

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**

Facility	2017 LRA	CON Approved Proposed Changes		CON Approved Future Licensed Inventory	Proposed NHCOS Project Under Review	Proposed Future Inventory
		Project ID #G-8165-08 Shift	Project ID #G-11150-16 Shift			
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**

County	Percent	PY 1	PY 2	PY 3
		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.

*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.

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

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](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 NHCOS 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 X 1.5 hours = 3,573 hours; 3,573 hours/1,872 hours = 1.9 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 NHCOS 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 NHCOS 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 NHCOS (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 2016	4-Yr CAGR	2017 Jan- Jul	2017 Aug -Dec	2018	2019 Jan- July	2019 July- Dec	CY 2020	CY 2021	CY 2022
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 NHCOS 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	2019	CY2020	CY2021	CY2022
	Jan-Jul	July-Dec			
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 = 1/2 CY2019 + 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 Jul2019-Jun2020	PY2 Jul2020-Jun2021	PY3 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

	CY2016	4-Yr CAGR	2017	2017	CY2018	CY2019	CY2020	CY2021	CY2022
			Jan- Jul	Aug -Dec					
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

	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.

NHCCM Projected Outpatient Surgical Cases 2017-2022

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

Step 9: Project Operating Room Need for NHCCM

The applicant projects future inpatient and outpatient surgical volume at NHCCM (Steps 6 through 8) and converts the calendar year projections to the applicant’s project years to project operating room need at NHCCM, 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.

NHCCM Projected Operating Room Need

	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022
Inpatient Volume at NHCCM (Step 6)	382	1,619	2,082	2,082	2,082	2,082
Outpatient Volume at NHCCM (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 NHCCM				2,082	2,082	2,082
Outpatient Cases at NHCCM				1,802	1,844	1,889
Weighted Inpatient Surgical 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 Hours				8,949	9,012	9,080
ORs Needed at 1,872 Hours per OR				4.8	4.8	4.9
Rounded OR Need per 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.

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

<i>Surgical Facility</i>	<i>CY 2012</i>	<i>CY 2013</i>	<i>CY 2014</i>	<i>CY 2015</i>	<i>CY 2016</i>	<i>CAGR 2012-2016</i>
<i>Inpatient</i>	7,627	7,837	7,629	7,368	7,615	-0.04%
<i>Annual Growth</i>		2.8%	-2.7%	-3.4%	3.3%	
<i>Outpatient</i>	14,132	14,545	14,016	14,568	14,440	0.5%
<i>Annual Growth</i>		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 Jul2019-Jun2020	PY2 Jul2020-Jun2021	PY3 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 NHCOS 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 NHCOS and NHKOS) 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 NHCOS. 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.

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

	PY1 Jul2019-June2020	PY2 Jul2020-June2021	PY3 Jul2021-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.

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 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)	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.

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 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.

C

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;

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.2014EstimateasofDecember22,2015>.

*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;

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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 NHCOS. 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.

C

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.

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.

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 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)	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 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

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 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

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 NHCMS 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.

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 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: $\{[(\text{Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of facility's projected outpatient cases times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$ 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, as summarized below:

Novant Health Clemmons Outpatient Surgery Projected Volume			
	PY1 Jul2019-June2020	PY2 Jul2020-June2021	PY3 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: $\{[(\text{Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of projected$*

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

- (2) *The number of rooms needed is determined as follows:*
- (A) *in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*
 - (B) *in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*
 - (C) *in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-NA- The 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.