

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 26, 2016

Findings Date: August 26, 2016

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

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Project ID #: G-11150-16

Facility: Novant Health Kernersville Outpatient Surgery

FID #: 160113

County: Forsyth

Applicant: Novant Health Kernersville Outpatient Surgery, LLC

Project: 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 on the campus of Novant Health Kernersville Medical Center

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

The applicant, Novant Health Kernersville Outpatient Surgery, LLC [NHKOS] proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from Novant Health Forsyth Medical Center in Winston-Salem (Forsyth County) to a new facility to be developed on the campus of Novant Health Kernersville Medical Center in Kernersville (Forsyth County). In addition to the two outpatient surgical operating rooms, the proposed facility will also include one minor procedure room. There are no need determinations in the 2016 State Medical Facilities Plan (SMFP) applicable to this review.

Policies

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4 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, the Certificate of Need Section 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 IX.8, page 109, the applicant states it “will use modern energy controls and the most energy efficient material when implementing the proposed construction and upfit for the surgery center.” Exhibit 15 of the application contains a copy of Novant Health’s “Sustainable Energy Management Plan” for 2016, which the applicant states will include the proposed facility. The applicant adequately demonstrate 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, NHKOS, 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 Kernersville Medical Center (NHKMC) in Kernersville. In addition to the two outpatient surgical operating rooms, the proposed facility will also include one minor procedure room. In Section I.1, page 1, the applicant states that NHKOS is a new limited liability company with 100% of membership interests owned by Novant Health, Inc. In Section III.1, pages 22-23, the applicant describes the project as follows:

“Novant Health Kernerville Outpatient Surgery (NHKOS) is seeking approval to relocate two licensed surgical operating rooms from the Novant Health Forsyth Medical Center’s (NHFMC) main campus in Winston Salem to a new separately licensed freestanding ambulatory surgery center on the campus of Novant Health Kernersville Medical Center (NHKMC) in Kernersville. Upon completion of the project, Novant Health will have two licensed freestanding ambulatory surgical operating rooms at NHKOS and four shared inpatient/outpatient operating rooms at NHKMC in Kernersville. ... Upon completion of the proposed project Novant Health will utilize its 47 Forsyth County operating rooms as reflected in the following table.

**Novant Health Forsyth County Operating Rooms
 Current and Proposed Distribution**

Facility	LRA 2016	Approved/Proposed Changes		Proposed Future Inventory
		Additional ORs Shifted to NHKMC in Project G-8165-08	Proposed Project	
Proposed Novant Health Kernersville Outpatient Surgery	0		2	2
Novant Health Kernersville Medical Center	4			4
Novant Health Forsyth Medical Center*	23	-1	-2	20
Novant Health Hawthorne Outpatient Surgery	4			4
Novant Health Kimel Park Orthopedic Outpatient Surgery	2			2
Novant Health Clemmons Medical Center	2	3		5
Novant Health Medical Park Hospital	12	-2		10
Total	47			47

Source: LRAs and ongoing CON Projects; Exhibit 3, Table 12.

Notes: *Novant Health Forsyth Medical Center inventory includes Open Heart or C-Section ORs

Population to be Served

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, 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 57, the applicant provides the projected patient origin for ambulatory surgical services at the proposed NHKOS facility for the first three project years (PY), as summarized in the table below.

**Novant Health Kernersville Outpatient Surgery
 Projected Patient Origin**

County	Percent	PY 1 April 2018 – March 2019	PY 2 April 2019 – March 2020	PY 3 April 2020 – March 2021
Forsyth	64.9%	1,040	1,231	1,446
Guilford	16.4%	263	312	366
Other*	18.6%	298	353	414
TOTAL	100.0%	1,601	1,895	2,226

Source: Table on page 57 of the application.

*The applicant states the counties included in the “Other” category are “Counties and other non-NC locations as identified in the NHFMC 2016 LRA page 27E.” Page 27E of the 2016 Hospital License Renewal Application for Novant Health Forsyth Medical Center is a listing of the North Carolina counties and other states from which NHKMC ambulatory surgical patients originated in FY2015.

In Section III.5, pages 55-56, and Exhibit 3, Table 10, the applicant describes the historical patient origin for ambulatory surgical services for NHKMC. 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 NHKMC, based on the patient origin data reported in the applicant’s 2016 Hospital License Renewal Application, and the patient origin data reported by the applicant in Exhibit 3, Table 10, of the application. The applicant adequately identified 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 supports the need for the proposed project, including:

- The increasing demand for outpatient surgery due to advances in medical technology and increasing emphasis on cost containment (page 22).
- The historical growth rates in the utilization of surgical services at NHKMC from FFY2012 to FFY2015 (pages 25-28).
- Changes in reimbursement for outpatient surgery that encourages the use of ambulatory surgery centers as opposed to hospital outpatient departments (pages 28-29).

- The historical and projected growth in the number of surgical specialists on the medical staff of NHKMC (pages 29-31).
- The historical growth in NHKMC’s outpatient surgery market share in the eastern Forsyth County and western Guilford County service area (pages 31-32).
- The projected population growth and continued development in the municipalities within the service area (pages 33-38).

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

Projected Utilization

In Section IV.1, page 61, the applicant provides projected utilization for the proposed ambulatory surgery facility through the first three years of operation following completion of the project (April 2018-March 2021), which is summarized below.

**Novant Health Kernersville Outpatient Surgery
Projected Utilization, April 1, 2018 – March 31, 2021**

	PY 1 April 2018 – March 2019	PY 2 April 2019 – March 2020	PY 3 April 2020 – March 2021
Outpatient Surgical Operating Rooms	2	2	2
Outpatient Surgical Cases	1,601	1,895	2,226

As shown in the above table, the applicant projects it will perform 2,226 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 [$2,226 \times 1.5 \text{ hours} = 3,339 \text{ hours}$; $3,339 \text{ hours} / 1,872 \text{ hours} = 1.8 \text{ operating rooms}$].

In Section III.1(b), pages 38-47, the applicant describes its assumptions and methodology, in seven steps, for projecting utilization of the four existing shared operating rooms at NHKMC and two proposed outpatient surgical operating rooms at NHKOS, as summarized below.

Step 1: Determine Baseline Volume for Use in Surgical Projections

On page 39, the applicant states it reviewed the historical utilization data for NHKMC’s four shared operating rooms. After reviewing data from Novant Health’s two internal databases, Trendstar Data System and EPIC, as well as data reported on the *Hospital License Renewal Application* (LRA) forms, the applicant determined that internal (Trendstar) data on surgical utilization during the most recent full calendar year (CY2015) was the most reasonable baseline from which to project future utilization. The applicant adequately documents that using the Trendstar data is reasonable.

Step 2: Project Inpatient Surgical Cases at NHKMC

On page 39, applicant provides a table showing the historical inpatient surgical case volumes at NHKMC, as reported on the *Hospital License Renewal Application* forms for FY2011 through FY2015, which is summarized below.

**Novant Health Kernersville Medical Center
 Inpatient Surgery Utilization, FY2011 – FY2015**

Fiscal Year	Inpatient Surgical Cases	Annual Percent Change
2011	126	---
2012	346	174.6%
2013	601	73.7%
2014	766	27.5%
2015	854	11.5%
Average Annual Growth Rate		37.5%

Source: Table on page 39 of the application.

On page 40, the applicant states,

“Based upon data included in Exhibit 3, Table 3, previously discussed in response to Question III.1(a), annual inpatient surgical growth at NHKMC has exceeded 37.5% on average since opening. The highest growth rates reflected in the previous table since 2013 exceed 25% and the lowest one-year growth rate in the table is 11.5%. To remain conservative, NHKOS projected future inpatient surgical cases for NHKMC using the 11.5% growth rate, the most conservative rate available. This rate is less than half of most other growth rates reflected in the previous table since 2013 and is only one third of the average annual growth rates for all three databases. The following table projects future inpatient surgical volume for NHKMC using Trendstar CY 2015 data as the base year and an 11.5% annual growth rate.

**Novant Health Kernersville Medical Center
 Projected Inpatient Surgical Volume**

CY	2015	Surgical Growth Rate	2016	2017	2018	2019	2020	2021
<i>Inpatient</i>	901	11.5%	1,005	1,120	1,249	1,392	1,552	1,730

Step 3: Project Outpatient Surgical Utilization

On page 42, applicant provides a table showing the historical outpatient surgical case volumes at NHKMC, as reported on the *Hospital License Renewal Application* forms for FY2011 through FY2015, which is summarized below.

**Novant Health Kernersville Medical Center
 Outpatient Surgery Utilization, FY2011 – FY2015**

Fiscal Year	Outpatient Surgical Cases	Annual Percent Change
2011	742	---
2012	1,657	123.3%
2013	1,970	18.9%
2014	2,180	10.7%
2015	2,347	7.7%
Average Annual Growth Rate		12.4%

Source: Table on page 42 of the application.

The applicant projects future annual outpatient surgical case volumes at NHKMC based on the historical rate of growth from FY2014 to FY2015, which was 7.7 percent. On page 43, the applicant states,

“Based upon data included in Exhibit 3, Table 3, and previously discussed in response to Question III.1(a), annual outpatient surgical growth at NHKMC has exceeded 11.0% on average since opening using all three database/timeframes. The highest growth rates reflected in the previous table since 2013 exceed 17% and the lowest one-year growth rates in the table are from 2013 to 2014, which is expected, as this is the timeframe that NHKMC opened two additional procedure rooms, appropriately shifting low acuity non-surgical outpatient cases from the operating rooms.

To remain conservative, NHKOS projected future outpatient surgical cases for NHKMC using the 7.7% growth rate from the previous table for FFY 2012 to FFY 2015 based on LRA data. This rate is from the same time period as the inpatient surgery growth rate used in Step 2; it is less than the average annual outpatient surgical growth for all three databases; and is less than most of the other growth rates reflected in the previous table since 2013. The following table projects future outpatient surgical volume for NHKMC using Trendstar CY 2015 data as the base year and a 7.7% annual growth rate

**Novant Health Kernersville Medical Center
 Projected Outpatient Surgical Volume**

CY	2015	Surgical Growth Rate	2016	2017	2018	2019	2020	2021
<i>Outpatient</i>	2,517	7.7%	2,710	2,917	3,141	3,382	3,641	3,919

Step 4: Determine Percentage of Outpatient Surgical Cases that are Acuity Appropriate for NHKOS

The applicant assumes that 50 percent of projected outpatient surgical cases at NHKMC will be shifted to NHKOS in the first project year, 55 percent will be shifted to NHKOS in the second project year, and 60 percent will be shifted to NHKOS in the third first project year. On page 44, the applicant states,

“This assumption is based on the level of support from surgeons who currently perform outpatient surgeries in the NHKMC ORs as reflected in the letters in Exhibit 4 and on expert input from the Novant Health Forsyth Medical Center Vice President for Surgical services and the NHKMC Director of Operations. ... In addition, as illustrated on the site map in Exhibit 14, the location of the new ASC is within easy walking distance of the NHKMC existing operating rooms, by a short walk down the sidewalk. This proximity also makes is [sic] easy for surgeons to choose, when clinically appropriate, to perform their outpatient surgeries at the new ASC. Many of these surgeons will also have their offices in the medical office building where NHKOS will be located.”

Step 5: Project Operating Room Need for Novant Health Kernersville Outpatient Surgery

Based on the projected volumes of outpatient surgical cases at NHKMC and the percentage of outpatient surgical cases that will be clinically appropriate to be performed in an ambulatory surgery facility, the applicant projects the annual outpatient surgical case volumes that will be performed at NHKOS. On page 45, the applicant states,

“The following table reflects the projected surgical utilization for Novant Health Kernersville Outpatient Surgery, LLC.

Projected Novant Health Kernersville Outpatient Surgery Utilization and Operating Room Need

CY	2015	Surgical Growth Rate	2016	2017	2018	2019	2020	2021
<i>NHKMC Projected Outpatient Volume</i>	2,517	7.7%	2,710	2,917	3,141	3,382	3,641	3,919
<i>Converted to Project Years</i>					<i>PY 1 Apr18- Mar19</i>	<i>PY 2 Apr19- Mar20</i>	<i>PY 3 Apr20- Mar21</i>	
<i>Outpatient Cases – NHKMC</i>					3,201	3,446	3,710	
<i>Percent Clinically Appropriate to shift to NHKOS</i>					50.0%	55.0%	60.0%	
<i>Novant Health Kernersville Outpatient Surgery Projected Volume</i>								
<i>First Three Project Years</i>					<i>PY 1 Apr18- Mar19</i>	<i>PY 2 Apr19- Mar20</i>	<i>PY 3 Apr20- Mar21</i>	
<i>Projected NHKOS Outpatient Surgery</i>					1,601	1,895	2,226	
<i>Weighted Outpatient Hours</i>					2,401	2,843	3,339	
<i>Outpatient OR Need</i>					1.28	1.52	1.78	
<i>OR Need (Rounded per SMFP)</i>					1	2	2	

Source: Exhibit 3, Table 1

As shown in the previous table, NHKOS projects 2,226 ambulatory surgical cases in the third year of operation. Projected ambulatory volume is sufficient to fully support two ambulatory [surgical] operating rooms by the third year of the project as shown in the previous table.”

Step 6: Project Operating Room Need for Novant Health Kernersville Medical Center

On page 45, the applicant states,

“Utilizing the inpatient and outpatient surgical volumes projected in Steps 2 and 3, NHKOS projected future operating rooms needed at NHKMC. Projected inpatient and outpatient surgical cases were converted to Project Years 1-3 and volumes were weighted to determine projected operating rooms hours as shown in the following table.

**Novant Health Kernersville Medical Center
 Projected Operating Room Need**

CY	2015	Surgical Growth Rate	2016	2017	2018	2019	2020	2021
<i>Inpatient</i>	901	11.5%	1,005	1,120	1,249	1,392	1,552	1,730
<i>Outpatient</i>	2,517	7.7%	2,710	2,917	3,141	3,382	3,641	3,919
Converted to Project Years					PY 1 Apr18- Mar19	PY 2 Apr19- Mar20	PY 3 Apr20- Mar21	
<i>Inpatient Cases – NHKMC</i>					1,284	1,432	1,596	
<i>Outpatient Cases – NHKMC</i>					3,201	3,446	3,710	
<i>Percent Clinically Appropriate to shift to NHKOS</i>					50.0%	55.0%	60.0%	
<i>Adjusted Outpatient Cases-NHKMC</i>					1,601	1,551	1,484	
<i>Total Weighted Surgical Hours</i>					6,254	6,622	7,016	
<i>ORs Needed</i>					3.3	3.54	3.7	
<i>ORs Needed (Rounded per SMFP)</i>					3.0	4.0	4.0	

Source: Exhibit 3, Table 1

Step 7: Project Operating Room Need at NHKMC and NHKOS Combined

On page 46, the applicant states,

“Novant Health Kernersville Medical Center and Novant Health Kernersville Outpatient Surgery are on the same campus in Kernersville and share an overlapping surgical medical staff. NHKOS looked at the combined operating room need for the two facilities to illustrate that the proposed two dedicated ambulatory surgery operating rooms at NHKOS and the four shared operating rooms at NHKMC are needed and developing NHKOS with two operating rooms does not represent a duplication of services in the market. ... As shown [in the table on page 46 of the application], combined operating room need for NHKMC and NHKOS reflect a need for 6 operating rooms in the third project year.”

As discussed above, the applicant projects outpatient surgical volumes at the proposed ambulatory surgery facility based on the historical utilization of the outpatient surgical services at NHKMC. Specifically, the applicant assumes that outpatient surgical volumes at NHKMC will grow at the rate of 7.7 percent per year from 2015 through 2021, which is equal to the rate

of growth experienced by NHKMC from 2014 to 2015, and is lower than the average annual rate of growth in outpatient surgical cases at NHKMC from 2011 to 2015 of 12.4 percent. Also, the applicant projects that 60 percent of the projected outpatient surgical volumes at NHKMC will be clinically appropriate to be shifted to the proposed ambulatory surgical facility by the third operating year (2021). Exhibit 4 contains letters from surgeons expressing support for the proposed project and their intention to perform surgeries at the proposed ambulatory surgical facility. Projected utilization of the two outpatient surgical operating rooms at NHKOS is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrated the need to develop two outpatient surgical operating rooms at the proposed ambulatory surgical facility.

Minor Procedure Room

The applicant proposes to develop one minor procedure room as part of the project. On pages 48-49, 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 NHKOS. Five surgeons (two general surgeons, two orthopedic surgeons and one ophthalmologist) have indicated their support for a procedure room to perform joint manipulations, Femto laser treatments, excisions, incisions, and drainage cases as reflected in the procedure room letters of support included in Exhibit 4.

Non-surgical minor procedure volume at the proposed NHKOS are estimated based upon discussion with NHKMC surgical management staff and a review of procedure volume data for the surgeons who signed procedure room support letters. This procedure volume data was reviewed to determine the volumes appropriate to shift to a procedure room in a freestanding surgery center setting. Estimate volumes are held constant to remain conservative: 1,300 in Project Year 1; 1,300 in Project Year 2; and 1,300 in Project Year 3. This equates to an average of 5.2 cases per day in the NHKOS procedure room.”

Exhibit 4 contains letters from surgeons expressing support for the proposed project and their intention to perform minor (“*clinically appropriate non-surgical*”) procedures in the proposed minor procedure room. Projected utilization of the minor procedure room at NHKOS is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrated the need to develop one minor procedure room at the proposed ambulatory surgical facility.

Access

In Section VI.2, pages 70-72, the applicant states its commitment to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.13, page 79, the applicant reports that 58 percent of outpatient surgical cases at NHFMC were provided to Medicare or Medicaid recipients in FY2015. In

Section VI.14, page 80, the applicant projects that 44 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 identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated 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.

C

The applicant, NHKOS, proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from Novant Health Forsyth Medical Center (NHFMC) in Winston-Salem to a new facility to be developed on the campus of Novant Health Kernersville Medical Center (NHKMC) in Kernersville. NHFMC reported a total of 23 licensed operating rooms in its *2016 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: 2016 Hospital License Renewal Application.

Also, on December 4, 2009, in Project I.D. # G-8165-08, and as modified by a September 11, 2015 Material Compliance Approval letter, Novant Health was approved to relocate one shared operating room from NHFMC to Novant Health Clemmons Medical Center (NHCMC). Therefore, upon completion of Project I.D. G-8165-08 and this project, NHFMC will operate a total of 20 licensed operating rooms, including 15 shared operating rooms ($18 - 1 - 2 = 15$), two dedicated C-section surgical operating rooms, and three dedicated open heart surgery operating rooms.

In Section III.3(c), pages 50-51, the applicant states,

“As reflected in the following table, surgical utilization at NHFMC has declined in the last four 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

<i>Surgical Facility</i>	<i>CY 2012</i>	<i>CY 2013</i>	<i>CY 2014</i>	<i>CY 2015</i>	<i>Growth Rate 2014-2015</i>	<i>Avg Annual Growth Rate 2012-2015</i>
<i>Inpatient</i>	7,180	7,419	7,296	6,977	-4.4%	-0.9%
<i>Outpatient</i>	5,370	5,423	5,376	5,426	0.9%	0.4%
<i>Total All Surgery</i>	12,550	12,842	12,672	12,403	2.1%	-0.37

Source: Exhibit 3, Table 7

On page 51, the applicant states,

“In addition, when the three additional operating rooms at NHCMC become operational August 2017 several orthopedic surgeons will relocate from the Winston-Salem campus to the Clemmons campus. These surgeons performed around 1,500 inpatient joint cases and 230 outpatient joint cases in CY 2015. This volume is expected to shift to NHCMC when the new inpatient beds and 3 additional ORs become operational allowing inpatient surgical cases as well as outpatient surgical cases to be performed at NHCMC.”

On page 51, the applicant provides a table showing the projected utilization of the operating rooms at NHFMC through the first three operating years of the project, which is shown below:

Projected Surgical Utilization Novant Health Forsyth Medical Center

CY [sic]	2015	Weighted Population Growth Rate	2016	2017	2018	2019	2020	2021
<i>Projected Inpatient Cases</i>	6,976	0.65%	7,022	7,068	7,114	7,160	7,207	7,254
<i>Less Inpatient Volume shifted to NHCMC</i>				625	1,500	1,500	1,500	1,500
<i>Adjusted Inpatient Volume</i>	6,976		7,022	6,443	5,614	5,660	5,707	5,754
<i>Weighted Inpt Hrs</i>	20,928		21,065	19,328	16,842	16,981	17,122	17,263
<i>Inpatient ORs Needed</i>	11.2		11.3	10.3	9.0	9.1	9.1	9.2
<i>Projected Outpatient Cases</i>	5,425	0.67%	5,461	5,498	5,535	5,572	5,609	5,647
<i>Less Outpatient Volume shifted to NHCMC</i>				100	240	240	240	240
<i>Adjusted Outpatient Volume</i>	5,425		5,461	5,398	5,295	5,332	5,369	5,407
<i>Weighted Outpt Hrs</i>	8,138		8,192	8,097	7,942	7,998	8,054	8,110
<i>Outpatient OR Need</i>	4.3		4.4	4.3	4.2	4.3	4.3	4.3
<i>Total OR Need</i>	15.5		15.6	14.6	13.2	13.3	13.4	13.6
<i>NHFMC OR Inventory*</i>	18.0		18.0	18.0	18.0	18.0	18.0	18.0
<i>OR Surplus</i>	2.5		2.4	3.4	4.8	4.7	4.6	4.4

Source: Exhibit 3, Table 8

*Note: FMC OR inventory and volumes excludes OH and C-section operating rooms at NHFMC
 NCMC additional operating rooms will open August 2017

As shown in the table above, the applicant projects to perform 5,754 inpatient surgical cases and 5,407 outpatient surgical cases in the shared operating rooms at NHFMC in the third operating year of the project (2021). Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be 14 [(5,407 X 1.5 hours) + (5,754 X 3.0 hours) = 25,373 hours; 25,373 hours/1,872 hours = 13.6 operating rooms]. Therefore, 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 52, the applicant states,

“The proposed project will result in meeting the need for surgical services in the Kernersville 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 NHKOS 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 79, the applicant reports the following payer mix for ambulatory and inpatient surgical services for NHFMC for FFY2015:

Payer Category	Ambulatory Surgery Cases as Percent of Total	Inpatient Surgery Cases as Percent of Total
Self Pay/Indigent	2.27%	3.22%
Commercial Insurance	0.36%	0.45%
Medicare/Medicare Managed Care	48.18%	61.03%
Medicaid	9.58%	8.01%
Managed Care	36.99%	25.57%
Other	2.62%	1.71%
Total	100.0%	100.0%

In Section VI.14, page 80, the applicant projects the following payer mix for surgical services at NHKOS in the second operating year of the project.

Payer Category	Ambulatory Surgery Cases as Percent of Total
Self Pay/Indigent	3.13%
Commercial Insurance	0.55%
Medicare/Medicare Managed Care	37.64%
Medicaid	5.97%
Managed Care	49.81%
Other	2.90%
Total	100.0%

On page 80, the applicant states, *“The assumptions used to develop this payor mix are based on a three-year average of the payor mix for outpatient surgical cases at Novant Health Kernersville Medical Center, since the applicant anticipates that many NHKMC clinically appropriate outpatient surgical cases will shift to the Novant Health Kernersville Surgery Center in the future.”* As shown in the table above, the applicant projects that 43.6 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 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 NHKOS. 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 57-58, 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 the existing operating rooms at NHKMC will not have adequate capacity to meet the growing need for surgical services.
- 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 new, separately licensed ambulatory surgery center.
- Develop an Ambulatory Surgery Center in Another Location – The applicant states that developing an ambulatory surgery center in another location is not an effective alternative because the demand for surgical services is greatest in the NHKMC service area.

After considering those alternatives, the applicant states the alternative 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 and approved subject to the following conditions.

- 1. Novant Health Kernersville Outpatient Surgery, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Novant Health Kernersville 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, Novant Health Forsyth Medical Center shall be licensed for no more than 20 operating rooms, including 15 shared operating rooms, three dedicated open heart surgery operating rooms, and two dedicated C-section operating rooms.**

4. **Novant Health Kernersville 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 Kernersville 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 Kernersville 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.

C

NHKOS 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 Kernersville Medical Center in Kernersville.

Capital and Working Capital Costs

In Section VIII.1, page 92, the applicant states the total capital cost is projected to be as follows:

NHKOS Project Capital Cost

Site Costs	\$238,450
Construction Costs	\$5,401,973
Miscellaneous Project Costs	\$4,159,988
TOTAL CAPITAL COST	\$9,800,411

Source: Table on page 92 of the application.

In Section IX.1, page 101, the applicant states there will be \$108,544 in start-up expenses and \$382,392 in initial operating expenses associated with the project, for total working capital required of \$490,936.

Availability of Funds

In Section VIII.3, page 93, the applicant states that the total project capital costs will be funded by the accumulated reserves of Novant Health, Inc., the sole member of NHKOS. Also, in

Section IX.2, page 101, the applicant states that the working capital costs will be funded by the accumulated reserves of Novant Health, Inc. In Exhibit 7, the applicant provides a letter dated February 24, 2016, from the Senior Vice President, Finance for Novant Health, Inc., documenting its intention to fund \$9,800,411 in capital costs and \$490,936 in working capital costs for the proposed project. Exhibit 7 also contains a copy of the Consolidated Financial Statements for Novant Health, Inc. and Affiliates that indicate it had \$354 million in cash and cash equivalents, \$903 million in current assets, and \$2.7 billion in total net assets, as of December 31, 2014. The applicant adequately demonstrate 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 NHKOS'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 NHKOS Revenue and Expenses

	PY1 2018	PY2 2019	PY3 2020
Total Net Revenue	\$6,319,754	\$7,638,030	\$8,933,625
Average Net Revenue/Case	\$2,178	\$2,391	\$2,534
Total Operating Expenses	\$4,435,335	\$4,797,150	\$5,232,822
Net Income (Loss)	\$1,884,419	\$2,840,880	\$3,700,803

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 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.

C

The applicant, NHKOS, 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 Kernersville Medical Center.

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, 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 Proposed 2017 SMFP. Surgical case volume for Novant Health facilities are from the applicant’s 2016 Hospital License Renewal Application form, and include utilization data from FY2015.

Forsyth County Operating Room Inventory

	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP 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)	3	0	0	2,224	0
North Carolina Baptist Hospital (3)	0	4	36	19,549	14,214
Novant Health Forsyth Medical Center (4)	0	5	18	5,552	10,484
Novant Health Hawthorne Outpatient Surgery	4	0	0	6,036	0
Novant Health Orthopedic Outpatient Surgery	2	0	0	2,491	0
Novant Health Kernersville Medical Center	0	0	4	2,347	854
Novant Health Clemmons Medical Center (5)	0	0	2	1,019	0
Novant Health Medical Park (6)	0	0	12	8,613	897

Source: Proposed 2017 SMFP, Table 6A, and the 2016 Hospital License Renewal Application for NHFMC.

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 in the 2016 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 counted in the inventory in the 2016 SMFP.
- (4) The operating room total for NHFMC includes one shared operating room that will be relocated to NHCRC upon completion of Project I.D. # G-8165-08.
- (5) NHCRC will have a total of five shared operating rooms following completion of Project I.D. # G-8165-08.
- (6) The operating room total for NHMP includes two operating rooms that will be relocated to NHCRC upon completion of Project I.D. # G-8165-08.

NHKOS 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 Kernersville Medical Center in Kernersville. Therefore, the applicant does not propose to increase the inventory of operating rooms in the service area. The applicant adequately demonstrated the need to relocate the existing operating rooms, and adequately demonstrated 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 demonstrated 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 82, the applicant provides the proposed staffing for the facility in operating year 2 (April 2019 – March 2020), as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Administrator	1.0
Clinical Coordinator	1.0
Registered Nurse	8.0
Surgical Technician	3.0
Certified Nursing Assistant	1.5
Sterile Processing Technician	1.0
Patient Access Specialist	1.5
TOTAL	17.0

Source: Table VII.2, page 82.

In Section VII.3, page 83, and Section VII.7, pages 86-87, the applicant describes their 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. 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. 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

The applicant, NHKOS, proposes to develop a new ambulatory surgery center in 14,403 square feet of space in a medical office building to be constructed on the campus of Novant Health Kernersville 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 92 of the application. In Section IX.8, page 109, 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;

C

In Section VI.13, page 79, the applicant reports the following payer mix for NHFMC's surgical services for FFY2015:

Payer Category	Outpatient Surgical Cases as Percent of Total	Inpatient Surgical Cases as Percent of Total
Self Pay/Indigent	2.27%	3.22%
Commerical Insurance	0.36%	0.45%
Medicare/Medicare Managed Care	48.18%	61.03%
Medicaid	9.58%	8.01%
Managed Care	36.99%	25.57%
Other	2.62%	1.71%
Total	100.00%	100.00%

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, Guilford 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%
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

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

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

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

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

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

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

C

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 77-78, the applicant states,

“Novant Health’s hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago. ... FMC, PMC 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. ... Novant Health’s acute care hospitals have continued their commitment to providing care to all persons, regardless of their ability to pay.”

In Section VI.10, page 77, the applicant states that no civil rights access complaints have been filed against any Novant Health facility in 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 80, the applicant projects the following payer mix for NHKOS's surgical services during the second operating year (April 2019 – March 2020):

Payer Category	Outpatient Surgical Cases as Percent of Total
Self Pay/Indigent	3.13%
Commercial Insurance	0.55%
Medicare/Medicare Managed Care	37.64%
Medicaid	5.97%
Managed Care	49.81%
Other	2.90%
Total	100.00%

On page 80, the applicant states, *“The assumptions used to develop this payor mix are based on a three-year average of the payor mix for outpatient surgical cases at Novant Health Kernersville Medical Center, since the applicant anticipates that many NHKMC clinically-appropriate outpatient surgical cases will shift to the Novant Health Kernersville Surgery Center in the future.”* The applicant demonstrated 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.

C

In Section VI.9, page 76, the applicant describes the range of means by which a person will have access to NHKOS’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.

C

In Section V.1, page 62, the applicant states that Novant Health has extensive relationships with health professional training programs. Exhibit 9 contains a list of educational institutions with which Novant Health has training arrangements, including Wake Forest University, Guilford Technical Community College, Miller-Motte College, South Piedmont Community College, Catawba College, Central Piedmont Community College, Forsyth Community College and UNC-Charlotte, 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

The applicant, NHKOS, proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from Novant Health Forsyth Medical Center (NHFMC) in Winston-Salem to a new facility to be developed on the campus of Novant Health Kernersville Medical Center (NHKMC).

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, 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 Proposed 2017 SMFP. Surgical cases volumes for Novant Health facilities are from applicant’s *2016 Hospital License Renewal Application* form, and include utilization data from FY2015.

Forsyth County Operating Room Inventory

	OP ORs	IP ORs	Shared ORs	OP Surgery Cases	IP 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)	3	0	0	2,224	0
North Carolina Baptist Hospital (3)	0	4	36	19,549	14,214
Novant Health Forsyth Medical Center (4)	0	5	18	5,552	10,484
Novant Health Hawthorne Outpatient Surgery	4	0	0	6,036	0
Novant Health Orthopedic Outpatient Surgery	2	0	0	2,491	0
Novant Health Kernersville Medical Center	0	0	4	2,347	854
Novant Health Clemmons Medical Center (5)	0	0	2	1,019	0
Novant Health Medical Park (6)	0	0	12	8,613	897

Source: Proposed 2017 SMFP, Table 6A, and the 2016 Hospital License Renewal Application for NHFMC.

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 in the 2016 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 counted in the inventory in the 2016 SMFP.
- (4) The operating room total for NHFMC includes one shared operating room that will be relocated to NHCRC upon completion of Project I.D. # G-8165-08.
- (5) NHCRC will have a total of five shared operating rooms following completion of Project I.D. # G-8165-08.
- (6) The operating room total for NHMP includes two operating rooms that will be relocated to NHCRC upon completion of Project I.D. # G-8165-08.

NHKOS proposes to develop a new ambulatory surgery center by relocating two existing operating rooms from NHFMC in Winston-Salem to a new facility to be developed on the campus of Novant Health Kernersville Medical Center in Kernersville. Therefore, the applicant does not propose to increase the inventory of operating rooms in the service area.

In Section V.7, pages 67-68, 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,

“In the Kernersville market area encompassing zip codes in both eastern Forsyth County and western Guilford County, the applicant is proposing development of one of the first freestanding, multi-specialty surgery centers in many years.

The applicant is intentionally seeking to become a licensed freestanding Ambulatory Surgery Center (ASC). Traditionally, patient co-pays and charges have been lower at freestanding ASC surgery programs, than at hospital-based outpatient surgery and endoscopy programs. This approach will offer a new option for outpatient surgical care in the Kernersville market area, covering two counties (Forsyth and Guilford) and more choices for surgeons and their patients. NHKOS will also promote beneficial competition and choice with other outpatient surgery providers in and near the Kernersville market area. Competition can be a useful tool in expanding local access to services, promoting

cost effectiveness by putting downward pressure on costs of care, and encouraging the consistency in the delivery of quality care....

NHKOS will promote access to its services in a wide variety of ways. First, NHKOS will have an electronic health record system (EPIC-Dimensions) to make patient information more readily available to physicians and patients. Second, NHKOS will participate in care delivery under the umbrella of the Novant Health Charity Care policy which promotes access to care for medically underserved populations. ... Third, due to its location in Kernersville, 'the Heart of the Triad,' NHKOS's services will be geographically accessible to residents of both Forsyth and Guilford Counties....

In addition, consistent with Novant Health's other surgical programs, Novant Health Kernersville Outpatient Surgery will use the following tools, policies, and programs [listed on page 68 of the application] to insure and maintain quality care for outpatient surgeries and outpatient non-surgical procedures performed in the surgery center's procedure room....

In addition, as discussed in response to CON Application Question X.1, the design and construction/upfit of the NHKOS space is based on a proto-typical surgery center model. This approach to the design of the surgery center promotes smooth patient flow, patient safety, as well as efficiency and effectiveness of care delivery by surgeons and surgery center staff. In addition, this approach promotes value-based construction/upfit and reduced future maintenance costs for the surgery center."

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 (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) 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

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.

C

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

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

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

-C- In Section II.10, page 17, the applicant states that NHKOS is projected to operate five days per week and 52 weeks a year.

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

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

-C- The 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, which is shown below:

Novant Health Kernersville Outpatient Surgery Projected Volume			
	PY 1 Apr18- Mar19	PY 2 Apr19- Mar20	PY 3 Apr20- Mar21
Projected NHKOS Outpatient Surgery Cases	1,601	1,895	2,226
Weighted Outpatient Hours (1.5 hours per case)	2,401	2,843	3,339
ORs needed at 1,872 hours per room	1.28	1.52	1.78
Total Operating Rooms Needed	1	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: $\{[(\text{Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$ minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and*
- (2) The number of rooms needed is determined as follows:*
 - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*
 - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*
 - (C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-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 38-49, and Exhibit 3 of the application.