used the North Carolina Emergency Department Visit Use Rate for community hospitals defined by the American Hospital Association (AHA)⁴⁴ to project emergency department visits. Data compiled from the AHA Annual Survey are used to calculate state specific utilization rates. The 2005 North Carolina Emergency Department Visit Use Rate was 434.0 visits per 1,000 population as reflected in publicly available. The 2006 NC Emergency Department Visit Use Rate is the most current data that is publicly available. The 2006 North Carolina Emergency Department Visit Use Rate was held constant for purposes of these projections, even though literature suggests the increasing use of emergency services in North Carolina and nationally⁴⁵. The projected North Carolina Emergency Department Visit Use Rate

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American College of Emergency Physicians, "The National Report Card on the State of Emergency Medicine"

WWW 1974-05 Fig.; included in ..., Emergency Department Projections; The Advisory Board Company, "Future of EDs", June 11, 2005; "A Growing Hole in the Safety Net: Physician Charity Care Declines Again," Center for Health System Change, www.specience.com; American College of Physicians-American Society of Internal Medicine,

was used to determine total emergency department visits and NHTR Winston Salem market share by zip code in the defined service area for the first three years of the proposed project.

Current Emergency Department Visits and Market Share in the Defined Service Area

Using April 2007 — March 2008 emergency visit data from the NHTR internal Trendstar database, CLMC calculated the NHTR market share for each zip code in the defined service area. Relevant data is included in the defined service area emergency visits, and NHTR market share for zip codes in the defined service area.

Novant Health Outpatient Market Share in the Defined Service Area July 2006 - June 2007

Zip Code	County	NH Winston Salem Emergency Visits	Total Emergency Visits	NH Winston Salem Market Share
27006	Davie	1,721	5,809	29.6%
27012	Forsyth	4,220	10,889	38.8%
27023	Forsyth	1,585	4,791	33.1%
27028 (Includes 28014 Volume)	Davie	2,133	12,007	28.8%

Source:

Market Volume Shift and Market Share Assumptions

The following assumptions related to the percent market volume shift are used in the projections.

a. Percent Market Volume Shift to CLMC

The following percent market volume shift from FMC to CLMC was used to project emergency visit volume at CLMC.

Percent Market Volume Shift from Existing NHTR Winston Salem Facilities to CLMC

Zip.Code	Percent Market Volume Shift
27006	85.0%
27012	85.0%
27023	85.0%
27028 (Includes 28014 Volume)	85.0%

Source:

b. Market Share Resulting From Proposed Project

CLMC expects a market share increase in emergency visits once CLMC becomes operational in Clemmons, its home zip code, and the adjacent Advance zip code, as shown in the following table.

Projected Increase in CLMC ED Visit Market Share

Zip Code	Projected Market Share Increase
27006	30.0%
27012	30.0%
27023	0.0%
27028 (Includes 28014 Volume)	0.0%

Source:

CLMC projects a 30% increase in emergency visit market share from only the two adjacent service area zip codes, Clemmons 27012 and Advance 27006. The proposed facility will be located near the border (only two miles) of these two zip codes. For a Davie County resident traveling eastbound on I-40 the Harper Rd. Exit, where CLMC will be located, is the first I-40 Exit after entering Forsyth County from Davie County.

The following factors were considered important to the determination the projected CLMC market share of emergency visits from each zip code:

- The new hospital will bring a new emergency service to a growing population;
- As a community hospital patients will avoid the confusion and wait times associated with larger trauma centers and busy urban emergency departments.
- CLMC is closer to areas of each of the five zip codes than existing NHTR Winston Salem facilities as reflected in Anthony 1984 and May 1 resulting in shorter travel time for emergency services;
- The proposed location of CLMC adjacent to I-40 at the Harper Rd. interchange will result in ease of access for the existing population in the defined zip code service area;
- Some patients will choose to seek emergency care at other NHTR Winston Salem hospitals, and the
 protocols for emergency care defined by FMC with area ambulance providers will result in
 bypassing CLMC emergency department less than 5% of the time⁴⁶, therefore 100% of the demand
 for services in the five zip codes will not shift to CLMC.

Furthermore, as previously discussed, according to a recent American College of Emergency Physicians (ACEP) report, The National Report Card on the State of Emergency Medicine, North Carolina carned a "C-overall for its support of emergency care" and there is a need for additional emergency departments in North Carolina. The proposed project will provide increased accessibility to emergency medicine facilities for residents of a growing market located in western Forsyth and Davie Counties.

Actual NHTR Winston Salem market share for ED visits was adjusted to reflect the percent market shift and the projected increase in market share. The following table shows CLMC's future market share of emergency services (ED visits) in the defined service area.

In 2006, in preparation for FMC-Kernersville CON Application, the following method was used to determine the percent of patient bypassing the proposed emergency department. Based upon input from the FMC Emergency Department Administrator, the percent of inpatients at FMC with Level V and Level VI conditions was multiplied by the percent of inpatients arriving by ambulance. Projections ranged from 0.8 % to 4.0%. As a result, it is estimated that less than 5.0% of patients would by-pass the proposed facility. CLMC used the same assumption to determine patients bypassing the proposed emergency department.

CLMC Projected Emergency Dept Visit Market Share Project Year 3

Zip Code	Town	Current NHTR Winston Salem Mkt Share	Percent Market Share Shift	Projected Market Share Increase	CLMC Market Share PY 3
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27006	Advance	29.6%	85.0%	10.0%	55.2%
27012	Clemmons	38.8%	85.0%	10.0%	62.9%
27023	Lewisville	33.1%	85.0%	10.0%	28.1%
27028 (Includes 28014 Volume)	Mocksville	28.8%	85.0%	10.0%	15.1%

Source:

CLMC also assumed that the proposed market share shift will occur gradually over the first three years of operation, realizing 70% of projected market share in Project Year 1, 85% in Project Year 2, and 100% in Project Year 3.

CLMC Emergency Dept Visit Market Share Project Years 1-3

Zip Codes	Town	PY 1 Jul11-Jun12	PY 2 Jul12-Jun13	PY 3 Jul13-Jun14
27006	Advance	38.6%	46.9%	55.2%
27012	Clemmons	44.1%	53.5%	62.9%
27023	Lewisville	19.7%	23.9%	28.1%
27028 (Includes 28014 Volume)	Mocksville	10.6%	12.8%	15.1%

Source:

The projected market share for each zip code was used to determine projected emergency visits by zip code in the defined service area for the first three years of the proposed project.

<u>Projected Emergency Department Visits and Emergency Department Treatment Room Need in the Defined Service Area</u>

CLMC projected emergency department visits for the first three years of operation using the following methodology:

Projected Emergency Department Visits = (Defined Service Area Population x North Carolina Hospital Emergency Department Visit Use Rate x Market Share) + "Other Inmigration"

CLMC projected emergency department visits by zip code in the defined service area are reflected in the following table. Projected "Other Inmigration" and total emergency department visits also are included.

CLMC Projected Emergency Department Visits Project Years 1 – 3

Zip Code	PY 1 Jul11-Jun12	PY 2 Jul12-Jun13	PY3 Jul13-Jun14
27006	2,458	3,054	3,676
27012	5,102	6,292	7,517
27023	995	1,225	1,460
27028 (Includes 28014 Volume)	1,362	1,684	2,017
Other Inmigration (10%)	1,102	1,362	1,630
Total Emergency Department Visits	11,020	13,616	16,300
Emergency Treatment Rooms Needed @ Planning Capacity	8.3	10.2	12.2

Source

The previous table reflects total emergency department visits, and emergency department treatment rooms needed based upon American College of Emergency Physicians emergency planning capacity of 1,333 Emergency Visit per Treatment Room for Emergency Departments reflected in Example 1,334 We, which results in a need at CLMC for 12 emergency treatment rooms in the third year of operation.

The need for emergency services at CLMC is further substantiated by the future need for additional emergency services in the entire Forsyth-Davie County service area. The following table calculates area Emergency Department need projections for the three county area, Forsyth, Davie and Yadkin. As shown in the following table there will be a significant need for additional ED treatment space in the combined three county area by the third year of operation of the proposed MPH Clemmons.

The following table presents the historic growth rate of emergency department visits at the four hospitals in the three county area.

Historical ED Utilization Forsyth, Davie and Yadkin Counties

Hospital	2003	2004	2005	2006	2007
Forsyth Memorial Hospital	76,126	77,533	86,118	89,941	97,685
North Carolina Baptist Hospital	62,119	69,066	74,768	81,790	87,772
Hoots Memorial Hospital	6,958	7,076	6,774	6,806	7,516
Davie County Hospital	11,573	11,419	12,579	12,389	11,866
Total Forsyth.Davie.Yadkin ED					
Visits	156,776	165,094	180,239	190,926	204,839
Annual Growth		5.3%	9.2%	5.9%	7.3%
CAGR				5 7	6.9%

Source: LRAs;

As reflected in the previous table ED growth in the three county region averaged almost 7% growth annually. This is consistent with data and information presented in this application regarding the growth of emergency services in the service area, North Carolina and nationally.

A review of emergency department growth in the eight counties included in Forsyth Medical Center's primary and secondary service area is presented in the following table.

^{*&}quot;Other Inmigration represents volume from outside of the proposed zip code service area, surrounding zip codes in surrounding counties as discussed in responses to Question III.1.a.

Historical ED Utilization Forsyth Medical Center Primary and Secondary Service Area*

Hospital	2003	2004	2005	2006	2007
	Total	Total	Total	Total	Total
Forsyth Memorial Hospital	76,126	77,533	86,118	89,941	97,685
North Carolina Baptist Hospital	62,119	69,066	74,768	81,790	87,772
Thomasville Medical Center	21,545	21,813	22,059	22,917	27,558
Lexington Memorial Hospital	27,000	27,461	29,555	31,732	31,577
Stokes-Reynolds Memorial					
Hospital	10,666	11,280	10,847	10,709	12,863
Hugh Chatham Memorial Hospital	17,072	18,000	19,692	26,548	23,869
Northern Hospital of Surry County	31,839	34,046	35,753	36,099	38,799
High Point Regional Health System	53,764	55,927	57,335	57,501	57,902
Moses Cone Health System	110,327	114,325	111,333	112,412	114,564
Wilkes Regional Medical Center	24,681	28,291	30,257	31,391	32,000
Hoots Memorial Hospital	6,958	7,076	6,774	6,806	7,516
Davie County Hospital	11,573	11,419	12,579	12,389	11,866
Total FMC Sv Area ED Visits	453,670	476,237	497,070	520,235	543,971
Annual Growth		5.0%	4.4%	4.7%	4.6%
CAGR					4.6%

Source: LRAs;

As reflected in the previous table ED growth in the eight county region averaged over 4.5% growth annually. Again this is consistent with data and information presented in this application regarding the growth of emergency services in the service area, North Carolina and nationally that ED use is growing faster than population growth.

To determine if the existing and approved ED treatment room capacity at FMC, FMC-Kernersville, NCBH and DCH was sufficient to meet the future ED need in the three county region CLMC projected future ED need using both the three county and eight county historical growth rates, as presented in the following table.

^{*}Includes: Forsyth, Davie, Yadkin, Davidson, Guilford, Surry, Stokes and Wilkes

Projected ED Treatment Rooms Needed Forsyth, Yadkin and Davie Counties

	Growth Rate	2008	2009	2010	2011	2012	2013	2014	2015
Projected ED Need Using Forsyth.Davie. Yadkin ED Growth Rate	6.9%	219,022	234,187	250,402	267,739	286,277	306,099	327,293	349,955
ED Beds Needed Visits per Room at High Range	1,350	162	173	185	198	212	227	242	259
Current ED Bed Inventory Forsyth.Davic.Yadkin		133	147	147	192	192	192	192	192
ED Beds/Treatment Rooms Additional Need		29	26	38	6	20	35	50	67
Projected ED Need Using FMC SA ED Growth Rate	4.6%	214,350	224,302	234,716	245,613	257,017	268,950	281,437	294504
ED Beds Needed Visits per Room at High Range	1,350	159	166	174	182	190	199	208	218
Current ED Bed Inventory Forsyth.Davic.Yadkin		133	147	147	192	192	192	192	192
ED Beds/Treatment Rooms Additional Need		26	19	27	-12	-2	7	16	26

Assumptions: FMC Kville -12 new treatment rooms come on line 2009;

NCBH—new ED comes on line in 2011 increasing ED treatment space at NCBH by 31 as reflected in Project I.D. G-7691-06; however, only one progress report has been filed to date with the State and it is unclear if and when NCBH intends to move forward with the project.

Includes existing and approved ED treatment rooms at all hospitals in Forsyth, Davie and Yadkin Counties.

Source:

As reflected in the previous table, a need for additional ED treatment rooms is projected in Forsyth, Yadkin and Davie Counties using either the historical ED growth rate from just these three counties or using the historical ED growth rate from the eight county FMC service area. Both methodologies project that additional ED treatment space will be needed in Forsyth, Davie and Yadkin Counties by 2014. This analysis takes into account the expansion of NCBH ED (+31 rooms), approved in Project I.D. G-7691-06 and the new ED treatment space (16 rooms) approved for FMC Kernersville. This analysis also provides additional support for the proposed ED located at CLMC, since the service area should add more ED capacity now to prepare for future demand. As previously noted, the applicant is informed that NCBH's proposed ED/ICU tower project is on hold, so that project should not be viewed as a reason disapprove ED capacity in Clemmons.

In addition, residents of Lewisville, Clemmons and Advance have not historically sought emergency services at the DCH ED in Mocksville. The current location of the DCH ED treatment rooms is further from the majority of the proposed population than the existing ED at FMC. Furthermore, inpatient services available at DCH are limited. Therefore, it would be unreasonable to assume that many residents of the proposed service area would go to DCH for emergency care when historically Davie residents often commute out of Davie County to Forsyth County for not only medical care, but also for employment, entertainment, and shopping. Many of the use patterns of the market are to go to Forsyth County for services and jobs, rather to Mocksville. See the Commuter Map included in Example 2009.

8. Projected Ancillary Services Utilization

As previously discussed, CLMC will be a community hospital with a full range of inpatient and outpatient services. The following projections for ancillary services reflect the need for the equipment at CLMC. Previous projections for outpatient visits at CLMC reflect the number of patients seeking ancillary and other outpatient treatments or services. Total outpatient visits are utilized in the financial ProFormas to determine the financial feasibility of the proposed project. These ancillary projections reflect total procedures, scans or individual tests completed by department or services, not total patients. In most cases a patient receives services from more than one department or has more than one test or procedure at one visit. The following projected ancillary volumes substantiate the need for equipment routinely found in a community hospital.

Equipment planning for the proposed CLMC was completed by Novant Health's Director of Capital Equipment, a professional with considerable experience in hospital equipment planning. Included in is a letter from the experienced Novant Health Equipment Planning Director, which documents his experience and the need for the following equipment at CLMC. See also the articles which are attached to his letter for further explanation.

CLMC will have a comprehensive array of diagnostic equipment including:

- A full-service laboratory;
- A full-service pharmacy;
- A new 16-slice CT scanner;
- A contract with vendor for mobile MRI scanner service.
- Other imaging equipment including:
 - One digital routine x-ray unit/room
 - One digital combination x-ray/fluoro unit/room
 - One nuclear medicine camera (no coincidence circuitry)
 - One 64-slice digital CT scanner
 - One digital mammography unit
 - One digital ultrasound unit
 - Two portable, digital x-ray units for use on the patient floors, ED, and ORs
 - One Mini C-Arm unit—for use in the ED for Post-Reduction studies (x-ray after the fracture is casted)
 - o Two multi-purpose C-Arm units for use in the ORs
 - O PACS system within NHTR connecting CLMC to FMC

A complete list of diagnostic imaging equipment valued at more than \$10,000 is included in the base of a

In addition, a substantial amount of laboratory and pharmacy equipment will be needed at CLMC. A complete list of laboratory equipment valued at more than \$10,000 is included in (1996) and .

Additional equipment itemized in a partial includes equipment needed for physical therapy, speech therapy, and respiratory therapy services available for inpatients and outpatients. CLMC will treat a variety of patients as inpatients, emergency patients and patients referred from local physicians with asthma, strokes, orthopedic injuries and other diagnosis which require outpatient therapy services such as physical therapy, speech therapy, occupational therapy, respiratory therapy.

Ancillary utilization projections were calculated based upon existing ancillary utilization patterns at existing Novant Health community hospitals: Thomasville Medical Center (TMC), Brunswick Community Hospital (BCH), Presbyterian Hospital Matthews (PHM) and Presbyterian Hospital Huntersville (PHH). CLMC assumes that projected ancillary utilization at CLMC will imitate current ancillary utilization

patterns at TMC, BCH, PHM and PHH. This methodology has been used in previously approved by the Agency in a community hospital CON application (Presbyterian Hospital Mint Hill) submitted by Novant Health in mid-2006.

Relevant data was acquired from Hospital Licensure Renewal Applications from FFY 2003 to 2007 as available for PHH, PHM, TMC and most recently BCH. BCH was acquired by Novant Health in 2006 and FFY 2006 was the first full year of operation by Novant. This data is included in handless and and and and according to determine the relationship between ancillary volumes and inpatient, outpatient and ED volumes. Inpatient ancillary volumes for CLMC were projected using total average data across the facilities and the years. High and low values were deleted from the average. The resulting average was used to calculate ancillary services at CLMC.⁴⁷ Outpatient ancillary volumes were projected using the average percent of total outpatient and ED visits as shown in the following table.

AT Ratios for laboratory, pharmacy and ultrasound were calculated based upon historical utilization at FMC and MPH. The resulting projections, when compared to the community hospital ratios used in the PHMH application, were very high. Therefore, CLMC utilized the ratios used in the PHMH application to project future laboratory, pharmacy and ultrasound volumes in this application.

Projected Ancillary Service Utilization: CLMC

	ALL Hospitals	Proj	ected Utiliz	ation
Ancillary Service	and Years Minus Hi/Lo	PY 1	PY2	PY3
MRI*		**************************************		
Inpatient - % Discharges	10.3%	487	496	505
Outpatient - % Outpatient + ED	4.8%	1,178	1,444	1,720
Total MRI		1,670	1,945	2,230
CT				
Inpatient - % Discharges	53.5%	2,536	2,581	2,626
Outpatient - % Outpatient + ED	23.4%	5,763	7,067	8,415
Total CT		8,299	9,647	11,041
Nuclear Medicine				
Inpatient - % Discharges	17.7%	840	855	870
Outpatient - % Outpatient + ED	4.8%	1,183	1,450	1,727
Total Nuclear Medicine		2,023	2,305	2,597
Mammograms			7	
Inpatient - % Discharges	0.0%	0	0	0
Outpatient - % Outpatient + ED	8.0%	1,982	2,431	2,894
Total Mammograms		1,982	2,431	2,894
Other Radiology		_		
Inpatient - % Discharges	124.5%	5,897	5,999	6,104
Outpatient – % Outpatient + ED	39.9%	9,841	12,068	14,370
Total Other Radiology		15,738	18,067	20,474
Ultrasound				
Inpatient - Ratio to Discharges	0.19	900	916	932
Outpatient - Ratio to Outpatient + ED	0.09	2,220	2,722	3,241
Total Ultrasound		3,120	3,638	4,173
Pharmacy				
Inpatient - Ratio to Discharges	79.27	375,531	382,080	388,746
Outpatient - Ratio to Outpatient + ED	3.04	74,983	91,946	109,487
Total Pharmacy		450,514	474,025	498,233
Laboratory				
Inpatient - Ratio to Discharges	17.38	82,335	83,771	85,233
Outpatient - Ratio to Outpatient + ED	1.36	33,545	41,134	48,981
Total Laboratory		115,880	124,905	134,214

Source: CLMC CON Application;

The above table reflects total ancillary services utilization at CLMC in the defined service area for the first three years of the proposed project.

Projected Impact of Clemmons Medical Center on Other Acute Care Providers in Forsyth and Davie Counties

As part of the CLMC utilization analysis, CLMC defined hospital service areas and projected future acute care bed need for the following North Carolina Hospitals in the Forsyth/Davie County area.

- Forsyth Medical Center
- North Carolina Baptist Hospital
- Davie County Hospital

Data from Solucient/Thomson and Annual Hospital Licensure Renewal Applications for these hospitals were used to calculate current and projected service areas and market shares. The potential for CLMC to have a material impact on the volume of services at each hospital was considered. CLMC projected April 2012 to March 2015 bed need using county specific population growth rates for each hospital including the impact of the proposed CLMC. This allowed the applicant to determine CLMC's projected impact on each existing hospital.

CLMC did not include any projected shift in market share in patient days from NCBH or DCH to the proposed Clemmons Medical Center as part of the volume projections for the proposed project. In addition, projection for each facility determined that the positive impact of continued population growth in the region exceeded any negative impact of the proposed project on existing facilities.

The proposed project is for the relocation of existing beds and operating rooms to serve a market that currently is well-served by FMC and MPH and its physicians. The market shift impacts only FMC as no increase in market share was projected. Total FMC projected utilization and the impact of CLMC on Novant hospitals is included in the Impact Analysis included in Example 5 and Ember 5 and

Future acute care bed need projections for North Carolina Baptist Hospital and Davie County Hospital are based upon county specific population growth rates, which is the same methodology used to project CLMC and FMC bed need. These projections are presented in Falance Statutes and Statutes and Statutes and Statutes are projections reflect a decreasing surplus in acute care beds at North Carolina Baptist Hospital and continued use of Davie County Hospital as a Critical Access Hospital.

Conclusion

The reasonableness of locating a new community hospital in the Clemmons area is shown by the projected need for services due to significant population growth experienced over the past years and projected to continue in the foreseeable.

Upon completion, CLMC can begin to meet the growing acute care needs in the defined service area. The table below shows the projected patient days and occupancy rates for CLMC in the first three years of operation. Note that CLMC's projected occupancy rate will be greater than the target occupancy rate required by Policy AC-5 – Replacement of Acute Care Capacity in the 2008 State Medical Facilities Plan. As the Clemmons area continues to grow, its future acute health care needs can be met by the development and expansion of CLMC.

Average Daily Census, Licensed Number of Beds and Occupancy Percentage for CLMC First Three Years of Operations

	PY 1 Jul11-Jun12	PY 2 Jul12-Jun13	PY 3 Jul13-Jun14
Total Acute Care			
Days	11,438	12,696	13,994
ADC	47.0	52.1	57.5
Beds	50	50	50
Occupancy	62.7%	69.6%	76.7%

Source: Clemmons Medical Center Summary Statistics

The relocation of 50 acute care beds and 5 existing licensed operating rooms from FMC and MPII to CLMC will result in increased access to high quality patient care services in a local community that has depended on NIITR inpatient facilities and physicians for many years. In addition, the proposed project also results in maximizing utilization of existing NHTR Forsyth County resources. The proposed project responds to one of

Attachment 5

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

Decision Date: April 27, 2018 Findings Date: May 4, 2018

Project Analyst: Gregory F. Yakaboski

Co-Signer: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #: O-11434-17

Facility: New Hanover Regional Medical Center

FID #: 943372 County: New Hanover

Applicant: New Hanover Regional Medical Center

Project: Develop one new OR pursuant to the need determination in the 2017 SMFP for a

total of 39 ORs at NHRMC upon project completion

Project ID #: O-11437-17

Facility: Wilmington SurgCare

FID #: 923566 County: New Hanover

Applicant: Wilmington Surgery Center, L.P.

Project: Develop one new OR pursuant to the need determination in the 2017 SMFP for a

total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add

3 ORs and one procedure room)

Project ID #: O-11441-17

Facility: Wilmington ASC

FID #: 170523 County: New Ha

County: New Hanover
Applicant: Wilmington ASC, LLC

Project: Develop a new multispecialty ambulatory surgical facility by developing one new

OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms

from Wilmington Health

Project ID #: O-11444-17

Facility: New Hanover Surgical Center

FID #: 170529

County: New Hanover

Applicants: New Hanover Surgical Center, LLC

OWP4, LLC

Project: Develop a new ambulatory surgical facility with one new OR pursuant to the need

determination in the 2017 SMFP and two procedure rooms

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 NHRMC WASC NHSC

NC Wilmington SurgCare

Need Determination

Chapter 6 of the 2017 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 2017 SMFP identifies a need for one additional OR in the New Hanover County operating room service area. Four applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to develop one new OR in the New Hanover County operating room service area. The four applicants each applied for one OR, for a combined total of four additional ORs. Pursuant to the need determination in Table 6C, page 82 of the 2017 SMFP, only one new OR may be approved in this review for the New Hanover County operating room service area.

Policies

The following policy is applicable to all four applications in this review:

POLICY GEN-3: BASIC PRINCIPLES

The following policy is applicable to only two of the four applications in this review:

 POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

POLICY GEN-3: BASIC PRINCIPLES states:

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

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES 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 for 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."

New Hanover Regional Medical Center (NHRMC) proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County Operating Room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 18-19, Section III.4, pages 62-64 and Exhibit 7. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> - The applicant describes how it believes the proposed project would promote equitable access in Section V.7, pages 66-67, and Exhibits 7 and 13-14. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> - The applicant describes how it believes the proposed project would maximize health care value in Section V.7, pages 68-69, Section X, pages 95-97 and the applicant's pro forma financial statements, pages 105-123. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this projected is less than \$2.0 million, therefore, Policy GEN-4 is not applicable to the review of this application.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the 2017 SMFP for the New Hanover County operating room service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicant uses existing policies, historical data and verifiable sources to project utilization, and
- The applicant adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.

Wilmington Surgery Center, L.P. (Wilmington SurgCare) proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 14-15, Section III.4, pages 53-54 and Exhibits 8, 14, 15 and 17. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, pages 53-55, Section VI, pages 78-85 and Exhibits 12, 25, 26, 33 and 34. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, pages 53-55, Section X, pages 102-104 and the applicant's pro forma financial statements, pages 115-131.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to add one OR to its facility in New Hanover County. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2017 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this projected is less than \$2.0 million, therefore, Policy GEN-4 is not applicable to the review of this application.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to add one OR to its existing facility in New Hanover County.

Wilmington ASC, LLC (WASC) proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, page 50, Section III.4, page 101 and Exhibit 12. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, pages 101-102, Section VI, pages 140-158, and Exhibits 12. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, pages 102-103, Section X, pages 187-190 and the applicant's pro forma financial statements in Section XIII. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and

maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5.0 million therefore Policy GEN-4 is applicable to the review of this application. In Section III, page 104, Section XI.8, page 203 and Exhibit 22, the applicant explains why it believes its application is consistent with Policy GEN-4. On pages 104 the applicant states, "WASC understands and agrees to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of DHSR. The plan will include a written statement describing the project's plan to assure improved energy efficiency and water conservation in a way that does not affect patient or resident health, safety or infection control."

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the 2017 SMFP for the New Hanover County operating room service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant uses existing policies, historical data and verifiable sources to project utilization, and
 - The applicant adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.
- The applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation.

New Hanover Surgical Center, LLC (NHSC, LLC) and OWP4, LLC (OWP4), known collectively as NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> - The applicants describes how the proposed project would promote safety and quality in Section II.8, page 22, Section III.4, pages 57-59 and Exhibit 7 and 13. The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would promote safety and quality.

<u>Promote Equitable Access</u> - The applicants describes how the proposed project would promote equitable access in Section III.4, pages 57-59, Section VI, pages 76-87, and Exhibits 4. The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would promote equitable access.

Maximize Healthcare Value - The applicants describes how the proposed project would maximize health care value in Section III.4, pages 56-57, Section X, pages 106-108 and the applicants pro forma financial statements in Section XIII of the application. The information provided by the applicants is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would maximize healthcare value and that the applicants projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5.0 million therefore Policy GEN-4 is applicable to the review of this application. In Section XI.8, page 117, the applicants explain why the application is consistent with Policy GEN-4. On page 117, the applicant states, "NHSC will work with experienced architects and engineers to ensure energy efficient systems and water conservation are an inherent part of the planned facility project."

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants do not propose to develop more ORs than are determined to be needed in the service area.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicants use existing policies, historical data and verifiable sources to project utilization, and
- The applicants adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.
- The applicants provide a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Decision

The applications submitted by NHRMC, Wilmington SurgCare, WASC and NHSC are conforming to the need determination in the 2017 SMFP, which identifies a need for one OR in the New Hanover County operating room service area. However, the limit on the number of ORs that can be approved is one. Collectively, the applicants propose a total of four ORs. Therefore, all of the applications cannot be approved even if all are conforming to all statutory and regulatory review criteria.

The applications submitted by NHRMC, WASC and NHSC are consistent with Policy GEN-3.

The application submitted by Wilmington SurgCare is not consistent with Policy GEN-3.

The applications submitted by WASC and NHSC are consistent with Policy GEN-4. As stated above, Policy GEN-4 is not applicable to the applications submitted by NHRMC and Wilmington SurgCare.

See the Conclusion 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 NHRMC WASC NHSC

NC Wilmington SurgCare

NHRMC. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of 39 operating

rooms (ORs) at NHRMC upon project completion. The applicant proposes to develop the new OR as a shared OR in NHRMCs existing surgical pavilion.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 40, the applicant provides NRMC's historical patient origin for inpatient (IP) and outpatient (OP) surgical cases for fiscal year (FY) 2017 and the projected patient origin for the first two operating years (OY) FY2021 and FY2022 as shown in the table below.

County	Current: FY2017 10/1/16 to 9/30/17	Projected: OY1(FY2020)	Projected: OY2(FY2021)
New Hanover	42.6%	42.6%	42.6%
Brunswick	19.9%	19.9%	19.9%
Pender	11.5%	11.5%	11.5%
Onslow	9.6%	9.6%	9.6%
Columbus	5.1%	5.1%	5.1%
Other	11.4%	11.4%	11.4%
Total	100.0%	100.0%	100.0%

Source: Table page 40 of the application.

In Section III.6, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 27-34, the applicant describes the need for the proposed project and states that the need for an additional OR at NHRMC is supported by the factors as listed below and discussed thereafter:

- Surgery Utilization- NHRMC has operated at over 100.0 percent of OR capacity since FY2014. Since FY2016 NHRMC has had a facility need for three (3) ORs. (See pages 32-34 and Exhibit 8.)
- Population Growth Trends- The population of New Hanover County, from 2012-2017, grew by 8.3 percent. New Hanover County is projected to grow another 8.0 percent from 2017-2022 with the elderly segment of the population (65+ years old) projected to grow at 18.5% during that time. Further, NHRMC's primary service area of New Hanover Brunswick, Columbus, Onslow and Pender counties is projected to grow an additional 7.6 percent from 2017 -2022 on top of 7.4 percent growth from 2012-2017 with the elderly segment of the population projected to grow at 19.4% during that time (See pages 28-29)

- New NHRMC Services- Focusing on market capture, both current and future, in January 2014, NHRMC began operating and Accountable Care Organization (ACO) called Physician Quality Partners. An ACO is a set of health care providers, including primary care physicians, specialists and hospitals that work together collaboratively... "ACOs may be the most promising mechanism to control costs and improve quality and access in the American healthcare system". (See pages 31-32)
- NHRMC Physician Group Growth- NHRMC's medical staff has increased by 80 physicians over the last 10 years, from 470 to 550. In addition, 20 additional physicians are scheduled to be added to NHRMC's physician's network over the next three years.

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop one OR in the New Hanover County operating room service area in accordance with the OR need determination in the 2017 SMFP.
- NHRMC's current OR utilization shows a need in excess of one OR.
- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.

Projected Utilization

In Section IV.1, pages 44-45, the applicant provides historical and projected utilization as illustrated in the following tables.

Historical: Total NHRMC Surgical Cases with Exclusions

NHRMC: Total Historical Surgical Cases- Inpatient/Outpatient

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
OP Cases*	15,928	19,526	21,666	21,944	23,421	25,574
IP Cases**	8,341	8,688	9,717	9,299	9,936	9,273
Total Cases	24,269	28,214	31,383	31,243	33,357	34,847

Source: Tables on pages 44-45 of the application.

Projected NHRMC Surgical Cases based on Historical Cases excluding Open-Hear, C-Section and Trauma cases.

^{*}The number of OP Cases for FY2012 and FY2013 reflect corrections NHRMC made to the License Renewal Applications (LRA) to adjust for dental cases being mistakenly included in the OR OP cases for those respective LRAs.

^{**}The number of IP surgical cases does not include any Open-Heart, C-Section or Trauma cases. Under the OR rules for calculating utilization and need Open-Heart, C-Section and Trauma cases are excluded.

NHRMC: Projected Surgical Cases Inpatient/Outpatient

	FY2018	FY2019	FY2020	FY2021	FY2022
	(Interim)	(Interim)	(OY1)	(OY2)	(OY3)
OP Cases	27,027	28,564	30,187	31,903	33,716
IP Cases	8,930	8,777	8,626	8,478	8,330
Total Cases	35,957	37,341	38,813	40,380	42,046

Source: Table page 44 of the application.

In Section IV, pages 45-51, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1. <u>Historical Analysis</u>: NHRMC identified its historical IP and OP cases for the years FY2012-FY2017. The applicant then subtracted out all Open-Heart, C-Section and Trauma cases from the IP Case total. The applicant then subtracted out all dental cases from the total OP cases. (See page 45.)

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
OP Cases	17,204	20,761	21,666	21,944	23,421	25,574
Dental Cases*	(1,276)	(1,235)	na	na	na	na
OP Cases with corrections	15,928*	19,526*	21,666	21,944	23,421	25,574
IP Cases*	10,686	11,167	12,289	11,978	12,815	12,389
Open Heart	(563)	(594)	(554)	(619)	(679)	(710)
C-Section	(1,120)	(1,067)	(1,110)	(1,046)	(1,099)	(1,122)
Trauma	(662)	(818)	(908)	(1,014)	(1,101)	(1,284)
IP Cases with exclusions	8,341	8,688	9,717	9,299	9,936	9,273
Total Cases**	24,269	28,214	31,383	31,243	33,357	34,847

Source: Table on page 45 of application

Step 2. <u>Calculate Historical CAGR</u>: NHRMC calculated the 2 year, 3 year, 4 year and 5 year historical CAGR for its surgical cases (IP and OP) for FY2012 to FY2017. The lowest historical CAGR was the 3 year CAGR: -1.5% for IP Cases and 5.7% for OP Cases. (See page 46.)

Historical Growth CAGR

	2yr	3yr	4yr	5yr
OP Cases	8.0%	5.7%	7.0%	9.9%
IP Cases	-0.1%	-1.5%	1.6%	2.1%

Source: Table on page 46.

Step 3. Project IP and OP Utilization through OY3 utilizing 3 year CAGR (See page 46.)

^{*}The number of OP Cases for FY2012 and FY2013 reflect corrections NHRMC made to the License Renewal Applications (LRA) to adjust for dental cases being mistakenly included in the OR OP cases for those respective LRAs. The LRAs for FY2014 through FY2017 did not include dental cases in the OP OR case totals for which a correction had to be made.

^{**}Total Cases equals OP Cases with corrections + IP Cases with exclusions

	CAGR applied	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022
OP Cases	5.7%	25,574	27,027	28,564	30,187	31,903	33,716
IP Cases	-1.5%	9,273	9,130	8,988	8,849	8,712	8,578
Total Cases		34,847	36,157	37,552	39,036	40,615	42,294

Source: Table on page 46.

Step 4. Adjust or "Back Out" IP Surgical Cases Projected to Shift to Wilmington SurgCare (See page 47.)

	FY2018	FY2019	FY2020	FY2021	FY2022
Projected NHRMC IP Cases	9,130	8,988	8,849	8,712	8,578
Total Projected Case shift to Wilmington	(200)	(211)	(223)	(235)	(248
SurgCare					
Projected NHRMC IP Cases after shift	8,930	8,777	8,626	8,478`	8,330

Source: Table on page 47.

Step 5. <u>Consolidate Projected IP and OP Cases</u> – Table below reflects the adjustments calculated in Step 4. (See pages 48-49.)

	FY2017 (Historical)	FY2018 (Interim)	FY2019 (Interim)	FY2020 (OY1)	FY2021 (OY2)	FY2022 (OY3)
OP Cases	25,574	27,027	28,564	30,187	31,903	33,716
IP Cases	9,273	8,930	8,777	8,626	8,478	8,330
Total Cases	34,847	35,957	37,341	38,813	40,381	42,046

Source: Table page 48 of the application.

Step 6. OY3: Calculate OR Need at NRHMC in OY3 (See pages 50-51.)

OR Cases	OY3 (FY2022)	Hours/Case	OR Hours
OP Cases	33,716	1.5	50,574
IP Cases	8,330	3.0	24,989
Total OR Hours			75,563
OR Need (hours/1872)			40.36
# of Existing OR *			32
OR Need (ORs Needed – Existing ORs)			8.36
NHRMC OR Need			8

^{**}NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs. Source: Tables on pages 50-51.

As shown in the table above, in OY 3 (FY 2022), the applicant projects that 75,563 surgical hours will be performed at NHRMC, which documents a need for eight ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Total Surgical Hours	Total Hours/ 1,872 Hours / OR / Year	# of existing ORs	# of ORs Needed
OY3	75,563	40.36	32	8

Furthermore, based on NHRMC's historical data from FY2017, NHRMC demonstrates a need for 3 ORs in FY2017. If NHRMC had projected no growth from FY2017 through OY3(FY2022), NHRMC's OR utilization would have shown a need for 3 ORs as shown on the table below.

OR Cases	FY2017	Hours/Case	OR Hours
OP Cases	25,574	1.5	38,361
IP Cases	9,273	3.0	27,819
Total OR Hours			66,180
OR Need (hours/1872)			35.4
# of Existing OR *			32
NHRMC OR Need			3
(ORs Needed – Existing ORs)			

^{**}NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.

Projected utilization is reasonable and adequately supported for the following reasons:

- NHRMC's historic and current OR utilization shows a need in excess of one OR, even with no OR utilization growth going forward.
- The applicant applied conservative CAGR growth rates in its projections.
- The applicant, again conservatively, backed out certain OP OR cases that, in a different application, are projected to shift from NHRMC to another facility.
- The methodology and assumptions are reasonable and adequately supported.

Access

In Section VI.4, page 72, the applicant states, "It is the policy of all departments within NHRMC to admit and to treat all patients without regard to race, color, religion, creed, national origin, sex, sexual preference, disability, age, or ability to pay." In Section VI. 14, page 78, and in Form D, pages 115 and 117 of the proformas, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as shown in the table below.

OR Services at NHRMC: OY2 10/1/20 to 9/30/21 IP and OP Combined

Payor Category	Services as Percent of Total Surgical (IP + OP combined)	Actual Cases (Combined IP and OP)
Self Pay/Charity	4.6%	1,539
Medicare/Medicare	50.6%	18,965
Managed Care		
Medicaid	11.2%	3,151
Managed	27.6%	14,304
Care/Commercial		
Insurance		
Other	6.0%	2,423
Total	100.0%	40,381

Source: Page 78 of the application and Proformas Form D, pages 115 &117

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

Wilmington SurgCare. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover County operating room service area for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and a procedure room). Wilmington SurgCare is an existing multispecialty ambulatory surgical center (ASC) that is currently licensed with seven ORs. On April 28, 2017, the facility was approved to develop three additional ORs, however, that project is currently under appeal and no certificate of need (CON) has been issued.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as, "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, pages 58 and 61, the applicant provides Wilmington SurgCare's historical patient origin for OP surgical cases for FY2017 and the projected patient origin for the second operating year CY2022 as shown in the table below.

OR Surgery Cases: Historical and Projected Patient Origin

County	Curr (October 1, 2016 to S	rent September 30, 2017)	Second Full FY of Operation following Project Completion (1/1/2022 to 12/30/2022)		
	Patients	% of Total	Patients	% of Total	
New Hanover	3,638	42.64%	5,515	42.64%	
Brunswick	2,112	24.76%	3,202	24.76%	
Pender	691	8.10%	1,047	8.10%	
Onslow	800	9.38%	1,213	9.38%	
Columbus	426	4.99%	646	4.99%	
Duplin	276	3.24%	418	3.24%	
Sampson	73	0.86%	111	0.86%	
Bladen	104	1.22%	158	1.22%	
Carteret	91	1.07%	138	1.07%	
Craven	57	0.67%	86	0.67%	
Jones	29	0.34%	44	0.34%	
Robeson	13	0.15%	20	0.15%	
Wake	8	0.09%	12	0.09%	
Pitt	6	0.07%	9	0.07%	
Pamlico	5	0.06%	8	0.06%	
Wayne	5	0.06%	8	0.06%	
Halifax	4	0.05%	6	0.05%	
Cumberland	4	0.05%	6	0.05%	
Guilford	3	0.04%	5	0.04%	
Mecklenburg	3	0.04%	5	0.04%	
Harnett	2	0.02%	3	0.02%	
Hyde	2	0.02%	3	0.02%	
Lenoir	2	0.02%	3	0.02%	
Randolph	2	0.02%	3	0.02%	
Other NC Counties	22	0.26%	33	0.26%	
South Carolina	118	1.38%	179	1.38%	
Georgia	2	0.02%	3	0.02%	
Tennessee	1	0.01%	2	0.01%	
Virginia	6	0.07%	9	0.07%	
Other States	26	0.30%	39	0.30%	
Totals	8,531	100.00%	12,932	100.00%	

Source: Pages 58 and 61 of the Application.

Note: Wilmington SurgCare currently has a GI endo room which they will be delicensing as part of Project ID# O-11272-16 (add 3 ORs and a procedure room). In Project ID# O-11272-16 the applicant projects the cases that were being performed in the GI endo room would be performed in an OR upon project completion.

In Section III.6, page 59, the applicant provides the assumptions and methodology used to project its patient origin for surgical services. The applicant's assumptions are reasonable and adequately supported.

In Section III, page 60, the applicant provides Wilmington SurgCare's projected patient origin for procedure room for the first two operating years (CY2021 and CY2022) as shown in the table below.

Procedure Room Cases- Wilmington SurgCare

County	OY1-Patients	OY2-Patients	% of Total Patients
	(CY 2021)	(CY 2022)	
New Hanover	141	144	42.64%
Brunswick	82	84	24.76%
Pender	27	27	8.10%
Onslow	31	32	9.38%
Columbus	17	17	4.99%
Duplin	11	11	3.24%
Sampson	3	3	0.86%
Bladen	4	4	1.22%
Carteret	4	4	1.07%
Craven	2	2	0.67%
Jones	1	1	0.34%
Robeson	1	1	0.15%
Other Counties	4	4	1.21%
South Carolina	5	5	1.38%
Total	331	338	100.0%

^{*}Other North Carolina Counties include: Alamance, Ashe,, Beaufort, Burke, Cabarrus, Camden, Catawba, Dare, Davie, Edgecombe, Forsyth, Franklin, Lee, Lincoln, Montgomery, Moore, Nash, Rockingham, Stanly, Watauga and Wilson counties.

In Section III.6, page 60, the applicant provides the assumptions and methodology used to project its patient origin for the procedure room. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 25-51, the applicant describes the need for the proposed project and states that the need for an additional OR at Wilmington SurgCare is supported by the factors as listed below and discussed thereafter:

- Population Factors (Aging and Growth). The populations of New Hanover, Pender, Onslow and Brunswick counties are projected to grow by a combined 50,280 residents from 2018 to 2023. The segment of the population that is over 60 years old is projected to grow by a combined 27,071 residents for New Hanover, Brunswick, Pender, Onslow, Columbus, Duplin and Bladen counties from 2016 to 2021. (See application pages 26-28)
- Advances in anesthesia and surgical techniques for ambulatory surgery. A continued shift of surgical procedures to an ambulatory setting is being supported by changes in surgical and anesthesia techniques. (See application page 29)
- *Utilization trends in ASCs*. The number of surgical procedures in freestanding ambulatory centers has increased. (See application pages 30-31)

- Reimbursement changes incentivizing separately licensed ASC use. The Centers for Medicaid Services (CMS) has expanded its lists of procedures that can be reimbursed when performed in an ASC. (See application pages 31-33)
- Need to expand physician access to multi-specialty ASC. There are a limited number of ORs in freestanding ASC's in New Hanover County while the number of ambulatory surgery cases continues to increase. (See application page 33-34)
- Additional capacity needed at Wilmington SurgCare. Based on historic utilization. (See application pages 33-51)
- *Need to support physician recruitment and productivity.* Need additional OR to permit effective OR scheduling and physician productivity. (See application pages 36-51)
- Need to add an OR consistent with the 2017 SMFP OR need determination. Based on the need determination in the 2017 SMFP for an OR in the New Hanover County operating room service area. (See application pages 34-35)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop one OR in the New Hanover County Operating Room Service Area in compliance with the OR need determination in the 2017 SMFP
- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The population (current and future) of the service area identified by the applicant, and especially the elderly population, has grown the last five years and is projected to grow at over 8.0% for the next five years.
- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.
- The list of surgical procedures received at an ASC which are reimbursable under Centers for Medicaid Services (CMS), Medicare and commercial insurance companies has expanded.
- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, page 68, the applicant provides historical utilization for FY2016 through CY2017 as illustrated in the following table.

Wilmington SurgCare: Historical Utilization

	2016**	2017 **	Actual Utilization 10/1/2016 to 9/30/2017 (will be 2018 LRA)	Current* 1/1/2017 to 12/31/2017
OP OR cases	8,463	8,589	8,531	8,531
# of OR rooms	7	7	7	7
GI Endoscopy Cases**	240	231	233	233
# of GI/Endoscopy Rooms	3	3	3	3
# of Procedures	212	226	223	223
# of Procedure Rooms	0	0	0	0

^{*}Procedure Cases were performed in the GI/Endoscopy Rooms

Note: The applicant is switching from a FY of October 1st through September 30th to a calendar year as of CY2017.

In Section IV.1, page 68, the applicant provides interim and projected utilization for CY2018 through CY2023(OY3) as illustrated in the following table.

Wilmington SurgCare: Interim and Projected Utilization

Willington Surgeare. Interim and Projected Comzation										
	Interim CY2018	Interim CY2019	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023				
OP OR cases	8,958	9,405	10,921	11,891	12,932	13,813				
# of OR rooms	7	7	10	10	10	11				
Annual Growth Rate- OR Cases	na	5.0%	16.12%	8.9%	8.76%	6.8%				
GI Endoscopy Cases*	224	215	0	0	0	0				
# of GI/Endoscopy Rooms	3	3	0	0	0	0				
Procedure Room Cases	234	246	285	311	338	361				
# of Procedure Rooms	0	0	1	1	1	1				

^{**}The applicant has 3 existing GI/endoscopy rooms which it is delicensing as part of Project ID #: O-11272-16 and shifting the GI/endoscopy cases to the ORs.

Source: Table on page 68 of the application.

In Section III, pages 46-52, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Steps 1-2. Historical IP and OP OR cases for the last four federal fiscal years (FFY2013 through FFY2016) from all the facilities in New Hanover County with licensed ORs. (See page 46.)

Licensed Facilities with ORs in New	FY2013	FY2014	FY2015	FY2016	
Hanover County					
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687	
Wilmington SurgCare Cases	8,378	7,935	8,463	8,589	
Total OP OR	29,139	30,859	31,666	33,276	
Cases					

*Source: Tables on p.47 of the application.

^{**}Based on 2016 and 2017 LRA

Steps 3-4. Calculate the CAGR for the IP and OP OR cases from FFY2013 through FFY2016. (See page 46.)

Licensed Facilities with ORs in New Hanover County	FY2013	FY2014	FY2015	FY2016	3-YR CAGR
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687	
Wilmington SurgCare	8,378	7,935	8,463	8,589	
Total OP OR	29,139	30,859	31,666	33,276	6.67%
Cases					

^{*}Source: Tables on p.47 of the application.

Steps 4-7. Project total combined future OP OR utilization for all licensed OR facilities in New Hanover County that perform OP surgery in ORs by applying a CAGR of 5.5%, which is below the historical CAGR of 6.67% for OP OR cases in New Hanover County. (See page 46-48)

		CY2016	CY2017	CY2018	CY2019	CY2020	OY1	OY2	OY3
				(Interim)	(Interim)	(Interim)	(CY2021)	(CY2022)	(CY2023)
Annual	Growth	na	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Rate*									
Projected	combined	33,276	34,940	36,687	38,521	40,447	42,470	44,593	46,823
OP OR o	cases from								
NHRMC	and								
Wilmingto	on								
SurgCare									

^{*}Note: In Step 4 on page 46 the applicant states that to project future ambulatory surgery cases a 5.5% CAGR was used. However, the Table on p.47 refers to both a 5.5% CAGR and a 5.0% CAGR. The calculations utilized a 5.0% CAGR as reflected in the table above.

Source: Table on page 47 of the application.

Step 8-9. Calculate Wilmington SurgCare's OP OR market share for CY2017 through CY2023 and projected OR Utilization (See pages 48-49)

The applicant calculated Wilmington SurgCare's market share of by dividing the most recent 12 months actual annual utilization of 8,531 by the total OP OR cases in performed New Hanover County for CY2017 (34,940) [Market Share CY2017: 8,531/34,940 = .24416 or 24.4%.]

The market share, 24.4%, is used to project OR utilization for Wilmington SurgCare for CY2017, CY2018 and CY2019 during which time Wilmington SurgCare has seven ORs.

	CY2017	CY2018	CY2019
# of ORs	7	7	7
Total OP OR cases in New Hanover County Facilities	34,940	36,687	38,521
Market Share Assumption	24.4%	24.4%	24.4%
Wilmington SurgCare Cases	8,531	8,958	9,405

Source: Table on page 47 of the application.

Based on the approval of Project ID# O-11272-16 (add 3 ORs and one procedure room), Wilmington SurgCare is proposed to have 10 ORs in CY2020. With the approval of this project, Wilmington SurgCare assumes they will have 11 ORs in CY2021, CY2022 and CY2023. The first three Operating Years for this project are CY2021-CY2023. Wilmington SurgCare projects a market share of 27.0%, 28.0%, 29.0% and 29.5% for CY2020 through CY2023 based on the projected increase in the number of ORs at Wilmington SurgCare and the recruitment of new physicians. See both Exhibit 35 regarding the recruitment of new physicians and Exhibit 48 for additional information regarding projected market share and utilization projections as illustrated in the table below. (See page 48-49.)

	CY2020	OY1	OY2	OY3
	(Interim)	(CY2021)	(CY2022)	(CY2023)
Total OP OR cases in New Hanover County	40,447	42,470	44,593	46,823
Facilities (NHRMC and Wilmington				
SurgCare)				
Market Share Assumption	27.0%	28.0%	29.0%	29.5%
Wilmington SurgCare Cases	10,921	11,891	12,932	13,813

Source: Table on page 47 of the application.

Steps 10-11. Calculate annual OR surgical case hours for Wilmington SurgCare for OY1-OY3 and the number of ORs needed at Wilmington SurgCare (See page 47 and 49)

	CY2020	OY1	OY2	OY3
	(Interim)	(CY2021)	(CY2022)	(CY2023)
# of ORs*	10	11	11	11
Wilmington SurgCare Cases	10,921	11,891	12,932	13,813
Surgical Hours (OP Cases x 1.5 hrs)	16,381	17,837	19,398	20,719
# of ORs needed (Surgical Hours/1,872)	8.75	9.53	10.36	11.07
# of ORs needed per Rule**	9.0	10.0	10.0	11.0

^{*}Wilmington SurgCare

As shown in the table above, in OY 3 (CY 2022), the applicant projects that 20,719 outpatient surgical cases will be performed in the 11 ORs (7 existing, 3 approved, one proposed) at the Wilmington SurgCare facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of Existing ORs*	# of ORs Needed
OY 3	13,813	20,719	11.07	10.0	1.0

*7 existing and 3 approved. See Project ID#O-11272-16

Source: Table on page 47 of the application.

However, projected OR utilization is not reasonable and adequately supported for the following reasons:

^{**}In Operating Room Service Areas with more than 10 ORs 0.5 is rounded up and 0.4 is rounded down. Source: Table on page 47.

<u>First:</u> An inaccurate CAGR Calculation was used in Steps 3-4 of the methodology to project overall OP OR cases in New Hanover through OY3

As shown in the table below from page 47 of the application, the applicant calculated a CAGR of 6.67% for the last four historical years of OR OP cases in New Hanover County facilities.

Licensed Facilities with ORs in New	FY2013	FY2014	FY2015	FY2016	CAGR
Hanover County					
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687	
Wilmington SurgCare Cases	8,378	7,935	8,463	8,589	
Total OP OR	29,139	30,859	31,666	33,276	6.67%
Cases					
CORRECTED CAGR					4.52%

^{*}Source: Tables on p.47 of the application.

However, the mathematical calculation showing a CAGR of 6.67% is incorrect. The correct CAGR is 4.52%. The incorrect CAGR of 6.67% was "reduced" by the applicant to 5.0% and then applied in Steps 4-7 to project total overall OP OR cases for New Hanover County in OY3(CY2023) from all facilities with ORs (NHRMC and Wilmington SurgCare).

Using the correct CAGR of 4.52%, the table below projects overall OP OR cases for New Hanover County in OY3(CY2023) from all facilities with ORs (NHRMC and Wilmington SurgCare).

	CY2016	CY2017	CY2018	CY2019	CY2020	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
Annual Growth Rate*	na	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Projected combined OP OR cases from NHRMC and Wilmington SurgCare	33,276	34,940	36,687	38,521	40,447	42,470	44,593	46,823
CORRECTED CAGR	na	4.52%	4.52%	4.52%	4.52%	4.52%	4.52%	4.52%
CORRECTED combined OP OR cases from NHRMC and Wilmington SurgCare	33,276	34,780	36,352	37,995	39,712	41,507	43,383	45,344

^{*}Note: In Step 4 on page 46 the applicant states that to project future ambulatory surgery cases a 5.5% CAGR was used. However, the Table on p.47 refers to both a 5.5% CAGR and a 5.0% CAGR. The calculations utilized a 5.0% CAGR as reflected in the table above.

If a CAGR of 4.52% is utilized instead of a CAGR of 5.0% total projected OP OR cases in OY3 (CY2023) would be 45,343 not 46,823. The reason this is important is that to calculate projected OP OR cases in the OY3 Wilmington SurgCare utilized a methodology of projecting

total OP OR cases in New Hanover County for OY3(CY2023) and then multiplying that number by a projected market share assumption for Wilmington SurgCare. As shown above, Wilmington SurgCare's projected total of OP OR cases in New Hanover County for OY3(CY2023) was not reasonable. Furthermore, as discussed below, the projected market share assumption (the second part of the critical equation) utilized by Wilmington SurgCare was also not reasonable.

Second: The Market Share Assumptions and Projections in Step 8 of the methodology are unsupported and not reasonable:

The applicant utilizes its market share of OP OR cases in New Hanover County as part of its methodology to project utilization. See Step 8 above and on page 48 of the application. For CY2017 Wilmington SurgCare' market share is calculated by dividing its OP OR cases for CY2017 (8,531 cases) by the total OP OR cases for New Hanover County (34,940) to arrive at 24.4% market share assumption [8,531 / 34,940 = .2442 or 24.4%]. The applicant applies that market share percentage for CY2017 through CY2019 before starting to apply a higher market share assumption. However, as shown below, the applicant has declined in market share by -3.53% from FY2013 through FY2016.

	FY2013	FY2014	FY2015	FY2016	Change in Market
					Share OR CAGR
Total New Hanover OP	29,139	30,859	31,666	33,276	
OR Cases					
Wilmington SurgCare	8,378	7,935	8,463	8,589	
OP OR Cases					
Wilmington SurgCare	28.75%	25.71%	26.73%	25.81%	(-3.53%)
OP OR Market Share					
Average Change in					(-1.18**)
Market Share from					
FY2013 to CY2016					

^{*}Under the applicant's method of converting FY to CY the years above are analogous.

Based on the historical decline in market share for Wilmington SurgCare from FY2013 to FY2016 it was not reasonable for Wilmington SurgCare to hold projected market share for CY2017 to CY2019 steady at 24.4%. Rather, based on the historical trend, the applicant should have reasonably applied a decreasing market share percentage for CY2017, CY2018 and CY2019 which would have lowered the projected market share for the first three operating years of the project.

Using the average yearly change in market share (or CAGR) for Wilmington SurgCare of (-1.18%) calculated in the table above the table below reflects the corrected market share assumptions for CY2017 through CY2023(OY3).

Projected Market Share CY2017: 25.81% (FY2016) - 1.18% = 24.63%

Projected Market Share CY2018: 24.63% - 1.18% = 23.45% Projected Market Share CY2019: 23.45% - 1.18% = 22.27%

^{**} -3.53 / 3 years = -1.176 or -1.18% per year

The applicant projected a 2.6% increase in Market Share in CY2020 based on three additional ORs being placed in service at Wilmington SurgCare pursuant to CON Project ID #O-11272-16. For CY2021 (OY1) and CY2022 (OY2) the applicant projected consecutive 1.0% increases in projected market share and for CY2023 (OY3) the applicant projected a 0.5% increase in market share. The projected market share for CY2021- CY2023 is calculated below keeping those same projected market share increases

Projected Market Share CY2020: 22.27% + 2.6% = 24.87%Projected Market Share CY2021: 24.87 + 1.0% = 25.87%Projected Market Share CY 2022: 25.87% + 1.0% = 26.87%Projected Market Share CY2023: 26.87% + 0.5% = 27.37%

The table below shows both the applicants original market share assumptions for CY2017 to CY2023(OY3) and the corrected market share assumptions calculated above which factor in the historical decline in market share for Wilmington SurgCare from FY2013 to FY2016.

	CY2016	CY2017	CY2018	CY2019	CY2020	OY1	OY2	OY3
			(Interim)	(Interim)	(Interim)	(CY2021)	(CY2022)	(CY2023)
# of ORs*	7	7	7	7	10	11	11	11
Applicants		24.4%	24.4%	24.4%	27.0%	28.0%	29.0%	29.5%
Market Share								
Assumption								
CORRECTED	25.81%	24.63%	23.45%	22.27%	24.87%	25.87%	26.87%	27.37%
Market Share								
Assumption								
Change in	na	-1.085%	-1.085%	-1.085%	2.6%	1.0%	1.0%	0.5%
Market Share								

Projected OP OR cases for Wilmington SurgCare through OY3(CY2023) utilizing the corrected projected OP OR cases for New Hanover County from all facilities (NHRMC and Wilmington SurgCare) and the corrected market share percentage.

	CY2017	CY2018	CY2019	CY2020 (Interim)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
# of ORs*	7	7	7	10	11	11	11
	34,780	36,352	37,995	39,712	41,507	43,383	45,344
CORRECTED Market	24.63%	23.45%	22.27%	24.87%	25.87%	26.87%	27.37%
Share Assumption (-1.085)							
Total Projected OP OR							12,411
Cases from New Hanover							
County Facilities							
X 1.5 hours							18,617
Divided by 1,872							9.95
Total ORs Needed (round							10.0
up if .5 or higher)							
Total number of Existing or							10.00
Approved ORs							
Total ORs needed at Wilmington SurgCare							0.00

Based on the corrected projected total OP OR cases in New Hanover County OY3 (CY2023) and the corrected projected market share of Wilmington SurgCare the projected utilization at Wilmington SurgCare in OY3 shows a need for 10 ORs. Wilmington SurgCare already has 10 ORs (7 existing and 3 approved). Therefore, there is no need for an additional OR as Wilmington SurgCare.

Third: Unreasonable Time Frame: As part of its utilization projections for this project the applicant relies on having developed three new ORs with the first operating year for the three new ORs being CY2020. See CON Project ID #O-11272-17. In Steps 8-11 above, the applicant utilizes a percent of market share to calculate projected utilization. The applicant increases market share based on the number of ORs the applicant anticipates being in service at Wilmington SurgCare. However, that approval is currently under appeal. By the time the appeal is fully resolved the project, at a minimum, will have been significantly delayed. The approval could also potentially be overturned. A delay in the three new ORs being developed by Wilmington SurgCare negatively impacts projected utilization. The applicant did not address this issue in its application, but rather kept the original projected project completion date. Adding the 3 approved ORs to Wilmington SurgCare even just one year later in CY2021 would have negatively impacted the market percentage in OY3 (CY2023) such that the total ORs needed at Wilmington SurgCare would have been less than 10 ORs based on the market share utilization methodology in this application.

GI/Endoscopy Room and Procedure Room Utilization

In Section IV.1, page 68, and Section III, pages 50-52, the applicant provides historical and projected utilization as summarized in the following table(s).

Wilmington SurgCare: Historical GI Endoscopy and Procedure Room Cases

		1 /		
	2016**	2017 **	Actual Utilization	Current*
			10/1/2016 to 9/30/2017	1/1/2017 to 12/31/2017
			(will be 2018 LRA)	
GI Endoscopy Cases**	240	231	233	233
# of GI/Endoscopy Rooms	3	3	3	3
Procedure Room Cases*	212	226	223	223
# of Procedure Rooms	0	0	0	0

^{*}Procedure Cases were performed in the GI Endoscopy Rooms

Wilmington SurgCare: Interim and Projected GI Endoscopy and Procedure Room Cases

	Interim CY2018	Interim CY2019	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023
GI Endoscopy Cases*	224	215	0	0	0	0
# of GI/Endoscopy Rooms	3	3	0	0	0	0
Procedure Room Cases (from Minor Procedure Room)	234	246	285	311	338	361
# of Procedure Rooms	0	0	1	1	1	1

^{**}The applicant has 3 existing GI endoscopy rooms which it is delicensing as part of Project ID#O-11272-16 and shifting the GI endoscopy cases to the ORs.

Wilmington SurgCare had a ratio of OP OR Cases to procedure room cases of .026 for the last 12 months ending September 30, 2017. To project procedure room cases the applicant applied this historic ratio to projected OP OR cases at Wilmington SurgCare to project procedure room cases.

	Interim CY2018	Interim CY2019	Interim CY2020	OY1	OY2	OY3
OR Cases	8,958	9,405	10,921	11,891	12,932	13,813
Ratio	0.026	0.026	0.026	0.026	0.026	0.026
Procedure	234	246	285	311	338	361
Room						
Cases						

Projected Utilization of GI Endoscopy room cases and procedure room cases is reasonable and supported.

Access

In Section VI.2, page 78, the applicant states, ""The facility will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability or ability to pay. Wilmington SurgCare provides language translation services at no cost to patients. The facility holds Medicare and Medicaid certification and accreditation in support of expanded patient access."

^{**}Based on LRA

In Section VI.14, page 85, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Services as Percent of Total
Self Pay/Indigent	1.24%
Commercial Insurance	0.41%
Medicare/Medicare Managed Care	51.26%
Medicaid	7.78%
Managed Care	32.65%
Other	6.65%
Total	100.0%

Source: Table page 85 of application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- Projected utilization is not reasonable and is not adequately supported.
- The applicant was previously approved to develop 3 ORs (See Project ID#O-11272-16). The applicant does not adequately address why the surgical services proposed in this application are needed in addition to the approved capacity surgical services pursuant to Project ID #O-11272-17.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover County operating room service area, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New

Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, page 106, the applicant provides WASC's projected patient origin for the first and second operating years CY2020 and CY2021, as shown in the table below.

County	First Full FY of O Project Co (1/1/2020 to		Second Full FY of Operation following Project Completion (1/1/2021 to 12/30/2021)		
	Patients	Patients % of Total		% of Total	
New Hanover	3,335	43.0%	5,900	43.0%	
Brunswick	1,833	24.0%	3,243	24.0%	
Pender	713	9.0%	1,261	9.0%	
Onslow	694	9.0%	1,227	9.0%	
Columbus	405	5.0%	717	5.0%	
Other NC	432	6.0%	765	6.0%	
Duplin	237	3.0%	419	3.0%	
Other States	118	2.0%	208	2.0%	
Totals	7,766	100.0%	13,740	100.0%	

Source: Page 106 of the Application.

In Section III.6, pages 106-107, the applicant provides the assumptions and methodology used to project its patient origin for surgical services. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 64-96, the applicant describes the need for the proposed project and states that the need for an OR at WASC is supported by the factors as listed below and discussed thereafter:

- Growth, aging, and health status of the population and a need for new multi-specialty ASC that is organized around the needs of a moderate-income community that has a diversified population and substantial pockets of poverty of the population of the proposed service area (See application pages 66-68 and Exhibit 36)
- Growth in ambulatory surgical cases in New Hanover County. (See application pages 69-72)
- Historical development of ORs in New Hanover County (See application pages 73-75)
- Need for more ASC capacity in New Hanover County not under a hospital license. (See application pages 76-78)
- Need for an OR to complement Wilmington Health's procedure rooms. (See application page 79)
- Need to reduce the cost of spine surgeries, and other more common surgeries like cataract, which are extremely expensive in a hospital-based environment. (See application pages 80-81)
- *Need for specialized equipment.* (See application page 82)

- Need for standardized pre and post-surgical processes for neurosurgery cases. (See application page 83)
- *Need for increased patient convenience.* (See application page 84)
- Need to increase physician capacity to treat more patients in Southeastern North Carolina. (See application pages 85-86)
- Need for extended stay short stay recovery beds. (See application page 84)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop a new ASC with one OR in the New Hanover County Operating Room Service Area in compliance with the OR need determination in the 2017 SMFP.
- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.
- The population (future patient base for WASC) of the service area identified by the applicant is projected to increase by 57,145 residents over the next five years with the elderly population projected to increase by 22,597 people or a growth rate of 18.1%.
- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.
- The list of surgical procedures received at an ASC which are reimbursable under Centers for Medicaid Services (CMS), Medicare and commercial insurance companies has expanded.
- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, pages 117-118, the applicant provides projected utilization as illustrated in the following table(s).

WASC: Projected Utilization

	<u> </u>		
	OY 1 (CY 2020)	OY 2 (CY 2021)	OY 3 (CY 2022)
# of ORs	1	1	1
Total OR OP Cases	795	1,337	1,357
# of GI/Endoscopy Rooms	3	3	3
Total GI/Endoscopy Procedures	4,915	4,915	4,990
# of Procedure Rooms	3	3	3
Total Procedure Room Cases	8,744	12,331	12,518

Source: Tables IV.1 and IV.2 on pages 117-118.

In Section IV, pages 119-128, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

The applicant projected OR Cases by specialty as illustrated in the table below.

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	250	439	446
Neurosurgery	232	372	378
Ophthalmology	0	0	0
Oral Surgery	15	29	29
Orthopedics	135	228	231
Plastic Surgery	146	240	244
Urology	0	0	0
Vascular	16	29	29
Podiatry	0	0	0
Gastroenterology	0	0	0
Total	795	1,337	1,357

Source: Table page 127 of the application.

To develop the table above, the applicant first projected total cases for OY2, then OY1 and then OY3 utilizing the following steps. The applicant first applied all appropriate cases to OY2 and then calculated a "start-up lag" for OY1 and reduced the cases in OY2 by the startup lag to project cases for OY1.

- Step 1. Determined that the proposed WASC facility would be completed an offering services by January 1, 2020. Therefore OY1 through OY3 are CY2020 through CY2022, respectively. (See page 119)
- Step 2. Utilized physician support letters by specialty found in Exhibit 18 which includes the number of cases expected to be performed by each physician. See also Exhibit 25. The cases, by specialty, match the overall table in Exhibit 25. The applicant states that the physician practices evaluated the number of outpatient surgical cases that would be appropriate for WASC. (See page 119)
- Step 3. Eliminated referral cases that were not deemed appropriate for the proposed services at WASC. (See page 120)
- Step 4. OY2 projected utilization: Identified the appropriate cases identified in the physician referral letters for WASC and assigned them, by specialty, to OY2. (See page 120 and Exhibit 25).
- Step 5. By specialty, estimated the Medicaid and Medicare percentage of each specialty based on payor mix data and assumptions from Table VI.3 on page 156 of the application. (See page 121 and 156)

Specialties	% Medicare	% Medicaid	%
			Medicare/Medicaid
			Combined
General Surgery	40.7%	8.5%	49.3%
Neurosurgery	15.5%	0.0%	15.5%
Ophthalmology	71.8%	2.5%	74.3%
Oral Surgery	0.6%	73.7%	74.63%
Orthopedics	29.8%	4.8%	34.6%
Plastic Surgery	24.0%	2.0%	26.0%
Urology	34.0%	12.0%	46.0%
Vascular	55.0%	5.0%	60.0%
Podiatry	38.8%	6.3%	45.1%
Gastroenterology	35.0%	2.0%	37.0%

Step 6. OY1 projected utilization: Calculated a "Start-up Lag" for WASC and applied the "Start-up Lag" to the projected cases for OY2 to calculate projected cases for OY1. The "start-up lag" was based on a two-step process: first, the applicant applied a 35% reduction in all the cases listed by specialty, except for GI endo cases, to "allow time for all proposed WASC physicians to become comfortable with scheduling in the new facility"; and then, on top of the 35% reduction, the applicant applied a 25% reduction to all cases by specialty, except for GI endo cases, to allow for a three month delay associated with Medicare and Medicaid certification. Furthermore, the applicant assumed that all GI endo cases from Wilmington Health would transfer immediately upon WASC opening. See Table IV.4 and assumptions on pages 122-123 of the application.

Projected % Medicare & Medicaid	Specialty	WASC Cases OY2 (CY2021)	Start-up Lag (35%)	Medicare/Medicaid Certification Delay (25%)	WASC Cases OY1 (CY2020)
A	В	C	D	${f E}$	\mathbf{F}
49.3%	General Surgery	732	256	59	417
15.5%	Neurosurgery	372	130	9	232
74.3%	Ophthalmology	5,112	1,789	617	2,706
74.63%	Oral Surgery	48	17	6	25
34.6%	Orthopedics	432	151	24	257
26.0%	Plastic Surgery	480	168	20	292
46.0%	Urology	684	239	51	393
60.0%	Vascular	288	101	28	159
45.1%	Podiatry	1,092	382	80	630
37.0%	Gastroenterology	4,428	na	na	4,428
	Total	13,688	3,234	895	9,539

Step 7. OY3 projected utilization: In Table III.4, page 89 of the application, the applicant calculated, for 2017 through 2022, the five year CAGR (1.5%) for projected population growth for the counties consisting of the proposed service area. The applicant projected OY3 cases by multiplying OY2 projected cases by the 1.5% CAGR. (See Table IV.5 and methodology on page 124.)

Specialties	OY2 (CY2021)	Population Growth Rate*	OY3 (CY2022)
General Surgery	732	1.50%	743
Neurosurgery	372	1.50%	378
Ophthalmology	5,112	1.50%	5,189
Oral Surgery	48	1.50%	49
Orthopedics	432	1.50%	439
Plastic Surgery	480	1.50%	487
Urology	684	1.50%	694
Vascular	288	1.50%	292
Podiatry	1,092	1.50%	1,109
Gastroenterology	4,428	1.50%	4,495
Total	13,688	1.50%	13,876

^{*}Based on CAGR calculated in Table III.14, page 89.

The project analyst notes that the CAGR of 1.5% in Table III.14 on page 89 of the application is incorrect. The correct CAGR is 1.27% based on a starting population of 731,346 (2017), and ending population of 778,971 (2022) and a 5 year period. In the table below the CAGR of 1.27% is applied. The specialties in bold are the specialties the applicant projects performing in the proposed OR. Utilizing the corrected CAGR only reduced the projected number of OR cases in OY3 by 6 cases for a total of 1,351 OR cases in OY3 [1,357-6 = 1,351].

Specialties	OY2 (CY2021)	Population Growth Rate*	OY3 (CY2022)	Difference
General Surgery	732	1.27%	741	-2
Neurosurgery	372	1.27%	377	-1
Ophthalmology	5,112	1.27%	5,177	-12
Oral Surgery	48	1.27%	49	0
Orthopedics	432	1.27%	438	-1
Plastic Surgery	480	1.27%	486	-1
Urology	684	1.27%	693	-1
Vascular	288	1.27%	292	0
Podiatry	1,092	1.27%	1,106	-3
Gastroenterology	4,428	1.27%	4,484	-11
Total	13,688	1.27%	13,843	

^{*}Based on CAGR calculated in Table III.14, page 89.

Source: Table IV.5 on page 124 and Table III.14 on page 89.

Furthermore, note that for OY2 (CY2021) the applicant projected 1,337 OR cases and for OY3 (CY2022) the applicant projects 1,357 OR cases, or an increase from OY2 to OY3 of only 20 OR cases, which is a very conservative increase. The 0.23 difference in the CAGR [1.50 – 1.27 = 0.23] had no significant effect.

Step 8: Calculated WASC overall combined cases: OR and Procedure Room, by specialty, for OY1-OY3. (See page 125.)

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	417	732	743
Neurosurgery	232	372	378
Ophthalmology	2,706	5,112	5,190
Oral Surgery	25	48	49
Orthopedics	257	432	439
Plastic Surgery	292	480	487
Urology	393	684	694
Vascular	159	288	292
Podiatry	630	1,092	1,109
Gastroenterology	4,428	4,428	4,495
Total*	9,539	13,688	13,876

Source: Table page 125 of the application.

Step 9. Categorize WASC's projected cases, by specialty, as OR cases or Procedure Room cases. (See page 126.)

On page 126, the applicant states, "Staff of Wilmington Health and SCA reviewed case history provided by the professionals who proposed to become members of the WASC medical staff. Using their combined experience managing ambulatory facilities, assembling ASA code surgical data for ACO and other reports, consulting with the professionals, these staff members estimated cases appropriate for the operating room or procedure rooms, by specialty. The process involved assigning a percentage operating room and procedure room to each physician and multiplying the proposed cases for project year 2. See Tables IV.4 and IV.5 for the result of this analysis. See Exhibit 24 for a breakdown of project year two, 2021, cases for operating room procedure rooms, by specialty."

Steps 10-11. Projected WASC OR Cases and WASC Procedure Room Cases, By Specialty for OY1-OY3. The applicant applied the results of Step 9 to the table in Step 8 which resulted in the following tables. (See pages 126-128)

^{*}Note: the totals for OY1- OY3 in Table IV.6 on page 125 are incorrect. They were not totaled correctly. In addition, for OY1 there was a typographical error for gastroenterology. The number of cases of OY1 should have been 4,428 based on the rest of the application, not 2,612. The mathematical error was corrected and the total cases for OY1-OY3 are correct.

Projected OR Cases at WASC for OY1-OY3

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	250	439	446
Neurosurgery	232	372	378
Ophthalmology	0	0	0
Oral Surgery	15	29	29
Orthopedics	135	228	231
Plastic Surgery	146	240	244
Urology	0	0	0
Vascular	16	29	29
Podiatry	0	0	0
Gastroenterology	0	0	0
Total	795	1,337	1,357
Percent Increase	na	68.2%	1.5%
Case Increase	na	542	20

Source: Table page 127 of the application.

Projected Procedure Room Cases at WASC for OY1-OY3

Trojected Procedure Room Cases at WASC for OTT-013					
Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)		
General Surgery	167	293	297		
Neurosurgery	0	0	0		
Ophthalmology	2,706	5,112	5,190		
Oral Surgery	10	19	19		
Orthopedics	121	204	207		
Plastic Surgery	146	240	244		
Urology	393	684	694		
Vascular	143	259	263		
Podiatry	630	1,092	1,109		
Gastroenterology	4,428	4,428	4,495		
Total	8,744	12,331	12,518		

Source: Table page 127 of the application.

The number of ORs needed at WASC, based on projected utilization, is calculated in the table below:

ORs Needed based on Projected Utilization

	CY 2020 (OY1)	CY 2021 (OY2)	CY 2022 (OY3)
Total OR Cases	795	1,337	1,357
Total OR Hours Based on 1.5 Hrs per Case* (OP	1,192.5	2,005.5	2,035.5
Cases x 1.5 hrs per case)			
Annual Hrs Per OR	1,872	1,872	1,872
Total ORs Needed at WASC (Total OR	0.64	1.07	1.09
Hours/Annual Hrs (1,872) per OR)			
Existing ORs	0	0	0
Additional ORs needed	0	1.0	1.0
Year 3 Rounded up to Whole Number			1.0

Source: Table on page 58 of the application.

As shown in the table above, in OY 3 (CY 2022), the applicant projects that 2,035.5 outpatient surgical hours will be performed in the proposed OR at the WASC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3		1,357	2,035.5	1.09	1.0

Based on the analysis stated in Step 7 above, the applicant over projected OR cases by 6 cases. In the table below the OR need for WASC is projected based on 6 less OR cases than the applicant predicted. As shown in the table above, in OY 3 (CY 2022), the revised OR case projection results in 2,026.5 outpatient surgical hours to be performed in the proposed OR at the WASC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3		1,351	2,026.5	1.082	1.0

Projected Utilization: GI Endoscopy Procedures

Step 12. Project GI Endoscopy Procedures at WASC for OY1-OY3. (See page 128.)

^{*}In Chapter 6 "Operating Rooms" of the 2016 SMFP there is a section on page 64 entitled "The Methodology for Projecting Operating Room Need" which states: "For purposes of the State Medical Facilities Plan, the average operating rooms is anticipated to be staffed nine hours a day, for 260 days per year, and utilized at least 80 percent of the available time. The standard number of hours per operating room per year based on these assumptions is 1,872 hours. (Column K: 9 hours x 260 days x 0.8 – 1,872 hours per operating room per year)." (See page 64, Step 3, Section f, of the 2016 SMFP)

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
GI/Endoscopy Cases	4,428	4,428	4,495
Procedures per Case	1.11	1.11	1.11
GI/Endoscopy	4,915	4,915	4,990
Procedures			

Source: Table IV.9, page 128.

On page 128, the applicant states that the number of GI endo cases is conservatively estimated to start in 2021 "at the level estimated by the physicians." See Exhibits 18 and 25.

Projected utilization is reasonable and adequately supported for the following reasons:

- The methodology and assumptions are reasonable and adequately supported.
- The applicant documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b),

Access

In Section VI.2, page 141, the applicant states, "WASC will not discriminate on the basis of age, race, national, or ethnic origin, disability, sex, income, or ability to pay."

In Form D of the proformas, the applicant projects the following payor mix for the proposed OR surgical services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay	5.94%	70
Medicare/Medicare Managed Care	28.31%	378
Medicaid	5.67%	76
Commercial Insurance	54.86%	733
Other (Military, Workers Comp)	5.21%	70
Total	100.0%	1,337*

Source: Form D, Proformas of the application.

Note: Table VI.1, page 153 of the application appears to be a typographical error and is incorrect. The information in the table above is consistent with the information in the proformas and the rest of the application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

^{*}Totals as 1,336. Appears to be a rounding issue.

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

NHSC. The applicants propose to develop a new single specialty ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of one OR and two procedure rooms upon project completion.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, page 61, the applicants provide NHSC's projected patient origin for the first and second operating years (CY2020 and CY2021) as shown in the table below.

NHSC: Projected Patient Origin- OY1 and OY2

County	CY2020	CY2021
New Hanover	76.2%	74.5%
Onslow	11.1%	12.0%
Pender	12.6%	13.6%
Total	100.0%	100.0%

Source: Table on page 61 of the application.

In Section III.6, page 61, the applicants provide the assumptions and methodology used to project its patient origin. The applicants assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 31-47, the applicants explains describes the need for the proposed project and states that the need for an OR as NHSC is supported by the factors listed below and discussed thereafter:

In identifying the need, the applicants reviewed:

- Service Area Demographics and Growth Trends. The population of New Hanover County is projected to increase by 18,283 residents from 2017 to 2022. The young adult segment of the population, ages 18-44, is expected to comprise approximately 40% of the population of New Hanover County by 2020 and due to participation in all levels of sports and recreation activities, with the accompanying prevalence of injuries, the proposed ASC specializing exclusively in orthopedics would benefit this population. (See application pages 42-47)
- *Physician Support*. Exhibit 10 includes letters from 12 orthopedic surgeons, in addition to letters of support from physicians who perform pain management procedures. (See application page 47 and Exhibit 10)
- Ambulatory Surgery Centers. There is increased demand for ASC's based on convenience, high levels of quality, cost savings and efficient physician practice. (See application pages 32-36)
- Ambulatory Surgery for New Hanover County Residents. There is a high ambulatory surgery usage rate in New Hanover County over 74% of those cases being performed in hospital-based surgical ORs. (See application pages 37-39)
- Orthopaedic Surgery. Orthopedic surgeries represent over 22.0% of the outpatient surgical cases in New Hanover County with musculoskeletal symptoms and disorders projected to continue to increase. (See application pages 39-42)
- Ambulatory Surgery Growth Trends. Ambulatory surgery cases account for approximately 72% of all surgical utilization in North Carolina and this trend is projected to continue. (See application pages 31-32)

The information is reasonable and adequately supported for the following reasons:

• There is a need determination for one OR in the New Hanover County operating room service area in the 2017 SMFP. The applicants are applying to develop a new ASC with one OR in the New Hanover County operating room service area in compliance with the OR need determination in the 2017 SMFP.

- The applicants use historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The applicants use Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.
- The population (future patient base for NHSC) of New Hanover County, identified by the applicants as the prime county of its three county service area, and especially the elderly population, has a projected 5 year CAGR growth rate of 1.6% which equates to an additional 18,238 residents.
- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.
- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, pages 66-67, the applicants provide projected utilization as illustrated in the following table.

NHSC: Projected Utilization

	OY 1 (CY 2020)	OY 2 (CY 2021)	OY 3 (CY 2022)
# of ORs	1	1	12
Total OR OP Cases	1,335	1,515	1,704
# of Procedure Rooms	2	2	2
Total Procedure Room Cases	306	311	316

In Section III, pages 48-55, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

OR Utilization

Step 1. Historical Utilization and Background Information (pages 48-50)

- Identified the proposed service area as being New Hanover, Onslow and Pender counties.
- State that, only Orthopaedic Surgeons are projected to use the proposed NHSC facility.
- State that, "Based on recent data, orthopaedic ambulatory surgery cases from New Hanover, Onslow and Pender counties have increase by a CAGR of 6.5%"

- Identified twelve individual Orthopaedic Surgeons (NHSC User Surgeons) projected to utilize the NHSC facility (See page 48). These NHSC User Surgeons provided letters of support which also include the specific number of projected case referrals to the proposed NHSC facility. See Table on page 53 and Exhibit 10.
- Historical OP OR cases of NHSC User Surgeons: Identified historical OP OR cases, for CY2015-CY2017, for the NHSC User Surgeons for the three county service area as illustrated below.

NHSC User Surgeons: Historic Orthopaedic OP OR Cases**

County	CY2015	CY2016	CY2017*
New Hanover	1,046	1,079	1,212
Onslow	293	253	281
Pender	263	303	323
Total	1,602	1,635	1,816

^{*}Annualized based on data from January-September, 2017.

Source: NHSC member surgeons (this does not necessarily mean from the 12 identified docs)

Step 2. Projected Utilization at all OR facilities for NHSC User Surgeons through CY2022 (pages 50-51)

<u>First</u> calculated the three year CAGR for <u>all</u> OP OR cases (including, but not limited to, orthopaedic cases) performed on residents from the three county service area, as shown below

All OP OR Cases Performed on Service Area Residents, 2013-2016

County	2013	2014	2015	2016	3 yr CAGR
New Hanover	10,068	14,857	15,197	15,490	15.4%
Onslow	8,807	9,067	9,471	10,368	5.6%
Pender	3,715	3,853	3,916	4,235	4.5%

Source: Table on page 50.

Second: Calculate a 3 yr CAGR for only orthopaedic OP OR cases

To project orthopaedic OP OR cases for New Hanover County the applicant applied a CAGR of 3.9%. The 3.9% was determined by calculating one-fourth or 25% of the 3 year CAGR for New Hanover County identified in the table above $[15.4\% \times .25 = 3.85 \text{ or } 3.9\%]$

To project orthopaedic OP OR cases for Onslow County the applicant applied a CAGR of 1.9%. The 1.9% was determined by calculating one-third or 33% of the 3 year CAGR for Onslow County identified in the table above [5.6% x .33 = 1.848 or 1.9%].

To project orthopaedic OP OR cases for Pender County the applicant applied a CAGR of 1.5%. The 1.5% was determined by calculating one-third or 33% of

^{**}Does not included any OP Surgical Case volume performed at Wilmington SurgCare. See application page 49.

the 3 year CAGR for Pender County identified in the table above $[4.5\% \times .33 = 1.485 \text{ or } 1.5\%]$

<u>Third</u>: Utilizing the identified CAGR's the applicant projected utilization for the NHSC User Surgeons from CY2018 to CY2022 as shown in the table below.

NHSC User Surgeons: Projected ORTHO OP OR Cases** OY1-OY3

County	Growth	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022
•	Rate	(Historic)	(Interim)	(Interim)	(OY1)	(OY2)	(OY3)
New Hanover	3.9%	1,212	1,259	1,307	1,358	1,410	1,465
Onslow	1.9%	281	287	292	297	303	309
Pender	1.5%	323	327	332	337	342	347
Total		1,816	1,873	1,932	1,993	2,055	2,121
Yearly Growth Rate		na	3.13%	3.15%	3.16%	3.11%	3.21%

^{*}Annualized based on data from January-September 2017

Source: NHSC member surgeons (this does not necessarily mean from the 12 identified docs)

Step 3. <u>Projected Utilization at NHSC for NHSC User Surgeons through CY2022</u> (pages 51-54)

To project the number of OP OR cases of the NHSC User Surgeons that would be performed at the proposed NHSC facility the applicant projects that:

- During OY1(2020) 75% of the New Hanover Cases and 50% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.
- During OY2(2021) 80% of the New Hanover Cases and 60% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.
- During OY3(2022) 85% of the New Hanover Cases and 70% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.

NHSC: Projected ORTHO OP OR Cases for OY1-OY2 for NHSC User Surgeons at NHSC

County	CY2020	CY2021	CY2022
New Hanover	1,018	1,128	1,245
Onslow	149	182	216
Pender	169	205	243
Total	1,336	1,515	1,704

Source: Table on page 52.

In support of the percentages applied the applicant states:

- Anecdotal Feedback from patients that most of the hospital-based OP OR cases would utilize the new proposed NHSC facility.
- Benefits of access to OP OR Surgical Services that are not hospital-based such as: lower cost/charges.

^{**}Does not included any OP Surgical Case volume performed at Wilmington SurgCare.

- Epidemiological and demographic data support the continued growth of orthopaedic OP OR services in the service area.
- Letters of Support from the twelve NHSC User Surgeons each projecting the number of OP OR cases they anticipate performing at the proposed NHSC. The projected number of cases totals 2,210. See Table on page 53 and Exhibit 10.

The table shows the calculation of the number of ORs needed at NHSC, based on projected utilization, for OY3.

ORs Needed based on Projected Utilization

	CY2020(OY1)	CY 2021 (OY2)	CY 2022 (OY3)
Total OR Cases	1,336	1,515	1,704
Total OR Hours Based on 1.5 Hrs per Case* (OP	2,004	2,272.5	2,556
Cases x 1.5 hrs per case)			
Annual Hrs Per OR	1,872	1,872	1,872
Total ORs Needed at NHSC (Total OR	1.07	1.21	1.37
Hours/Annual Hrs (1,872) per OR)			
Existing ORs	0	0	0
Additional ORs needed	1.0	1.0	1.0
Year 3 Rounded to Whole Number			1.0

Source: Table on page 58 of the application.

*In Chapter 6 "Operating Rooms" of the 2016 SMFP there is a section on page 64 entitled "The Methodology for Projecting Operating Room Need" which states: "For purposes of the State Medical Facilities Plan, the average operating rooms is anticipated to be staffed nine hours a day, for 260 days per year, and utilized at least 80 percent of the available time. The standard number of hours per operating room per year based on these assumptions is 1,872 hours. (Column K: 9 hours x 260 days x 0.8 – 1,872 hours per operating room per year)." (See page 64, Step 3, Section f, of the 2016 SMFP)

As shown in the table above, in OY 3 (CY 2022), the applicants project that 2,035.5 outpatient surgical cases will be performed in the one projected OR at the NHSC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3		1,704	2,556	1.37	1.0

Projected utilization is reasonable and adequately supported for the following reasons:

- These NHSC User Surgeons provide letters of support which letters also include specific numbers of projected case referrals to the proposed NHSC facility. See Table on page 53 and Exhibit 10. The applicants project 1,336 orthopaedic OR cases at the proposed NHSC facility in OY1 and 1,704 orthopaedic OR cases in OY3. The twelve NHSC User Surgeons, per their letters of support, anticipate referring 2,210 orthopaedic OR cases to the proposed NHSC facility in OY1.
- The projected utilizations were conservative given the twelve NHSC User Surgeons anticipated OR case referrals in OY1

- NOTE: The projected OR methodology, without the above referenced letters of support with specific anticipated OR case referrals, was not reasonable and adequately supported for the following reasons:
 - The statement set forth in Step 1 "Based on recent data, orthopaedic ambulatory surgery cases from New Hanover, Onslow and Pender counties have increase by a CAGR of 6.5%" was not documented or supported.
 - The basis for the assumptions in Step 2 utilized to calculate the 3yr CAGR for New Hanover, Onslow and Pender were not adequately documented, explained or supported.
 - The basis for the assumptions in Step 3 utilized to calculate the number of the NHSC user surgeon cases that would be performed at NHSC was not documented, explained or supported.

Procedure Room Utilization

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
# of Procedure Rooms	2	2	2
# of Procedures (non-surgical)	306	311	318

As illustrated in the table below the applicants identified the non-surgical procedures performed by NHSC members on residents of New Hanover, Onslow and Pender counties at all facilities. To project utilization the applicant applied the New Hanover County population growth rate of 1.6%. The applicants then projected that approximately 10.0% of the projected procedures would be performed at NHSC based on historical analysis of the types of procedures performed on residents from the three county service area. Three physicians provided letters of support which included anticipated procedure case referrals. See pages 54-55 and Exhibit 10.

NHSC Pain Management Specialists: Procedures (non-surgical)

	Historical (CY2016)	Annualized (CY2017)	Interim (CY2018)	Interim (CY2019)	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
Procedures (non-surgical): All facilities	2,171	2,970	3,016	3,016	3,111	3,160	3,209
NHSC					306	311	316

Projected utilization is reasonable and adequately supported for the following reasons:

The methodology is reasonable, based on historic data and a reasonable growth rate and backed by physician letters of support with specific numbers of anticipated referrals that supports the applicants projections.

Access

In Section VI.2, page 76, the applicants state "NHSC will not discriminate against anyone, and will provide medical services without regard to race, ethnicity, creed, color, age, religion, national origin, gender or handicap." In Section VI.14, page 85, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	& Services as Percent of Total:
Self Pay/ Indigent	3.4%
Medicare/Medicare Managed Care	12.9%
Medicaid	10.5%
Managed Care and Commercial	23.8%
Care	
BCBS	39.7%
Other (Workers Comp, TRICARE,	9.7%
VA)	
Total	100.0%

Source: Table on page 85 of application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identified the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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.

C WASC

NA NHRMC Wilmington SurgCare NHSC

NHRMC. The applicant does not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

Wilmington SurgCare. The applicant does not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

The applicant proposes to relocate three multispecialty GI/Endoscopy rooms from Wilmington Health Endoscopy Center (a licensed and existing ambulatory center owned and operated by Wilmington Health) to the proposed WASC facility. Both the existing Wilmington Health Endoscopy Center and the proposed WASC facility are located within Wilmington, in New Hanover County. According to Map Quest, the proposed WASC facility will be located approximately 3.9 miles (a seven minute drive) from the existing Wilmington Health Endoscopy Center facility. Therefore, the three multispecialty GI/Endoscopy rooms would be geographically accessible to the same population (including underserved groups) presently served by Wilmington Health Endoscopy Center.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

• Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

NHSC. The applicants do not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

(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 NHRMC WASC NHSC

NC Wilmington SurgCare

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The project does not include any gastrointestinal endoscopy (GI/endoscopy) rooms.

In Section III.8, page 41-42, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

<u>Maintain the Status Quo</u>- The applicant states that NHRMC is the ultimate safety-net provider of surgical services in the New Hanover County operating room service area and must treat all patients even as its capacity constraints are threatening its ability to meet the community's need. NHRMC has shown an internal need for 3 ORs since FY2016. Maintaining the status quo is not the most effective alternative to meet the need for additional ORs at NHRMC.

<u>Joint Venture</u>- The applicant states that, because the project will be internal to NHRMC, a joint venture is impractical. Therefore, a joint venture to develop one new OR is not the most effective alternative.

On page 42, the applicant states that its proposal is the most effective alternative because there are not expensive renovation or equipment costs associated with the new OR, NHRMC has had an internal facility need for at least one additional OR since FY2014 and three ORs since FY2016 and the additional OR will meet the demand for surgical services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the New Hanover County operating room service area. Therefore, the application is conforming to this criterion.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room.)

In Section III.8, pages 62-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicant states that due to the growth and aging of the population in the service area the patients and physicians in New Hanover County will continue to need access to high quality, cost-effective ambulatory surgery services. Increasing demand for ambulatory surgical services is also being driven by changes in surgical technology and high demand for services. The most significant limiting factor Wilmington SurgCare has faced in the past has been the capacity of its operating rooms. The applicant states that despite the three additional ORs that will be developed at Wilmington SurgCare (CON Project ID# O-11272-16) it is not an effective alternative for Wilmington SurgCare not to seek to develop an additional OR when the opportunity arises.

<u>Developing a New ASC at an Alternate Location</u>- The applicant states that the current location of Wilmington SurgCare is in a highly effective location, can be expanded, and offers high quality services and a broad scope of services. Developing a new ASC in a new location in New Hanover County would necessitate incurring site, equipment and facility costs and be duplicative of what already exists at the Wilmington SurgCare facility. A new ASC would be more financially susceptible to changes in physicians or primary care referral patterns. Developing a new ASC at an alternate location would not be the least costly or most effective alternative.

On page 63, the applicant states that its proposal is the most effective alternative because the project avoids duplicative costs such as overall site development. Adding on to the existing project takes advantage of economies of scale, existing clinical and administrative services, agreements for professional services, support services and coordination with existing healthcare providers.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

• The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

In Section III.8, pages 108-109, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – The applicant states that per the 2017 North Carolina license renewal applications (LRAs) for hospitals and ASCs utilization of ORs in New Hanover County is high. The New Hanover County operating room service area had need determination in the 2016 SMFP for three new ORs and the 2017 SMFP had a need determination for one new OR. Delays for surgery could occur with surgery demand exceeding available OR time in New Hanover County. Maintaining the status quo by not seeking to develop a new OR pursuant to the 2017 SMFP OR need determination for the New Hanover County operating room service area is not the most effective alternative.

<u>SurgCare</u>- The applicant states that NHRMC and Wilmington SurgCare currently are the only two OR providers in New Hanover County. Simply adding OR capacity to one of the only two existing providers of OR surgical services in the New Hanover County operating room service area denies the patients in the proposed counties to be served the benefits of competition, the encouragement of lower cost and higher quality surgical services. Therefore, adding OR capacity to one of the only two existing providers of OR services and not adding a new provider in the New Hanover operating room service area is not the most effective alternative.

Joint Venture with Other Providers and/or include other Specialties- The applicant states that it has established a membership structure that will allow joint ventures with specialists who practice at the proposed facility. The proposed project is structured such as to permit ownership by participating specialties and accommodate interest from providers in those specialties.

<u>Choose a Different Location</u>- The applicant states that currently, NHRMC operates a surgery center, Atlantic SurgiCenter, in the northern part of New Hanover County, north of Wilmington. The proposed WASC facility would be south of Wilmington and south of NHRMC in a growing part of the county and accessible to both patients from New Hanover County, north of New Hanover County and from such counties as Brunswick and Columbus via major traffic corridors. Therefore, choosing a different location is not the most effective alternative.

On page 108, the applicant states that its proposal is the most effective alternative because it would add a new provider to the New Hanover County operating room service area, is structured in a flexible manner such as to permit ownership by participating specialties and makes joint ventures a possibility, and will be located in a growing area of the New Hanover County which is accessible to patients both from New Hanover County and surrounding counties.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR

in the New Hanover County operating room service area. Therefore, the application is conforming to this criterion.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

In Section III.8, pages 62-64, the applicants describe the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicants state that there is a need for ambulatory surgery services in New Hanover County that is both cost effective and offered in the comfort and convenience of a dedicated outpatient ambulatory surgery facility. Currently there is only one freestanding, non-hospital based ASC in New Hanover County. The applicant states that the number of New Hanover County residents receiving ambulatory surgery has increased as well as the number of residents from Onslow and Pender counties traveling to New Hanover County for surgery. The applicants state that in 2017 NHSC's physicians will perform over 1,200 ambulatory surgery cases in hospital-based operating rooms. Therefore, maintaining the status quo by not developing a new OR pursuant to the need determination in the 2017 SMFP is not the most effective alternative.

<u>Develop the Proposed ASC in Another Location</u>- The applicants state that the proposed location will be centrally located in New Hanover County in Wilmington in a new medical office building near EmergOrtho's clinic. Wilmington is the major population center for New Hanover County and the county's medical infrastructure. The applicants state that local residents are accustomed to and familiar with Wilmington as the destination for their healthcare services in New Hanover County. The proposed location will be in close proximity to referring physician offices and accessible to primary traffic corridors. Therefore, developing the proposed ASC in another location is not the most effective alternative.

<u>Develop an ASC Without Procedure Rooms</u>- The applicants state that the combination of one OR and two procedure rooms maximizes economies of scale in terms of resources and facility staff. Further, pain management specialists are able to rotate procedures between each procedure room while the other room is being cleaned. Therefore, developing an ASC without procedure rooms is not the most effective alternative.

<u>Develop a Multi-Specialty ASC with Procedure Rooms</u>- The applicants state that developing a multi-specialty ASC could potentially increase OR turn over time because of the need to prepare the OR for different specialties and increase capital costs because of the different equipment needed for different surgical specialties. Staff training would also be less efficient. Therefore, developing a multi-specialty ASC with procedure rooms was not the most effective alternative.

On pages 62-64, the applicants state that its proposal is the most effective alternative because a new ASC with two procedure rooms will provide an additional provider of needed

ambulatory surgery services in a dedicated, free-standing ASC, centrally located and accessible by major traffic corridors and efficiently organized and focused.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants demonstrate that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the New Hanover 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 NHRMC WASC NHSC

NC Wilmington SurgCare

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion.

Capital and Working Capital Costs

In Section VIII, page 90, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$450,000
Miscellaneous Costs	\$850,000
Total	\$1,300,000

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 94, the applicant projects that there will be no working capital costs as NHRMC is an existing facility.

Availability of Funds

In Section VIII, page 91, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total
Accumulated reserves	\$1.300,000
Total Financing	\$1,300,000

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form C, 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	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Cases (Combined IP and OP cases)	38,813	40,381	42,046
Total Gross Revenues (Charges)	\$1,140,795,430	\$1,219,933,548	\$1,306,078,005
Total Net Revenue	\$297,213,754	\$308,601,171	\$320,674,149
Average Net Revenue per case	7,657.58	7,642.24	7,626.75
Total Operating Expenses (Costs)	\$149,722,638	\$158,825,455	\$168,647,184
Average Operating Expense per case	3,857.54	3,933.17	4,011.02
Net Income	\$147,491,116	\$149,775,716	\$152,026,965

Source: Source: Form C and Form D in the proformas, pages 109-117.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section XIII 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.

Conclusion

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and a procedure room).

Capital and Working Capital Costs

In Section VIII, page 96, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$64,419
Construction Costs	\$673,092
Miscellaneous Costs	\$360,000
Total	\$1,097,511

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 101, the applicant projects that there will be no working capital costs as NHRMC is an existing facility.

Availability of Funds

In Section VIII, page 98, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Туре	Total
Cash of Surgery Partners	\$1.097,511
Total Financing	\$1,097,511

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Forms B & C, 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	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Cases*	12,202	13,270	14,174
Total Gross Revenues (Charges)	\$125,999,345	\$143,879,026	\$161,364,610
Total Net Revenue	\$18,659,651	\$20,443,693	\$21,959,413
Average Net Revenue per case	\$1,529.23	\$1,540.59	\$1,549.27
Total Operating Expenses (Costs)	\$17,099,589	\$18,442,832	\$19,587,318
Average Operating Expense per case	\$1,401.38	\$1,389.81	\$1,381.92
Net Income	\$1,560,062	\$2,000,861	\$2,372,095

^{*}Total Cases includes: OR cases and pain cases

Source: Forms C, B and D in the proformas, pages 116-123.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported for the following reasons:

• Projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Capital and Working Capital Costs

In Section VIII, pages 173-174, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	\$5,176,441
Miscellaneous Costs	\$8,211,510
Total	\$13,387,950

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 185, the applicant projects that start-up costs will be \$1,408,067 and initial operating expenses will be \$1,921,355 for a total working capital of \$3,329,422. On page 186 and in Exhibit 31, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section VIII, page 98, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Туре	Total
Bank Loan from Sun Trust Bank	\$13,387,950
Total Financing	\$13,387,950

In Section IX, page 186, the applicant states that the working capital needs of the project will be funded as shown in the table below.

	Sources of Financing for Working Capital	Amount
(a)	Bank Loan from Sun Trust Bank	\$3,329,422
(e)	Total	\$3,329,422

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Cases*	9,539	13,668	13,875
Total Gross Revenues (Charges)	\$43,615,351	\$64,493,886	\$66,453,729
Total Net Revenue	\$10,121,953	\$17,540,960	\$17,808,655
Average Net Revenue per case	\$1,061.11	\$1,283.36	\$1,283.51
Total Operating Expenses (Costs)	\$11,321,950	\$15,593,580	\$15,852,772
Average Operating Expense per case	\$1,186.91	\$1,140.88	\$1,142.54
Net Income	(-\$1,199,998)	\$1,947,380	\$1,955,884

*Total Cases includes both OR cases and procedure room cases.

Source: Proformas in Section XIII.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the proformas 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

Capital and Working Capital Costs

In Section VIII, pages 98-99, the applicants project the total capital cost of the project as shown in the table below.

OWP4

Site Costs	\$725,325
Construction Costs	\$3,947,088
Miscellaneous Costs	\$295,895
Total	\$4,968,308

Note: OWP4 will include the development and construction costs of the building where the new ASC will be located.

New Hanover Surgical Center

Site Costs	\$0.00
Construction Costs	\$0.00
Miscellaneous Costs	\$1,218,957
Total	\$1,218,957

In Section VIII, page 96 and in Section XI, the applicants provide the assumptions used to project the capital cost.

In Section IX, page 104, the applicants project that start-up costs will be \$160,000 and initial operating expenses will be \$360,000 for a total working capital of \$520,000. On page 104, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section VIII, page 98, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	OWP4	New Hanover Surgical Center	Total
Total Financing: Loans	\$4,968,308	\$1,218,957	\$ 6,187,265

In Section IX, page 186, the applicants state that the working capital needs of the project will be funded as shown in the table below.

	Sources of Financing for Working Capital	Amount
(a)	Bank Loan from Sun Trust Bank	\$520,000
(e)	Total	\$520,000

Financial Feasibility

The applicants provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B, the applicants project that revenues will exceed operating expenses in the first, second and third operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Cases*	1,642	1,826	2,020
Total Gross Revenues (Charges)	\$6,840,545	\$7,843,333	\$8,921,297
Total Net Revenue	\$3,153,158	\$3,618,377	\$4,118,507
Average Net Revenue per case	\$1,920.32	\$1,981.59	\$2,038.86
Total Operating Expenses (Costs)	\$2,793,853	2,968,566	\$3,163,185
Average Operating Expense per case	\$1,701.49	\$1,625.72	\$1,565.93
Net Income	\$359,304	\$649,811	\$955,322

^{*}Total Cases includes both OR cases and procedure room cases.

Source: Proformas in Section XIII.

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the proformas 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.

Conclusion

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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 NHRMC WASC NHSC

NC Wilmington SurgCare

The 2017 State Medical Facilities Plan (2017 SMFP) includes an Operating Room Need Determination for one operating room in the New Hanover County operating room service area.

On page 57, the 2017 SMFP defines the service area for ORs as "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this proposal is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 75 of the 2017 SMFP, there are 45 ORs in New Hanover County located in two facilities: Wilmington SurgCare (7 ORs) and NHRMC (38 ORs). In addition, the 2016 SMFP Need Determination contained a Need Determination for three ORs in the New Hanover County operating room service area. See table below. The decision

awarding the three ORs from the 2016 SMFP OR Need Determination, increasing the number of ORs to 48, is currently under appeal.

Operating Room Inventory for the New Hanover County Operating Room Service Area

	Inpatient	Ambulatory	Shared	CON	Total
	ORs	ORs	ORs	Adjustments	
2016 SMFP Need Determination*	0	0	0	3	3
Wilmington SurgCare	0	7	0	0	7
New Hanover Regional Medical Center	5	4	29	0	38
Total**	5	11	29	3	48

^{*} The 3 ORs in the 2016 SMFP were awarded to Wilmington SurgCare. That decision is under appeal.

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The applicant adequately demonstrates the need to develop one additional OR at NHRMC in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the OR in addition to the existing and approved ORs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

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

In Section III.1, pages 25-51, the applicant explains why it believes the population projected to utilize the proposed OR services needs the proposed services.

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

• Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health. The applicant adequately demonstrates the need to develop one OR at the proposed WASC facility in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the existing and approved ORs.

Conclusion

The Agency reviewed the:

Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms. The applicant adequately demonstrates the need to develop one additional OR at the proposed NHSC facility in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the existing and approved ORs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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 NHRMC Wilmington SurgCare

WASC NHSC

NHRMC. In Section VII, Table VII.1 and Table VII.2, pages 79-80, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current FTEs* FY2017	Projected FTEs OY2(FY2021)
Nursing Anesthetist	63.02	64.68
Staff Nurse	94.44	96.94
RN First Assistant	3.20	3.20
RN Specialty Nurse	7.56	7.56
Lead Intervention Rad Technician	1.09	1.09
Special Procedures Technician	4.27	4.27
Surgical Technician	10.28	10.53
Surgical Technology Extern	1.23	1.23
Certified Surgical Technologist	47.40	48.65
Nurse Aide II	0.98	0.98
Endoscopy Technician	0.97	0.97
OR Assistant I	4.84	4.84
OR Assistant II	21.46	21.96
Manager	1.00	1.00
Assistant Manager	1.94	1.94
Nurse Manager	1.00	1.00
Nursing Coordinator	2.65	2.65
Administrative Nursing Coordinator	1.00	1.00
Nurse Assessment	0.99	0.99
Schedule Facilitator	2.33	2.33
OR Charges Specialist- RN	1.00	1.00
Schedule Facilitator- WOW	0.65	0.65
Central Sterile Technician	1.41	1.41
Support Associate II	0.56	0.56
Support Associate III	5.73	5.73
Patient Liaison	1.03	1.03
Total	282.02	288.18

Source: Table VII.1 and Table VII.2, page 80 of the application.

The assumptions and methodology used to project staffing are provided in Section XIII, pages 111-113. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form C, which is found in Section XIII, page 109. In Section VII, pages 81, 84-85 and Exhibit 16, the applicant describes the methods used to recruit or fill new positions and its existing (or proposed) training and continuing education programs. In Section VII.9, page 87, the applicant identifies the current medical director. In Exhibit 12, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII.7, pages 85-87, the applicant describes its physician recruitment plans. In Exhibit 11 and 17, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

^{*}Full-Time Equivalent (FTE)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare. In Section VII, pages 86-87, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current FTEs FY 2017	Projected FTEs OY2(FY2022)
		` /
Administration	3.25	3.25
Medical Records/Billing	10.75	15.50
Materials Management	1.00	1.00
Clinical-Supervisors-RNs	2.00	2.00
Clinical-Infection/Quality	1.00	1.00
Coordinator		
Registered Nurses (RN)	21.75	30.50
Certified Nursing Assistants II	4.25	7.00
Certified Sterile Processing	2.75	3.50
Technicians		
Surgical Technicians	8.00	11.50
Clinical-Preadmission RN	2.00	2.50
Radiological Technologists	0.50	0.75
TOTAL	57.25	78.50

Source: Table VII.2 on pages 86-87 of the application.

The assumptions and methodology used to project staffing are provided in the financials section of the application pages 118 and 127-128. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the proformas pages 127-128, which is found in the Financials Section of the application. In Section VII.3-4, pages 88-89, and Section VII.7, page 92, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section VII.9, page 93, the applicant identifies the current medical director. In Exhibit 30, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII.7, page 92, the applicant describes its physician recruitment plans. In Exhibit 35, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

WASC. WASC is not an existing facility, therefore it has no current staffing to report. In Section VII, page 160, the applicant provides projected staffing for the proposed services for the second full operating year (CY2021) as illustrated in the following table.

Position	Projected FTEs
Professional Health Care Administrators	1.00
Director of Nursing	1.00
Business Office Lead	1.00
RN	23.85
LPN	5.83
Surgical Technician	8.48
Radiology Technician	1.59
OR Attendant	2.00
Sterile Processing Coordinator	1.06
Medical Records Tech	1.00
All "non-health professionals" and "technical" personnel*	18.12
TOTAL	64.93

Source: Table VII.2, page 160 of the application.

The assumptions and methodology used to project staffing are provided in Section XIII. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the proformas, which are found in Section XIII. In Section VII, pages 161-162, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section VII, page 168, the applicant identifies the proposed medical director. In Exhibit 6, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII, pages 165-168, the applicant describes its physician recruitment plans. In Exhibit 12, the applicant provides supporting documentation.

^{*}Includes Business Office Clerks, Purchasing Coordinators, Sterile Processing Clerk and Maintenance.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC. NHSC is not an existing facility, therefore it has no current staffing to report. In Section VII, page 89, the applicant provides projected staffing for the proposed services for the second full operating year (CY2021) as illustrated in the following table.

Position	Projected FTEs
Professional Health Care Administrator/Nurse Manager	1.0
Registered Nurses- Operating Room	2.0
Registered Nurses- Pre-admission, Pre-op, Post-op	3.0
Surgical Technicians/ Central Sterile	2.0
Medical Record Technician/Coder	0.5
Radiological Technologists and /or Technicians	1.0
All "non-health professionals" and "technical" personnel	2.5
TOTAL	12.0

Source: Table on page 89 of the application.

The assumptions and methodology used to project staffing are provided in Section XIII. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form B/C, which is found in Section XIII. In Section VII, pages 90-91 and 93, the applicants describe the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section VII, page 94, the applicants identified the proposed medical director. In Exhibit 5, the applicants provide a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII, page 93, the applicants describe its physician recruitment plans. In Exhibit 8, the applicants provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(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 NHRMC Wilmington SurgCare WASC NHSC

NHRMC. NHRMC is an existing hospital. In Section II, page 15, the applicant identifies the ancillary and support services necessary for the proposed project.

On page 15, and in Section XI, page 99, and Exhibit 22, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 5.

In Section V, pages 52-53, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits 5, 9 and 10.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. Wilmington SurgCare is an existing ASC. In Section II, page 10, the applicant identifies the ancillary and support services necessary for the proposed project.

On pages 10-12, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits 9-12 and 49.

In Section V, pages 69-70, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits 9-12, 23 and 49.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section II, pages 43-44, the applicant identifies the ancillary and support services necessary for the proposed project.

On pages 43-44, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits 9-10.

In Section V, pages 130-133, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit 11, 18 and 19.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section II, pages 14-15, the applicants identified the ancillary and support services necessary for the proposed project.

On page 15, the applicants adequately explain how each ancillary and support service will be made available and provides supporting documentation in Exhibit 18.

In Section V, pages 68-71, the applicants describe the efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit 5, 6, 8, 10 and 11.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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

None of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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- All Applications

None of the applicants are an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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 Wilmington SurgCare WASC NHSC

> NA NHRMC

NHRMC. The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to the review of this application.

Wilmington SurgCare. In Section XI, page 107, the applicant states that the project involves constructing 804 square feet of new space. Line drawings are provided in Exhibit 44.

On page 112, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 37.

On page 102, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibits 37, 44 and 46.

On pages 55-56 and pages 112-113, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 37.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section XI, page 200, the applicant states that the project involves constructing 18,875 square feet of new space. Line drawings are provided in Exhibit7.

On page 202, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 22.

On page 187, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit 22.

On pages 104 and 203, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 22.

On page191-192 and Exhibit 22, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section XI, page 114, the applicants state that the project involves up fitting 15,034 square feet of leased space. Line drawings are provided in Exhibit 12.

On page 116, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 12.

On page 106, the applicants adequately explain why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 117, the applicants identified any applicable energy and water saving features that will be incorporated into the construction plans.

On page 110, the applicants identified the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

• Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 NHRMC Wilmington SurgCare

> NA WASC NHSC

NHRMC. In Section VI.13, page 77, the applicant provides the historical payor mix for the last full operating year for the proposed services during 10/1/2016 - 9/30/2017, as shown in the table below.

Surgical Services- NHRMC: 10/1/2016 to 9/30/2017 Current Patient Days/ Procedures as Percent of Total Utilization

	IP	OP
Self Pay/ Charity	4.6%	3.6%
Medicare/Medicare Managed Care	50.6%	46.0%
Medicaid	11.2%	6.9%
Managed Care/Commercial	27.6%	`37.5%
Insurance		
Other	6.0%	6.0%
Total*	100.0%	100.0%

Source: Table on page 77 of application.

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 applicants service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
New Hanover	17%	52%	23%	17%	9%	12%
Brunswick	29%	51%	18%	14%	12%	15%
Pender	18%	50%	25%	15%	13%	14%
Onslow	9%	16%	33%	15%	12%	10%
Columbus	19%	51%	41%	24%	15%	15%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table
Latest Data 7/1/16 as of 8/22/17

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 Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant's adequately documents the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants service area which is medically underserved. Therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section VI.13, pages 84, the applicant provides the historical payor mix for the last full operating year for the proposed surgical services during 1/1/2016 - 12/31/2016, as shown in the table below:

^{*}Excludes "White alone" who are "not Hispanic or Latino"

^{**&}quot;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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

Wilmington SurgCare Payor Mix FY 2016 (1/1/16-12/31/16)				
Payor	Cases as % of Total Cases			
Self-Pay / Indigent	1.24%			
Medicare / Medicare Managed Care	51.26%			
Medicaid	7.78%			
Commercial Insurance	0.41%			
Managed Care	32.65%			
Other (Workers Comp, TriCare and Other)	6.65%			
Total	100.00%			

Source: Application page 84. Tables may not foot due to rounding.

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 applicants service area.

Percent of Population							
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**	
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate	
New Hanover	17%	52%	23%	17%	9%	12%	
Brunswick	29%	51%	18%	14%	12%	15%	
Pender	18%	50%	25%	15%	13%	14%	
Onslow	9%	16%	33%	15%	12%	10%	
Columbus	19%	51%	41%	24%	15%	15%	
Duplin	17%	51%	48%	25%	12%	21%	
Statewide	16%	51%	37%	16%	10%	13%	

Source: http://www.census.gov/quickfacts/table Latest Data 7/1/16 as of 8/22/17

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.

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

^{*}Excludes "White alone" who are "not Hispanic or Latino"

^{**&}quot;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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

 Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants service area which is medically underserved. Therefore, the application is conforming to this criterion.

WASC. Neither the applicant nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

NHSC. Neither the applicants nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

(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 NHRMC Wilmington SurgCare

> NA WASC NHSC

NHRMC. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section VI.11, page 76, the applicant states, "NHRMC fulfilled its Hill-Burton obligation and does not have any related obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and the handicapped."

In Section VI.10, page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against NHRMC.

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section VI, page 83, the applicant states, "Wilmington SurgCare has no obligations to provide uncompensated care."

In Section VI, page 83, the applicant states that during the last five years no patient civil rights access complaints exist.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. Neither the applicant nor any related entity owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13b) is not applicable to the review of this application.

NHSC. Neither the applicants nor any related entity owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13b) is not applicable to the review of this application.

(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 NHRMC Wilmington SurgCare WASC

NHSC

NHRMC. In Section VI. 14, page 78, and in Form D, pages 115 and 117 of the proformas, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Surgical Services at NHRMC OY2 10/1/20 to 9/30/21 IP and OP Combined

Payor Category	Services as Percent of	Actual Cases (Combined IP	
	Total Surgical (IP + OP	and OP)	
	combined)		
Self Pay/Charity	4.6%	1,539	
Medicare/Medicare	50.6%	18,965	
Managed Care			
Medicaid	11.2%	3,151	
Managed	27.6%	14,304	
Care/Commercial			
Insurance			
Other	6.0%	2,423	
Total	100.0%	40,381	

Source: Proformas Form D, pages 115 & 117 of the application.

Note: NHRMC surgical services does not include any procedure rooms.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for IP OR Services 4.6% of total services will be provided to self-pay/charity patients, 50.6% to Medicare patients and 11.2% to Medicaid patients and that for OP OR Services 3.6% of total services will be provided to self-pay/charity patients, 46.0% to Medicare patients and 6.9% to Medicaid patients.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

• The projected payor mix is based on historical payor mix of NHRMC.

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. In Section VI. 14, page 85, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services	OR Cases
Self Pay/Indigent	1.24%	160
Commercial Insurance	0.41%	53
Medicare/Medicare Managed Care	51.26%	6,629
Medicaid	7.79%	1,007
Managed Care	32.65%	4,222
Other	6.65%	860
Total	100.0%	12,932

Source: Table page 85 of application and Proformas- Form D, page 121.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.24% of total services will be provided to self-pay/indigent patients, 7.78% to Medicare patients and 51.26% to Medicaid patients.

On page 85, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. In the proformas, pages 124-126, the applicant projects the same payor mix for just the OR cases and the combination of OR and procedure room cases. The projected payor mix is reasonable and adequately supported for the following reasons:

• The projected payor mix is based on historical payor mix of Wilmington SurgCare for the entire facility, including ORs and GI procedure rooms.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Form D of the proformas, the applicant projects the following payor mix for the proposed OR surgical services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay	5.94%	70
Medicare/Medicare Managed Care	28.31%	378
Medicaid	5.67%	76
Commercial Insurance	54.86%	733
Other (Military, Workers Comp)	5.21%	70
Total	100.0%	1,337*

Source: Form D, Proformas of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.94% of total services will be provided to self-pay patients, 28.31% to Medicare patients and 5.67% to Medicaid patients.

Note: [Table VI.1, page 153 of the application the percentages for each payor category appear to be a typographical error and are incorrect.

Payor Category	OR Services as Percent of Total OR Services:
Self Pay	2.0%
Medicare/Medicare Managed Care	49.0%
Medicaid	4.0%
Commercial Insurance	43.0%
Other (Military, Workers Comp)	3.0%
Total	100.0%

In its response to comments WASC acknowledged the typos and stated that the payor mix projections in the proformas match the entire facility payor mix projections in Table VI.5 and that the data in the proformas is consistent with the proforma assumptions, utilization assumptions and income statements.] The information in the table above, not the table in the Note, is consistent with the information in the proformas and the rest of the application.

On pages 153-158, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

^{*}Totals as 1,336. Appears to be a rounding issue.

 The projected payor mix is based on historical payor mix of existing ASC facilities in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section VI. 14, page 85, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay/ Indigent (p. 85) (Just Self Pay in Form D)	3.4%	52
Medicare/Medicare Managed Care (p.85)(Just	12.9%	195
Medicare in Form D)		
Medicaid	10.5%	159
Managed Care and Commercial Care	23.8%	360
BCBS	39.7%	601
Other (Workers Comp, TRICARE, VA)	9.7%	148
Total	100.0%	1,515

Source: Table on page 85 of application and Proformas Form D

As shown in the table above, during the second full fiscal year of operation, the applicants project that 3.4% of total services will be provided to self-pay/indigent patients, 12.9% to Medicare patients and 10.5% to Medicaid patients.

On pages 86-87, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

 The projected payor mix is based on the historical payor mix of residents from New Hanover, Onslow and Pender County who obtained outpatient surgery from NHSC physicians during 2016.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 NHRMC Wilmington SurgCare WASC NHSC

NHRMC. In Section VI.9, page 75, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. In Section VI.9, page 83, the applicant adequately describes the range of means by which patients will have access to the proposed services.

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section VI.9, page 150, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section VI.9, page 82-83, the applicants adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that 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 NHRMC Wilmington SurgCare WASC NHSC

NHRMC. In Section V, pages 52-53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibits 9 and 10.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section V, page 69, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit 27.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

WASC. In Section V, page 129, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 23.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

NHSC. In Section V, page 68, the applicants describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 11.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming 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.

WASC NHSC

NC Wilmington SurgCare

The 2017 SMFP includes an Operating Room Need Determination for one operating room in the New Hanover County operating room service area.

On page 57, the 2017 SMFP defines the service area for ORs as "the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 60]." Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this proposal is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 75 of the 2017 SMFP, there are 45 ORs in New Hanover County located in two facilities: Wilmington SurgCare (7 ORs) and NHRMC (38 ORs). In addition, the 2016 SMFP Need Determination contained a Need Determination for three ORs in the New Hanover County operating room service area. See table below. The decision awarding the three ORs from the 2016 SMFP OR Need Determination, increasing the number of ORs to 48, is currently under appeal.

Operating Room Inventory for the New Hanover County Operating Room Service Area

	ν 1 Θ				
	Inpatient	Ambulatory	Shared	CON	Total
	ORs	ORs	ORs	Adjustments	
2016 SMFP Need Determination*	0	0	0	3	3
Wilmington SurgCare	0	7	0	0	7
New Hanover Regional Medical Center	5	4	29	0	38
Total**	5	11	29	0	48

^{*} The 3 ORs in the 2016 SMFP were awarded to Wilmington SurgCare. That decision is under appeal.

NHRMC. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The applicant proposes to develop the new OR as a shared OR in NHRMCs existing surgical pavilion.

In Section V.7, pages 58-69, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 58, the applicant states, "This project will foster competition. NHRMC competes not only with other hospitals in the service area, but also with much larger systems both inside and outside of North Carolina. NHRMC recognizes that patients have a choice of where to receive their care and it strives to earn the loyalty of its patients every day."

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

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

In Section V.7, pages 73-77, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 77, the applicant states, "Wilmington SurgCare's proposal to add one operating room promotes competition because it best responds to the need determination in the 2017 SMFP for the New Hanover County service area."

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

The applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate:

• The cost-effectiveness of the proposal. The discussion regarding analysis of need and projected utilization found in Criterion (3) and alternatives found in Criterion (4) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

In Section V.7, pages 137-139, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 137, the applicant states, "This project will increase the number of competing surgical providers in New Hanover County from two to three; this is a 50 percent increase in competitive options....WASC will provide a critical element in fostering competition."

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

In Section V.7, pages 72-75, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 73-74, the applicant states, "NHSC's proposal offers a cost-effective alternative in terms of cost to the patient compared to a hospital-based facility...the proposed project will increase access to cost-effective surgical services for the underserved population of the service area. NHSC's physician members have an excellent track record of providing care to persons covered by government insurance, and to persons dependent upon charity care....NHSC will utilize the quality measures to monitor quality of care and patient safety relevant to the proposed project."

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

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 NHRMC Wilmington SurgCare WASC

> NA NHSC

NHRMC. In Section I, page 8, the applicant identifies the health care facilities operated or managed by the applicant or a related entity.

In Section II.12, page 26, the application states that none of the facilities listed on page 8 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision incidents related to quality of care occurred in none of these facilities. 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 the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section I, pages 5-6, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section II.12, page 24, the application states that none of the facilities listed on pages 5-6 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement or certification revoked or terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision, incidents related to quality of care occurred in none of these facilities. 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 the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

WASC. In Section I, pages 15-66, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section II.12, page 63, the application states that none of the facilities listed on pages 15-16 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement or certification revoked or terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision, incidents related to quality of care occurred in four of these facilities. The problems have been corrected at three of the facilities. At the fourth facility a survey was conducted on February 2, 2018 which resulted in an immediate jeopardy. The immediate jeopardy issue was found to be have been abated in a follow up survey conducted on March 9, 2018. The survey on March 9, 2018 found a different issue which has not yet been confirmed to have been brought back into compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

NHSC. Neither the applicant nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

- (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 NHRMC WASC NHSC

NC Wilmington SurgCare

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

Wilmington SurgCare. The application is not conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

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

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

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

- (a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.
 - -C- **NHRMC.** In Section II, page 22, the applicant states that the ORs at NHRMC facility are considered to be available for use five days per week and 52 weeks a year.
 - -C- **Wilmington SurgCare.** In Section II, page 19, the applicant states that the ORs at Wilmington SurgCare are considered to be available for use five days per week and 52 weeks a year.
 - -C- WASC. In Section II, page 54, the applicant states that the OR at the proposed WASC facility are considered to be available for use five days per week and 52 weeks a year.
 - -C- **NHSC.** In Section II, pages 24-25, the applicants state that the OR at the proposed NHSC facility are considered to be available for use five days per week and 52 weeks a year.
- (b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:
 - (1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(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) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 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- **NHRMC.** The proposed project is in New Hanover County which has more than 10 ORs.

NHRMC is an existing facility with 38 ORs. Based on this rule NHRMC calculates projected OR need based on 32 ORs [*NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.] On page 23 of the application, the applicant projects the 32 ORs at NHRMC will perform 8,330 inpatient surgical cases and 33,716 outpatient surgical cases in the third year of operation (FY2022) which demonstrates a need for 8 ORs at the facility [8,330 IP cases x 3.0 hours per case = 24,989 hours + 33,716 OP cases x 1.5 hours per case = 50,574 hours totals to 75,562 hours; 75,562 hours/ 1,872 hours = 40.4 ORs needed. 40.4 ORs needed – 32 existing ORs = 8.4 OR deficit or 8.0 ORs needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

-NC- **Wilmington SurgCare**. The proposed project is in New Hanover County which has more than 10 ORs.

Wilmington SurgCare is an existing facility with 10 ORs (7 existing and 3 approved). On page 23 of the application, the applicant projects the 10 ORs (7 existing and 3 approved) at the Wilmington SurgCare facility will perform 20,719 outpatient surgical

cases in the third year of operation (CY2023) which demonstrates a need for 11 ORs at the facility [13,813 cases x 1.5 hours per case = 20,719 hours; 20,719 hours/ 1,872 hours = 11.07 ORs needed - 10 ORs (existing and approved) = 1.07 or 1.0 ORs needed]. However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is not conforming with this rule.

-C- **WASC**. The proposed project is in New Hanover County which has more than 10 ORs.

WASC is not an existing facility. WASC proposes to develop one OR in an ASC. On page 55 of the application, the applicants project the proposed OR at the proposed WASC facility will perform 1,337 outpatient surgical cases in the third year of operation which demonstrates a need for one OR at the proposed facility [1,337 cases x 1.5 hours per case = 2,006 hours; 2,006 hours/ 1,872 hours = 1.07 or 1 OR needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

-C- **NHSC**. The proposed project is in New Hanover County which has more than 10 ORs.

NHSC is not an existing facility. NHSC proposes to develop one OR in an ASC. On pages 52 and 66 of the application, the applicants project the proposed OR at the proposed NHSC facility will perform 1,704 outpatient surgical cases in the third year of operation which demonstrates a need for one OR at the proposed facility [1,704 cases x 1.5 hours per case = 2,556 hours; 2,556 hours/ 1,872 hours = 1.365 or 1 OR needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

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

operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

- (2) The number of rooms needed is determined as follows:
 - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;
 - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and
 - (C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.
- -C- **NHRMC.** In Section IV, pages 45-51, the applicant demonstrates the need for the number of proposed operating rooms in all of its facilities in the New Hanover County operating room service area in the third operating year of the proposed project as illustrated in the table below

Projected OR Utilization at NHRMC: ORs Needed

- 1 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4					
OR Cases	OY3	Hours/Case	OR Hours		
	(FY2022)				
IP Cases	8,330	3.0	24,989		
OP Cases	33,716	1.5	50,574		
Total OR Hours			75,563		
OR Need (hours/1872)			40.36		
# of Existing OR*			32*		
OR Need (ORs Needed –			8.36		
Existing ORs)					
NHRMC OR Need			8		

^{*}NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.

- -NA- **Wilmington SurgCare.** Neither Wilmington SurgCare nor a related entity has a controlling interest in any other ORs in the service area.
- -NA- **WASC.** Neither WASC nor a related entity has a controlling interest in any other ORs in the service area.
- -NA- **NHSC.** Neither NHSC nor a related entity has a controlling interest in any other ORs in the service area.

- (d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.
 - -NA- **NHRMC**. In Section II, page 25, the applicant states that it is not proposing to develop an additional dedicated C-Section OR.
 - -NA- **Wilmington SurgCare** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR.
 - -NA- **WASC** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR. WASC is not an existing facility.
 - -NA- **NHSC** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR.is not an existing facility. NHSC is not an existing facility.
- 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- **NHRMC** 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- **Wilmington SurgCare** 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- **WASC** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty ambulatory surgical program. WASC is not an existing facility.
- -NA- **NHSC** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty ambulatory surgical program. NHSC is not an existing facility.
- (f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.
 - -C- **NHRMC**. In Section III, pages 27-34 and Exhibit 8, 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.
 - -NC- **Wilmington SurgCare.** In Section III, pages 46-5, the applicant documents the assumptions and provides data supporting the methodology used for each projection in this Rule. However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is not conforming with this rule.
 - -C- WASC. In Section III, pages 87-96 and Section IV, pages 119-128, 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- **NHSC.** In Section III, pages 48-55 and Exhibits 10, the applicant document the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. §131E-183(a) (1) and the 2017 State Medical Facilities Plan, no more than one new or additional OR may be approved in this review for New Hanover County. Because the four applications in this review collectively propose four new ORs (one 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 should be approved to develop the new OR. For the reasons set forth below and in the rest of the findings, the application submitted by WASC is approved. The applications submitted by NHRMC, Wilmington SurgCare and NHSC are denied.

Conformity with Applicable Statutory and Regulatory Review Criteria

Wilmington SurgCare is not conforming with all applicable statutory and regulatory review criteria as discussed throughout the Findings. Therefore, the application of Wilmington SurgCare is not approvable.

NHRMC, WASC and NHSC are conforming with all applicable statutory and regulatory review criteria as discussed throughout the Findings.

Therefore, the applications submitted by **NHRMC**, **WASC** and **NHSC** are equally effective alternatives with respect to conformity with statutory and regulatory review criteria.

Geographic Accessibility

The 2017 SMFP identifies a need for one additional OR in the New Hanover County OR Service Area. All four applications propose to develop one new OR in Wilmington, New Hanover County.

Therefore, with regard to geographic accessibility the proposed projects of NHRMC, WASC and NHSC are equally effective alternatives.

Physician Support

NHRMC is an existing hospital. Exhibit 24 contains letters of support from 3 surgeons and the medical director. In its comments NHRMC states that over 100 surgeons currently utilize the ORs in the Surgical Pavilion.

Wilmington SurgCare is an existing ASC. Exhibit 23 contains letters of support from 28 surgeons who have performed OR cases at Wilmington SurgCare have expressed their intent to utilize the facility.

WASC- The applicant is proposing to develop a new ASC in Wilmington. Exhibit 18 contains letters of support from 30 physicians projecting to refer a total of 1,337 OP OR cases annually to the proposed WASC facility.

NHSC- The applicant is proposing to develop a new ASC in Wilmington. Exhibit 10 contains letters from twelve physicians who historically have provided OP OR surgical services to residents of NHSC's proposed three county service area projecting to refer a total of 2,210 orthopaedic cases annually to the NHSC facility.

Therefore, with regard to physician support the four proposed projects are equally effective.

Patient Access to Alternative Providers

In New Hanover County there are only two facilities with ORs: New Hanover Regional Medical Center and Wilmington SurgCare. NHRMC is a hospital and Wilmington SurgCare is a freestanding ambulatory surgical center. There are currently 48 ORs in the New Hanover County operating room service area (45 existing and 3 approved). NHRMC currently has 38 ORs and Wilmington SurgCare has 10 ORs (7 existing and 3 approved.) NHRMC is proposing to develop one new OR by converting a storage room at its Surgical Pavilion and Wilmington SurgCare is proposing to add one new OR to its existing ambulatory surgery center.

If Wilmington SurgCare's application is approved, Wilmington SurgCare would be the only provider of ORs in an ASC facility in New Hanover County.

Approval of WASC, which is ultimately owned by Surgical Care Affiliates, and NHSC, would introduce an alternative provider of OR services and, introduce an alternative ASC for OR services in New Hanover County.

Therefore, with regard to providing New Hanover County patients with access to an alternative provider of outpatient OR services the proposals submitted by **WASC** and **NHSC** are the most effective alternatives.

Patient Access to Low Cost Outpatient Surgical Services

There are currently 48 ORs in the New Hanover County operating room service area (45 existing and 3 approved). NHRMC currently has 38 ORs and Wilmington SurgCare has 10 ORs (7 existing and 3 approved.) Operating rooms can be licensed either under a hospital license or an ASC that does not operate under a hospital license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room (ASC) however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room.

NHRMC is an existing hospital that offers both inpatient and outpatient OR surgical services.

Wilmington SurgCare is an existing ASC offering outpatient OR surgical services.

WASC is a proposed ASC which would offer outpatient OR surgical services.

NHSC is a proposed ASC which would offer outpatient OR surgical services.

Therefore, as to patient access to low cost outpatient surgical services **NHRMC** is the least effective alternative and **Wilmington SurgCare**, **WASC** and **NHSC** are all equally effective alternatives.

Patient Access to Multiple Surgical Specialties

NHRMC provides access to all surgical specialties.

Wilmington SurgCare is a multispecialty facility providing gastroenterology, general surgery, vascular surgery, gynecology, neurology, ophthalmology, orthopedic surgery, otolaryngology, plastic surgery, podiatry and urology services, which equals eleven specialties.

WASC proposes a multispecialty ASC providing general surgery, neurosurgery, ophthalmology, oral surgery, orthopedics, plastic surgery, urology, vascular, podiatry and gastroenterology services, which equals ten specialties.

NHSC projects only orthopaedic cases, which equals one specialty.

Therefore, with regard to providing New Hanover County patients with access to more multiple surgical specialties **NHRMC**, **Wilmington SurgCare** and **WASC** are the most effective alternative and **NHSC** is the least effective alternative.

Access by Underserved Groups

Charity Care

The following table shows each applicant's projected Charity Care to be provided in the second operating year of each applicant's proposed project in terms of projected dollars. Generally, the application proposing to serve the highest number of Charity Care cases is the most effective alternative with regard to this comparative factor.

Charity Care Operating Year 2

Applicant	Projected Charity	Projected Charity	Basis of Projected Charity	
	Cases	Care Dollars	Care	
NHRMC	1,597	\$48,500,000	4.00% of Gross Revenue	
Wilmington SurgCare	171	\$112,226	0.55% of Net Revenue	
WASC	81	\$644,939	1.00% of Gross Revenue	
NHSC	59	\$54,903	0.70% of Gross Revenue	

Note: Charity Care Cases come from the cases listed under the payor category of Self Pay/ Indigent/Charity Care.

Source: NHRMC: Section VI.8, page 74.

Source: Wilmington SurgCare: Section VI.8, page 82.

Source: WASC: Section VI.8, page 148. Source: NHSC: Section VI.8, page 81.

As shown in the table above, NHRMC projects the highest amount of charity care in terms of cases. However, due to significant differences in how each applicant defines charity care, the fact that Wilmington SurgCare's projected charity care is provided as a percentage of net revenue and the other three applications project charity care as a percentage of gross revenue and the fact that WASC's projected charity care is derived from across all payor categories in contrast to the other applications it is not possible to make conclusive comparisons with regard to projected charity care. Thus, this comparative factor may be of little value.

Medicare/Medicaid

The following tables show each applicant's projected total number of cases to be provided to Medicare/Medicaid recipients in the third operating year (OY3) following completion of each of the proposed project, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing to serve the higher percentage of Medicare/Medicaid patients is the more effective alternative with regard to this comparative factor.

Medicare/Medicaid Cases Operating Year 3

	Projected Total Cases	Projected Total Medicare Cases	Projected Total Medicaid Cases	Projected Total Medicare/Medicaid Cases	Percent of Total Cases Provided to Medicare/Medicaid Recipients
NHRMC	42,046	19,724	3,259	22,983	54.66%
Wilmington SurgCare	14,174	7,266	1,104	8,370	59.05%
WASC	13,875	6,734	517	7,251	52.26%
NHSC	2,020	268	330	598	29.60%

Source: Proformas of each application.

As shown in the in the table above, Wilmington SurgCare projects the highest percentage of cases to Medicare/Medicaid recipients. However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, Wilmington SurgCare's application is not approvable. Furthermore, 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 Medicare/Medicaid cases. Therefore, this comparative factor may be of little value.

Projected Average Net Revenue per Facility

The following table shows the projected net revenue per OR 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 net revenue per case is the more effective alternative with regard to this comparative factor.

Operating Year 3	NHRMC	Wilmington SurgCare	WASC	NHSC
Net Revenue	\$359,856,489	\$21,945,588	\$17,808,655	\$4,118,507
Total Cases including procedure room cases	42,046*	14,174**	13,875	2,020
Net Revenue/Case	\$8,559	\$1,548	\$1,284	\$2,039

^{*}IP and OP Cases for NHRMC Combined (No procedure room cases of any type)

As shown in the table above, WASC projects the lowest average net revenue per case in the third operating year. However, due to differences in the types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to net revenue per surgical case. Thus, this comparative factor may be of little value.

Projected Average Operating Expense per Case (Total Facility)

The following table shows the projected average operating expense 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 operating expense per case is the more effective alternative with regard to this comparative factor.

Third Operating Year	NHRMC	Wilmington SurgCare	WASC	NHSC
Total Operating Expenses	\$168,647,184	\$19,587,318	\$15,852,772	\$3,163,185
Cases*	42,046	14,174	13,875	2,020
Operating Expense/Case	\$4,011	\$1,382	\$1,143	\$1,566

^{*}Cases is for the entire facility including both OR cases, GI endo cases and procedure room cases. (except not for NHRMC and NHSC)

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

^{**13,813 + 361} Procedure Cases=\$14,174

SUMMARY

Comparative Factor	NHRMC	Wilmington	WASC	NHSC
		SurgCare		
Conformity with Rules and Criterion	Equally	Least	Equally	Equally
	Effective	Effective	Effective	Effective
Geographic Accessibility		Equally	Effective	
Physician Support		Equally	Effective	
Patient Access to Alternative Providers	Least	Least	Equally	Equally
	Effective	Effective	Effective	Effective
Patient Access to Low Cost Outpatient	Least	Equally	Equally	Equally
Surgical Services	Effective	Effective	Effective	Effective
Patient Access to Surgical Specialties		Equally		Least
	Effective Effective			
Access by Underserved Groups		Inconclusiv	e Comparison	•
Projected Average Net Revenue per Case	Inconclusive Comparison			
Projected Average Operating Expense per	Inconclusive Comparison			
Case				

For each of the comparative factors listed below, all four applications were determined to be **equally** effective:

- Geographic Accessibility
- Physician Support
- Access by Underserved Groups
- Projected Average Net Revenue per Case
- Projected Average Operating Expense per Case

For each of the comparative factors listed below, **WASC** was determined to be **equally** effective alternative:

- Conformity with Rules and Criterion
- Patient Access to Alternative Providers
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties

As demonstrated in the table above, **WASC** was <u>not</u> the least effective alternative for any of the comparative factors.

For each of the comparative factors listed below, **NHRMC** was determined to be the **least** effective alternative:

- Patient Access to Alternative Providers
- Patient Access to Low Cost Outpatient Surgical Services

For each of the comparative factors listed below, **Wilmington SurgCare** was determined to be the **least** effective alternative:

- Conformity with Rules and Criterion
- Patient Access to Alternative Providers

For each of the comparative factors listed below, **NHSC** was determined to be the **least** effective alternative:

• Patient Access to Surgical Specialties

CONCLUSION

All four applications are conforming to the need determination in the 2017 SMFP for one new OR in the New Hanover Operating Room Service Area. N.C. Gen. Stat. §131E-183(a) (1) states that the need determination in the SMFP is the determinative limit on the number of ORs that can be approved in this review. The Agency determined that the application submitted by **Wilmington ASC, LLC, Project I.D. #O-11441-17** is the most effective proposed in this review for the development of one new OR in the New Hanover County operating room service area to meet the 2017 OR Need Determination for the New Hanover OR service area and that application is approved as conditioned below. Approval of either the NHRMC, Wilmington SurgCare or the NHSC applications for development of a new OR in the New Hanover OR service area would result in the approval of new ORs in New Hanover County operating room service area in excess of the operating room need determination in the 2017 SMFP and therefore, the applications of **NHRMC**, **Wilmington SurgCare** and **NHSC** are all denied.

The application submitted by Wilmington ASC, LLC is approved subject to the following conditions.

- 1. Wilmington ASC, LLC shall materially comply with all representations made in the certificate of need application.
- 2. Wilmington ASC, LLC shall develop a new multispecialty ambulatory surgical facility by developing one new OR, developing three procedure rooms, and relocating three existing multispecialty gastrointestinal endoscopy rooms from Wilmington Health.
- 3. Upon completion of the project, Wilmington ASC shall be licensed for no more than one OR, 3 multispecialty gastrointestinal endoscopy rooms and 3 procedure rooms.
- 4. Wilmington ASC, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.

- 5. Wilmington ASC, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.
- 6. For the first three years of operation following completion of the project, Wilmington ASC, LLC shall not increase charges more than 5% of the charges projected in Section X and Section XIII 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.
- 7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
- 8. The procedure rooms shall not be used for procedures that should be performed only in a gastrointestinal endoscopy room based on current standards of practice.
- 9. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 10. Procedures performed in the procedure rooms shall not be reported for billing purposed as having been performed in a gastrointestinal endoscopy room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room.
- 11. Upon project completion, Wilmington ASC, LLC and Wilmington Health, PLLC, shall take the steps necessary to delicense the three existing multispecialty gastrointestinal endoscopy rooms at Wilmington Health such that Wilmington Health a/k/a Wilmington Health Endoscopy Center (License # AS0045) shall no longer be licensed as an ambulatory surgical facility.
- 12. Wilmington ASC, LLC 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.
- 13. 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, Wilmington ASC, LLC 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.
- 14. Wilmington ASC, LLC 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.



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 Dosher Memorial
 Hospital (Dosher) 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 Dosher..." 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:

<u>Promote Safety and Quality</u> – 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.

<u>Promote Equitable Access</u> – 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.

<u>Maximize Healthcare Value</u> – 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:

<u>Promote Safety and Quality</u> – 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.

<u>Promote Equitable Access</u> – 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.

<u>Maximize Healthcare Value</u> – 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.

Page 12

OrthoWilmington/		BSC Cases
EmergeOrtho Surgeon	Hospital Affiliations*	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 – Dosher 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

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

^{*7} months of data annualized

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

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	CY2019		CY2020				
	Number of Percent of		Number of	Percent of			
County	Patients	Total Patients	Patients	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

	CYZ	2019	CY2	020
County	Number of Percent of Patients 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 19- Aug20		
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

Page 22

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

Tilbite Total Hojected Surgical Off Reed						
	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

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.

^{*}Rounded per SMFP and CON Criteria and Standards

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.

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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

110poseu 110jeet cuptui 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.

Page 29

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

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:

^{*}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)

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 Dosher 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.

		Number of Full-Time Equivalent (FTE)
Position		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 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

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.

^{*}Excludes "White alone" who are "not Hispanic or Latino"

^{**&}quot;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."

(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.

¹http://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

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

Page 42

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 Dosher 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.

 \mathbf{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

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:

^{*}Rounded per SMFP and CON Criteria and Standards

- (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).

- 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 Dosher 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 Dosher 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 x 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 7	Гotal Cases	Projected Total Cases Provided to Medicaid Recipients		Cases Provide	centage of Total ed to Medicaid pients
	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

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SURGICAL MEDICARE CASES OPERATING YEARS 2 AND 3

Applicant	Projected T	Гotal Cases	Projected Total Cases Provided to Medicaid Recipients		Cases Provide	eentage of Total ed to Medicaid pients
	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	Ne	t Revenue	Gro	oss 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	ow	P3/BSC	NI	HBOS
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:

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Comparative Factor	More Effective Less Effecti		
Conformity with Review Criteria	The two applications are comparable		
Demonstration of Need	The two application	s are comparable.	
Geographic Accessibility	The two application	s are comparable.	
Demonstration of Physician Support	The two application	s 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 - 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:

<u>Promote Safety and Quality</u> – 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.

<u>Promote Equitable Access</u> – 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.

<u>Maximize Healthcare Value</u> – 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:

<u>Promote Safety and Quality</u> – 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.

<u>Promote Equitable Access</u> – 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.

<u>Maximize Healthcare Value</u> – 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	AMBULATORY	SHARED ORS	EXCLUDED C-
	ORs	ORS		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

011011	2013	2014	2015	2016	CAGR 2013-	CAGR 2014-	AGR 2015-
					2016	2016	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.

<u>Step 2: Project Future Union County Outpatient Surgical Procedures at NH Mecklenburg</u> 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:

Novant Health Union County Projected OP Surgery

VARIABLE	GROWTH	GROWTH RATE**
	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

	- 0			
	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), Opthalmology (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#	CY 2020 %	CY 2021#	CY 2021 %
COCIVII	PATIENTS	OF TOTAL	PATIENTS	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:

Union County Outpatient Surgical Volume

Chion County Outpatient Surgical Volume					
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:

NH Capital Cost

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.

	1 ST FULL	2ND FULL	3RD FULL
	FISCAL YEAR	FISCAL YEAR	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:

UWSC Capital Cost

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.

	1 ST 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		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							
						% < 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.

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:

^{*}Excludes "White alone" who are "not Hispanic or Latino"

^{**&}quot;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."

Presbyterian Same Day Surgery Center Monroe FFY 2013 Data

PAYOR CATEGORY	# CASES AS PERCENT OF TOTAL
Calf Day/Indiana	
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

e (18e e 1 2010	I uj oi min
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 ambulatgory 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

	· · · · ·			EXCLUDED	AMB	IP
	IP	AMB	SHARED	C-SECTION	SURGERY	SURGERY
	ORS	ORS	ORS	ORS	CASES	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 costeffective 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: {[(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) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 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

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

^{*} 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.

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

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: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and
 - (2) The number of rooms needed is determined as follows:
 - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;
 - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next

^{*} 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.

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

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

^{*} 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.

-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

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-

^{*} 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.

- 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
Opthalmology	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 Surger	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	OY3	OY 2	OY3
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	36.3%	36.3%	45.7%	45.7%
Medicare Recipients				

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

_	NHI	MOS	UWSC		
	OY 2	OY3	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	OY3	
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.