

July 2, 2018

VIA E-MAIL ONLY TO [DHSR.CON.COMMENTS@DHHS.NC.GOV](mailto:DHSR.CON.COMMENTS@DHHS.NC.GOV) AND [CELIA.INMAN@DHHS.NC.GOV](mailto:CELIA.INMAN@DHHS.NC.GOV)

Celia Inman, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

RE: Written comments regarding certificate of need applications filed with the Health Care Planning and Certificate of Need Section to develop operating rooms in response to the need determination in the 2018 SMFP for four new operating rooms in Forsyth County

Dear Ms. Inman:

Attached please find comments prepared by North Carolina Baptist Hospital (NCBH) regarding the five certificate of need applications filed May 15, 2018 with the Health Care Planning and Certificate of Need Section to develop operating rooms in response to the need determination in the 2018 SMFP for four new operating rooms in Forsyth County.

As set forth in the comments, NCBH believes that the applications filed by Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center (NHFMC), Novant Health Clemmons Outpatient Surgery, LLC (NHCOS), MC Kernersville, LLC and The Moses H. Cone Memorial Hospital, d/b/a Triad Surgery Center (TSC-CONE), and Triad Center for Surgery, LLC (TCS) are each non-conforming with the applicable criteria and rules. NCBH further believes that the application filed by NCBH is comparatively superior to the other competing applications.

Comments specifically related to the NHFMC, NHCOS, TSC-CONE and TCS applications are set forth immediately hereafter, followed by a comparative analysis of all five applications.

If you have any questions about the information presented here, please feel free to contact me at 336.713-0697.

Sincerely,



Marisa A. Barone  
Senior Planning Manager, Strategic and Business Planning

**WAKE FOREST BAPTIST HEALTH COMMENTS**

**REGARDING NOVANT HEALTH CLEMMONS  
OUTPATIENT SURGERY APPLICATION**

**G-11518-18**

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING NOVANT HEALTH CLEMMONS OUTPATIENT SURGERY APPLICATION, G-11518-18**

**Criterion 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.”**

Policy GEN-3 Basic Principles states: “A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The Novant Health Clemmons Outpatient Surgery (NHCOS) application does not conform to Criterion 1 as it does not adequately demonstrate that the project will promote equitable access and maximize healthcare value for resources expended.

*Equitable Access*

The proposed project will not promote equitable access in the delivery of health care services. In fact, the proposed project will exacerbate inequities that exist in health care service delivery. As evidenced by the payer mix projections on page 72 in Section L of the application, the proposed project is projected to serve just 1.5% self-pay/charity care patients. Furthermore, the project is projected to serve just 5.3% Medicaid patients. In comparison, the total self-pay surgical cases in Forsyth County surgical facilities during FFY 2017 (as reported in the 2018 hospital and ambulatory surgery center license renewal applications) was 4.7% for inpatient cases and 3.9% for outpatient cases. The percent of Medicaid patients was 14.4% for inpatient cases and 13.7% for outpatient cases. The project is projecting to serve 61.5% fewer self-pay patients and 61.3% fewer Medicaid patients than are currently being served by the existing surgical facilities in Forsyth County. Reference Table 1.

Comparing the projected payer mix of NHCOS to the applicant’s own payer mix further illustrates that the project will promote inequities in health care. The applicant is projecting to serve 50% fewer self-pay patients than what the applicant currently serves at Novant Health Medical Park Hospital (NHMPH), the location from which cases are planned to be shifted. Reference Table 2.

Table 1  
Forsyth County Facility FFY 2017 Surgical Payer Mix

Payer Source	Forsyth County Surgical Payer Mix		Projected Payer Mix of Project (OR Only)	% Difference in Payer Mix (Proposed - Forsyth County / Forsyth County)
	IP	OP		
Self-Pay*	4.7%	3.9%	1.5%	-61.5%
Medicare	46.0%	37.1%	44.2%	19.1%
Medicaid	14.4%	13.7%	5.3%	-61.3%
Managed Care / Commercial	30.3%	41.4%	44.4%	7.2%
Other	4.6%	3.8%	4.6%	21.1%

Data Source: 2018 hospital and ambulatory surgery center license renewal applications

\*Includes charity care

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Table 2  
NHMPH and NHFMC FFY 2017 Payer Mix

	Projected Payer Mix NHCOS	NHMPH OP Payer Mix	% Difference in Payer Mix	NHFMC OP Payer Mix	% Difference in Payer Mix
Self-Pay*	1.5%	3.0%	-50%	2.02%	-26%
Medicare	44.2%	38.9%	14%	48.91%	-10%
Medicaid	5.3%	5.8%	-9%	8.79%	-40%
Managed Care / Commercial	44.4%	50.0%	-11%	37.08%	20%
Other	4.6%	2.3%	100%	3.19%	44%

Data Source: 2018 hospital and ambulatory surgery center license renewal applications  
\*Includes charity care

**Value**

The proposed project will not maximize value for healthcare resources expended for the following reasons:

- It represents a duplication of existing resources
- It involves an expansion of existing resources that are not fully utilized
- It will not meet the demand for operating room services in Forsyth County

Duplication of existing resources

The Clemmons area of Forsyth County is very well served with ambulatory surgery operating rooms. There are a total of eight existing and two planned ORs located within the Clemmons community – for a total of 10 ORs. Five of these ORs are, or will be, located within multispecialty ASCs. By comparison, there are zero multispecialty ASC ORs located within Winston-Salem, the county seat, and two located in eastern Forsyth County. In total, Clemmons comprises 71% of the current multispecialty ASC ORs in Forsyth County but just 10% of the population. If developed, this proposal will increase this disparity to 78% of the Forsyth County multispecialty ASC ORs located within the Clemmons community. Reference Table 3. Western Forsyth County has more than adequate access to ASC ORs. The addition of more ORs will result in the duplication of existing health care resources.

Table 3  
Forsyth County Population and Multispecialty ASC ORs

	2017 Population		Total Multispecialty ASC ORs	
Kernersville	65,418	16%	2	29%
Clemmons	40,325	10%	5	71%
Winston-Salem	292,128	73%	0	0%
Total	397,871	100%	7	100%

Population Data Source: Truven  
Clemmons = Zip codes 21012 and 27072  
Kernersville = zip codes 27284, 27009, and 27051  
Winston-Salem = all remaining zip codes

Expansion of existing resources that are not fully utilized

The proposed project will not maximize value for healthcare resources expended as the project involves an expansion of existing resources that are not fully utilized. Following the SMFP operating room need determination methodology, Novant Health surgical facilities in Forsyth County have a current surplus of 8.3 operating rooms with a 2020 projected surplus of 6.81 ORs. Converted to a utilization rate, the Novant Health ORs in Forsyth County are

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utilized at 18.4% below capacity. By comparison, the operating rooms at North Carolina Baptist Hospital (NCBH) are utilized at 10.3% above capacity, have a current deficit of 4.7 ORs and a projected 2020 deficit of 6.65 ORs. Development of the proposed two NHCOS ORs will not maximize healthcare value for resources expended as their development is unnecessary and represents an imprudent expenditure of resources.

Table 4  
Utilization of Forsyth County ORs

Facility	IP Surgical Cases	OP Surgical Cases	Total Adjusted Estimated Surgical Hours	OR Need	OR Supply	OR Surplus / Deficit (Surplus is "-")	OR Utilization
NHCOS	0	0	0	0.0	2	-2.0	0.0%
NHKOS	0	0	0	0.0	2	-2.0	0.0%
NHFCMC	9,262	17,706	51,607	26.5	31	-4.5	85.4%
NHMPH	871	8,665	17,994	10.3	10	0.3	102.5%
<b>Novant Health</b>	<b>10,133</b>	<b>26,371</b>	<b>69,601</b>	<b>36.7</b>	<b>45</b>	<b>-8.3</b>	<b>81.6%</b>
WFBH-OSC	0	0	0	0.0	0	0.0	NA
PSCNC	0	169	507	0.4	3	-2.6	12.9%
NCBH	14,534	19,925	96,823	49.7	45	4.7	110.3%
<b>WFBMC</b>	<b>14,534</b>	<b>20,094</b>	<b>97,330</b>	<b>50.0</b>	<b>48</b>	<b>2.0</b>	<b>104.2%</b>
POSC*	0	2,514	1,927	1.5	2	-0.5	73.4%

Source: 2018 NC SMFP

\*Single Specialty Demonstration Project

Demand for operating room services in Forsyth County

The project involves the expansion of a planned ASC in Clemmons. Per the letters of support, the project will include providers in Gynecology, Urology, General Surgery, Neurosciences, Podiatry and Orthopedics. As evident the applicant’s projection methodology in Section Q, Figure 6, over half of the cases projected for NHCOS consist of a shift from Novant Health Orthopaedic Outpatient Surgery (NHOOS). The proposed mix of the services is not representative of the needs in Forsyth County as surgical services have grown on both the inpatient and outpatient side in almost every surgical specialty. Contrary to volume trends in Forsyth County, two of the five specialties planned for the surgery center – Orthopedics and Obstetrics/Gynecology – have experienced a recent decline in outpatient surgical volume in Forsyth County overall. Reference Table 5.

A closer look at the applicant’s own historical experience in outpatient Gynecology, Urology, General Surgery, Neurosurgery, and Orthopedic volume illustrates that there has only been growth in two of these five specialties proposed (general surgery and neurosurgery). Aggregated, this volume has been flat with a CAGR of 0.2% and overall growth of 0.3%. Of particular interest is the decline in outpatient orthopedic surgery. Comprising over 50% of the proposed NHCOS volume, outpatient orthopedic surgery has declined 3% overall at Novant Health facilities. The NHOOS ORs, the facility from which the NHCOS cases will shift, have declined by 19% from FFY 2015 to FFY 2017. Reference Tables 6 and 7.

The need for ORs in Forsyth County is not driven by the need for more Novant Health outpatient surgery OR capacity. The development of this project will result in the development of unnecessary ORs that will not meet the need for surgical services in Forsyth County and therefore it does not maximize value for healthcare resources expended.

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Table 5  
Forsyth County Surgical Specialty Volume Trends

	Inpatient				Outpatient			
	FFY 2015	FFY 2016	FFY 2017	% Change	FFY 2015	FFY 2016	FFY 2017	% Change
CT	933	946	1,098	18%	87	100	90	3%
General	4,659	5,142	4,918	6%	7,277	7,232	7,819	7%
Neurosurgery	2,958	3,013	3,079	4%	1,721	1,748	1,836	7%
OB and Gyn	1,187	1,171	947	-20%	3,158	3,059	2,973	-6%
Open Heart	1,343	1,353	1,340	0%	-	-	-	-
Ophthalmology	87	118	81	-7%	7,637	7,979	8,831	16%
Oral/Dental	31	61	46	48%	973	1,131	1,063	9%
Orthopedics	6,563	7,283	6,880	5%	10,660	1,0371	10,476	-2%
Other	2,227	2,413	2,130	-4%	1,359	1,332	1,007	-26%
Otolaryngology	955	823	854	-11%	6,199	6,315	6,197	0%
Plastic Surgery	643	715	711	11%	2,476	2,468	2,517	2%
Podiatry	NA	NA	505	-	NA	NA	487	-
Urology	1,387	1,371	1,228	-11%	5,522	5,514	5,777	5%
Vascular	1,657	1,752	1,924	16%	9,33	848	1,003	8%
<b>Grand Total</b>	<b>24,630</b>	<b>26,161</b>	<b>25,741</b>	<b>5%</b>	<b>48,002</b>	<b>48,097</b>	<b>50,076</b>	<b>4%</b>

Source: Hospital and ASC LRAS, 2016-2018; Excludes all C-Sections (in C-Section OR and not in C-Section OR)

Table 6  
NHFMC and NHMPH OP Surgical Specialty Volume Trends

	NHFMC & NHMPH					NHMPH				
	FFY 2015	FFY 2016	FFY 2017	% Change	2-Year CAGR	FFY 2015	FFY 2016	FFY 2017	% Change	2-Year CAGR
General	4,449	4,362	4,935	10.9%	5.3%	3,141	3,299	3,325	5.9%	2.9%
Neurosurgery	1,120	1,149	1,220	8.9%	4.4%	47	65	72	53.2%	23.8%
OB and Gyn	2,522	2,375	2,283	-9.5%	-4.9%	518	522	463	-10.6%	-5.5%
Orthopedics	6,561	5,968	6,372	-2.9%	-1.5%	1,573	1,320	1,336	-15.1%	-7.8%
Urology	2,458	2,386	2,356	-4.1%	-2.1%	1,985	2,046	1,971	-0.7%	-0.4%
<b>Total</b>	<b>17,110</b>	<b>16,240</b>	<b>17,166</b>	<b>0.3%</b>	<b>0.2%</b>	<b>7,264</b>	<b>7,252</b>	<b>7,167</b>	<b>-1.3%</b>	<b>-0.7%</b>

Source: License Renewal Applications

Table 7  
NHOOS Surgical Volume Trends

	FFY 2015	FFY 2016	FFY 2017	% Change	2-Year CAGR
NHOOS	2,491	2,191	2,019	-19%	-10%

Source: License Renewal Applications

**Criterion (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."**

The applicant does not conform to Criterion 3 as it does not adequately demonstrate the need that this population has for the services proposed and does not adequately demonstrate the extent to which all residents of the area, particularly 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.

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**Demonstration of Need**

The applicant does not adequately demonstrate the need that this population has for the services proposed due to the following reasons:

- There is not a current need for additional ASCs in Forsyth County or in Clemmons
- The proposed service does not meet the demand for surgical services in Forsyth County
- Illogical Methodology for Translating to Calendar Year that is Inconsistent with Form C Instructions
- Overly Aggressive Projected Annual Growth Rate of Surgical Cases
- Inaccurate Baseline Surgical Data

***Not a Current Need for Additional ASCs in Forsyth County***

Growth and Aging of the Population is not Driving the need for an ASC in Forsyth County

The applicant points to the projected population growth and aging of the population in Forsyth County as rationale for a need for an ASC in Forsyth County. The applicant notes that the population ages 65+ is projected to grow at a greater rate than other age segments. While it is true that persons over age 65 tend to be higher utilizers of health care services, there is no data provided to support that persons over age 65 have a higher demand and utilization of *ambulatory* surgical center services or that they need more access to ASCs. To the contrary, the 2018 MedPAC Report to Congress on Medicare Payment Policy noted that “beneficiaries have adequate access to care in ASCs”. The report continues to state that the volume of services per FFS beneficiary declined by 0.5% from 2015 to 2016. This compares to an average annual growth of 0.7% per from 2011 to 2015.

Demand for Ambulatory Surgical Services is not driving the OR Need in Forsyth County

The applicant discusses the shift to outpatient services and the lower cost of care in ambulatory surgery centers as compared to hospital outpatient departments as part of the rationale for the need for expansion of NHCOS. Their discussion includes points regarding advances in surgical technologies as well as ASC reimbursement and ambulatory surgery trends. Although these data points are in fact accurate, they are also misleading. The shift to outpatient services in health care is undisputable, however the need for the ORs in Forsyth County cannot be attributed to this shift to outpatient and cannot be met by more outpatient/ambulatory ORs.

If the surgical data is reviewed more closely, it is clear that the need for ORs in Forsyth County was driven by utilization North Carolina Baptist Hospital (NCBH). It is also quite evident by this closer review that growth in inpatient surgical volume has outpaced growth in outpatient surgical volume at NCBH. From a statewide perspective, the facilities with the greatest OR deficits are North Carolina’s Academic Medical Centers (AMCs). In three of the four OR Service Areas with an AMC and a need determination for ORs in the 2018 SMFP (Durham, Forsyth, Mecklenburg, and Orange), the AMCs experienced greater inpatient surgical growth as compared to outpatient. The only exception to this is Duke University Hospital in Durham, whose inpatient growth (0.7%) was essentially equivalent to its outpatient growth (0.8%). This further supports that fact that the need for additional ORs in not only Forsyth County, but the state as a whole, must involve the development of operating rooms that support both inpatient and outpatient surgical services.

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Table 8  
Surgical Growth, Inpatient v Outpatient  
Counties with a Need Determination, Facilities within each County with a Deficit

	OR Deficit	Inpatient				Outpatient			
		FFY 2014	FFY 2015	FFY 2016	CAGR	FFY 2014	FFY 2015	FFY 2016	CAGR
<i>Buncombe</i>									
Orthopaedic Surgery Center of Asheville	0.50	0	0	0	NA	3,201	3,138	3,016	-2.9%
Asheville Eye Surgery Center	0.60	0	0	0	NA	3,931	4,074	4,648	8.7%
<i>Durham</i>									
Duke University Hospital	5.77	16,920	17,344	17,151	0.7%	22,292	23,728	22,642	0.8%
NC Specialty Hospital	2.59	1,685	1,597	1,629	-1.7%	3,583	3,737	3,606	0.3%
<i>Forsyth</i>									
<b>North Carolina Baptist Hospital</b>	<b>6.65</b>	<b>13,944</b>	<b>14,214</b>	<b>14,534</b>	<b>2.1%</b>	<b>19,749</b>	<b>19,549</b>	<b>19,925</b>	<b>0.4%</b>
<i>Mecklenburg</i>									
<b>Carolinas Medical Center</b>	<b>16.57</b>	<b>19,414</b>	<b>21,242</b>	<b>21,215</b>	<b>4.5%</b>	<b>21,074</b>	<b>21,593</b>	<b>22,756</b>	<b>3.9%</b>
CHS – University	0.99	1,067	1,019	846	-11.0%	7,036	6,854	6,513	-3.8%
<i>Orange</i>									
<b>UNC Hospitals</b>	<b>6.48</b>	<b>12,139</b>	<b>12,845</b>	<b>13,529</b>	<b>5.6%</b>	<b>16,547</b>	<b>16,960</b>	<b>15,736</b>	<b>-2.5%</b>
<i>Wake</i>									
<b>Duke Raleigh Hospital</b>	<b>6.77</b>	<b>3,586</b>	<b>3,616</b>	<b>4,389</b>	<b>10.6%</b>	<b>9,132</b>	<b>9,875</b>	<b>10,855</b>	<b>9.0%</b>

Source: 2016-2018 SMFPs

Forsyth County will be transitioning from a county with zero multispecialty freestanding ASCs to a county with three multispecialty freestanding ASCs by June 2019. Wake Forest Baptist Health – Outpatient Surgery Clemmons (WFBH-OSC) is a multispecialty ASC with three licensed ORs that opened in February 2018; Novant Health Kernersville Outpatient Surgery (NHKOS) is a planned ASC for Kernersville with two licensed ORs and a planned opening of July 2018; NHCOS is a planned ASC for Clemmons with two licensed ORs and a planned opening for June 2019. In total, these new ASCs will provide access to seven new freestanding ASC ORs in Forsyth County with a surgical capacity of 8,352 cases or 18% of all outpatient surgical cases in the Forsyth County OR Service Area<sup>1</sup>. As evidenced in response to Criterion 1, 71% of these ORs are located in Clemmons.

***Proposed Service Does not meet the Demand for Surgical Services in Forsyth County***

As illustrated in response to Criterion 1 and above, the proposed project does not meet the demand for surgical services in Forsyth County. This is a result of the following:

- 1) The proposed mix of surgical services does not align with the needs of Forsyth County
- 2) The proposed location in Clemmons has more than adequate operating room access
- 3) The proposed payer mix results in reduced access for self-pay and Medicaid patients
- 4) There is not a current need for more ASCs in Forsyth County in total, and not in Clemmons specifically
- 5) The applicant does not have a need for more outpatient ORs to support the proposed service mix

***Illogical Methodology for Translating to Calendar Year that is Inconsistent with Form C Instructions***

In lieu of providing actual historic FY 2015, 2016, and 2017 surgical volume as instructed in Form C, the applicant chose to use the federal fiscal year information that is reported in the license renewal applications and then apply an illogical methodology to convert FFY 2017 data to CY 2017. The applicant applies a methodology to convert FFY 2017 volume to CY 2017 by 1) multiplying FFY 2017 volume by the projected annual growth rate, 3.4% and 2) adding one quarter of the product to the FFY 2017 total surgical cases to convert to CY 2017. This methodology essentially

<sup>1</sup> Excludes Piedmont Outpatient Surgical Center Cases



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inflates the CY 2017 by a hypothetical growth factor. The rationale provided by the applicant for applying this methodology is that the accounting period for Novant Health is a calendar year, and therefore the federal fiscal year information needed to be converted to a calendar year for the utilization projections. Instead of relying on this methodology, the applicant should have appropriately reported actual surgical utilization for the applicant’s past three fiscal years: CYs 2015, 2016, and 2017 as instructed in Form C.

**Overly Aggressive Projected Annual Growth Rate of Surgical Cases**

The applicant provides historical surgical data for FFY 2015 to FFY 2017 as reported in the hospital license renewal applications and calculates the CAGR for inpatient and outpatient surgical cases. The CAGR is 4.7% for inpatient cases and 2.9% for outpatient cases. The applicant uses the combined inpatient and outpatient CAGR of 3.4% to project future Novant Health surgical volumes. The applicant supports the use of the 3.4% growth rate by discussing the potential impact of new surgical recruits and continued ramp-up of recently recruited surgeons. However, the applicant does not provide specifics related to projected volumes of the planned incremental and ramping-up surgeons.

A closer look at the Novant Health historic volumes illustrates that the two-year CAGR of 3.4% is the derivative of just one year of positive growth – from FFY 2016 to FFY 2017. A few more years of Novant Health surgical history provides a more comprehensive picture of the peaks and valleys in Novant Health surgical volume. As illustrated by the historic surgical volumes, a very high positive annual change can be followed by a low annual change or a negative annual change (for example, outpatient volume grew 9.5% from FFY 2014 to 2015 and then 1.2% from FFY 2015 to 2016). A CAGR representing a longer time horizon normalizes these variations and provides a more realistic barometer for projecting future volumes. Illustrated in Table 3 below is NHFMC’s five-year CAGR from FFY 2012 to FFY 2017, which represents a total CAGR of 2.0%, with inpatient volume at 0.0% and outpatient at 2.9%.<sup>2</sup> If the more realistic CAGR of 2.0% were substituted in Novant’s volume methodology, the Novant Health CY 2024 OR need would decrease to 0.9 ORs. Reference Table 11. It is unreasonable for the applicant to assume that volume will grow steadily for eight years into the future based upon a positive CAGR that is driven by just one year of positive volume growth.

Table 9  
Novant Health Forsyth Medical Center & Novant Health Medical Park Hospital  
Inpatient and Outpatient Annual Surgical Volume, FFY 2015-2017

	Inpatient		Outpatient		Total	
	Cases	Annual % Δ	Cases	Annual % Δ	Cases	Annual % Δ
<b>FFY 2015</b>	10,416	-	26,058	-	36,464	-
<b>FFY 2016</b>	10,133	-2.7%	26,371	1.2%	36,504	0.1%
<b>FFY 2017</b>	11,426	12.8%	27,574	4.6%	39,000	6.8%
<b>2-YR CAGR (2015-2017)</b>		<b>4.7%</b>		<b>2.9%</b>		<b>3.4%</b>

Source: Section C, p. 17, NHCOS CON Application

<sup>2</sup> NHFMC recognized this historical slow growth from FFY 2012 to demonstrate that NHFMC Main would have adequate capacity following relocation of operating rooms to NHKOS and NHCOS in order to demonstrate conformity with Criterion 3a. See **Exhibit 1**, NHKOS Agency Findings, Project ID # G-11150-16, pp. 11-13 and **Exhibit 2**, NHCOS Agency Findings, Project ID # G-11300-17, pp. 15-17.

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Table 10

Novant Health Forsyth Medical Center & Novant Health Medical Park Hospital  
Inpatient and Outpatient Annual Surgical Volume, FFY 2012-2017

	Inpatient		Outpatient		Total	
	Cases	Annual % Δ	Cases	Annual % Δ	Cases	Annual % Δ
<b>FFY 2012</b>	11,447	-	23,927	-	35,374	-
<b>FFY 2013</b>	12,415	8.5%	23,045	-3.7%	35,460	0.2%
<b>FFY 2014</b>	12,983	4.6%	23,805	3.3%	36,788	3.7%
<b>FFY 2015</b>	10,416	-19.8%	26,058	9.5%	36,464	-0.9%
<b>FFY 2016</b>	10,133	-2.7%	26,371	1.2%	36,504	0.1%
<b>FFY 2017</b>	11,426	12.8%	27,574	4.6%	39,000	6.8%
<b>5-YR CAGR (2013-2017)</b>		<b>0.0%</b>		<b>2.9%</b>		<b>2.0%</b>

Source: License Renewal Applications

Table 11

Novant Health OR Need with 2.0% Growth Rate

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.1	-1.8	-1.5	-1.1	-0.8	-0.5	-0.1	0.2
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.3	-2.3	-2.2	-2.2	-2.1	-2.0	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	0.8	0.5	-0.7	-0.5	-0.3	-0.1	0.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.6	1.7	1.7	1.8	1.9
<b>Total</b>	<b>-5.5</b>	<b>-5.3</b>	<b>-4.4</b>	<b>-3.4</b>	<b>-2.6</b>	<b>-1.7</b>	<b>-0.9</b>	<b>0.0</b>	<b>0.9</b>

Furthermore, a closer look at the historic growth in the planned surgical services that that applicant intends to shift to NHCOS illustrates that there been no recent growth in these services. Table 7 above illustrates the historic FFY 2015 – FFY 2017 volume of NHOOS, which has declined by 19% or by a CAGR of 10%. In addition, Table 6 above illustrates recent NHMPH outpatient volumes of the services that are planned for NHCOS, based upon physician letters of support. Lastly, Table 12 below illustrates the past five years of historic outpatient volume at NHMPH for the services that are intended to shift to NHCOS, as well as in total. Table 13 below illustrates the past five years of historical volume of NHOOS. If the more reasonable projection of 0.1% were used to project utilization at NHOOS and NHMPH and the more reasonable 5-year CAGR of 2.0% were used to project volume at all other Novant Health facilities, Novant Health would have a projected 2024 surplus of 0.6 ORs. Reference Table 14.

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Table 12

NHMPH Historic OP Surgical Volume, Specialties Supported by NHCOS Letters of Support

	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017	5-Year CAGR
General	2,879	3,116	3,146	3,141	3,299	3,325	2.9%
Neurosurgery	168	170	134	47	65	72	-15.6%
OB and Gyn	412	518	501	518	522	463	2.4%
Orthopedics	1,565	1,453	1,590	1,573	1,320	1,336	-3.1%
Urology	2,124	2,128	2,108	1,985	2,046	1,971	-1.5%
Total	7,148	7,385	7,479	7,264	7,252	7,167	<b>0.1%</b>
<i>Annual Change</i>		3.3%	1.3%	-2.9%	-0.2%	-1.2%	
Grand Total NHMPH OP Surgeries	9,540	9,295	9,195	8,613	8,665	8,782	<b>-1.6%</b>
<i>Annual Change</i>		-2.6%	-1.1%	-6.3%	0.6%	1.4%	

Source: License Renewal Applications

Table 13

NHOOS Historic OP Surgical Volume

	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017	5-Year CAGR
NHOOS Total	2,789	2,686	2,460	2,491	2,191	2,013	<b>-6.3%</b>
<i>Annual Change</i>		-1.1%	-2.4%	0.3%	-3.5%	-2.1%	

Source: License Renewal Applications

Table 14

Novant Health OR Need with 0.1% Growth Applied to NHMPH and NHOOS and 2.0% Growth Applied to All Other Facilities

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.1	-1.8	-1.5	-1.1	-0.8	-0.5	-0.1	0.2
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.3	-2.3	-2.2	-2.2	-2.1	-2.0	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.5	0.6	0.2	-1.1	-1.1	-1.0	-1.0	-0.9
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.4	1.4	1.4	1.4	1.4
<b>Total</b>	<b>-5.5</b>	<b>-5.3</b>	<b>-4.6</b>	<b>-3.9</b>	<b>-3.2</b>	<b>-2.6</b>	<b>-1.9</b>	<b>-1.2</b>	<b>-0.6</b>

***Inaccurate Baseline Surgical Data***

The Novant Health surgical volume and utilization projections are developed by growing the FFY 2017 surgical volume reported on the license renewal applications and in the respective SMFPs, converted to Calendar Year 2017, and then growing at the two-year historic CAGR of 3.4%. This methodology provides inaccurate baseline data that impacts the future volume and utilization projections. These inaccuracies include:

- Lack of adjustment of baseline data to reflect provider loss
- Lack of recognition of the impact of the opening of Wake Forest Baptist Health – Outpatient Surgery Clemmons on outpatient gynecology surgery volumes at NHFMC

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Lack of Adjustment of Baseline Data to Reflect Provider Losses

Wake Forest Baptist Health (WFBH) recently recruited a high-volume Orthopaedic surgeon from OrthoCarolina. Dr. Frank Edward Pollock Jr operated solely at Novant Health facilities prior to his recruitment to Wake Forest Baptist in March of 2018. A review of the Truven market data illustrates that Dr. Frank Pollock accounted for 526 surgical encounters at Novant Health facilities during FFY 2017. As Dr. Pollock is now part of WFBH and will no longer operate at Novant Health facilities, the 526 Novant Health surgical encounters that he performed at Novant Health facilities should be removed from the FFY 2017 baseline. Reference Table 15 below.

All other factors being constant, removal of Dr. Pollock’s surgical encounters from the baseline year reduces the Novant Health OR need to 5.0 ORs by CY 2024. Reference Table 16 below.

Table 15  
FFY 2017 Surgical Volume at Novant Health Facilities  
Dr. Frank Pollock

Facility Name	Pollock, Frank E		Grand Total
	Inpatient	Outpatient	
Clemmons Med Ctr	-	1	1
Forsyth Med Ctr	198	318	516
Kernersville Med Ctr	-	1	1
Medical Park	-	8	8
<b>Grand Total</b>	<b>198</b>	<b>328</b>	<b>526</b>

Source: Truven

Table 16  
Novant Health OR Need with Reduction of 526 Surgeries to Account for Loss of Dr. Frank Pollock

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.6	-2.0	-1.5	-0.9	-0.3	0.3	0.9	1.5
<b>KMC</b>	-0.3	-0.3	-0.7	-1.0	-1.0	-0.9	-0.8	-0.7	-0.6
<b>CMC</b>	-3.7	-3.4	-2.3	-2.2	-2.1	-2.0	-1.9	-1.8	-1.7
<b>HOS</b>	1.4	1.5	1.7	1.9	2.1	2.3	2.5	2.7	2.9
<b>OOS</b>	-0.5	-0.5	-0.4	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	1.0	0.8	-0.3	0.0	0.4	0.7	1.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.6	1.7	1.9	2.0	2.1	2.3
<b>Total</b>	<b>-5.5</b>	<b>-5.7</b>	<b>-4.2</b>	<b>-2.7</b>	<b>-1.3</b>	<b>0.2</b>	<b>1.8</b>	<b>3.4</b>	<b>5.0</b>

Lack of recognition of the impact of the opening of WFBH-OSC on outpatient gynecology surgery volumes at NHFMC

The February 2018 opening of WFBH-OSC provides a convenient new surgical location for WFBH providers and patients. Historically, WFBH Obstetricians and Gynecologists have performed the majority of their surgeries at NHFMC. NCBH does not have a birthing program, and as such WFBH Obstetrician/Gynecologists provide delivery services at NHFMC and have spent a great majority of their hospital time at NHFMC. Typically providers opt to perform surgery at NHFMC as it is more convenient and less challenging to obtain dedicated block time as compared to operating at NCBH where OR capacity constraints create difficulties in attaining dedicated block time. However, the opening of WFBH-OSC provides a new, convenient ambulatory surgical location for providers and patients as well as a lower-cost alternative to hospital-based outpatient surgery. The new WFBH-OSC is located on the same physical grounds as the primary WFBH Obstetrics/Gynecology outpatient clinic. As evidenced in the letter of support for WFBH-OSC, Dr. Andrea Fernandez projected that up to 140 outpatient gynecologic surgeries would be performed at WFBH-OSC per year. Please see **Exhibit 3** for Dr. Fernandez’s letter of support. These projections

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hold true today, and the projected cases will shift from NHFMC, as it represents the primary surgical facility for WFBH OB/Gyn providers.

The reduction of the Novant Health FFY 2017 baseline volume by an additional 140 cases to account for this shift of WFBH Ob/Gyn providers to WFBH-OSC reduces the Novant Health OR need to 4.9 ORs by CY 2024. Reference Table 17 below.

Table 17

Novant Health OR Need with Reduction of Additional 140 Surgeries to Account for WFBH Provider Volume Shift

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.7	-2.1	-1.6	-1.0	-0.5	0.1	0.7	1.4
<b>KMC</b>	-0.3	-0.3	-0.7	-1.0	-1.0	-0.9	-0.8	-0.7	-0.6
<b>CMC</b>	-3.7	-3.4	-2.3	-2.2	-2.1	-2.0	-1.9	-1.8	-1.7
<b>HOS</b>	1.4	1.5	1.7	1.9	2.1	2.3	2.5	2.7	2.9
<b>OOS</b>	-0.5	-0.5	-0.4	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	1.0	0.8	-0.3	0.0	0.4	0.7	1.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.6	1.7	1.9	2.0	2.1	2.3
<b>Total</b>	-5.5	-5.8	-4.3	-2.8	-1.4	0.1	1.7	3.2	4.9

**Conclusion**

The applicant’s overly aggressive growth rate combined with the applicant’s failed omission of known provider losses and volume shifts to WFBH-OSC results in an unrealistic projection of utilization and OR need. Adjusting the growth rate applied to NHMPH and NHOOS volumes to the more reasonable 0.1% annual growth rate, adjusting the growth rate of the remaining Novant Health facilities to the reasonable 2.0% 5-year CAGR, and applying appropriate reductions in the FFY 2017 baseline volume to account for known provider losses and the shift of WFBH provider outpatient surgery volume to WFBH-OSC results in a CY 2024 OR surplus of 1.3 ORs. Alternatively, if the 2.0% growth rate is applied to all Novant Health facilities, there is still not a need for incremental Novant Health ORs in Forsyth County. This illustrates that with the use of reasonable projections, there is not a need for additional Novant Health ORs. Reference Tables 18 and 19 below.

Table 18

Novant Health OR Need with: 0.1% growth applied to NHOOS and NHMPH; 2.0% growth applied to all other Novant Health facilities; reduction in baseline volume of 666 cases to account for loss of Dr. Pollock and shift of WFBH OP gynecology cases

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.7	-2.4	-2.1	-1.8	-1.5	-1.1	-0.8	-0.4
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.4	-2.3	-2.3	-2.2	-2.1	-2.1	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.5	0.6	0.2	-1.1	-1.1	-1.0	-1.0	-0.9
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.4	1.4	1.4	1.4	1.4
<b>Total</b>	-5.5	-5.9	-5.3	-4.5	-3.9	-3.3	-2.6	-2.0	-1.3

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Table 9

Novant Health OR Need with: 2.0% growth rate and reduction in baseline volume of 666 cases to account for loss of Dr. Pollock and shift of WFBH OP gynecology cases

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.7	-2.4	-2.1	-1.8	-1.5	-1.1	-0.8	-0.4
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.4	-2.3	-2.3	-2.2	-2.1	-2.1	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	0.8	0.5	-0.7	-0.5	-0.3	-0.1	0.0
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.6	1.7	1.7	1.8	1.9
<b>Total</b>	<b>-5.5</b>	<b>-5.9</b>	<b>-5.0</b>	<b>-4.1</b>	<b>-3.3</b>	<b>-2.4</b>	<b>-1.6</b>	<b>-0.7</b>	<b>0.2</b>

**Access**

As addressed in comments regarding Criterion 1, the proposed project does not enhance access, particularly for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The project is expected to serve just 1.5% self-pay and 5.3% Medicaid patients. This is drastically different from the existing mix of surgical patients in Forsyth County and of the applicant’s own historic experience. The project will promote inequities in healthcare, not expand access. From a surgical specialty perspective, the project will only provide enhanced access to a limited scope of outpatient surgical services to the healthiest subset of the population. The 2018 MedPAC Report to Congress noted that, while there are approximately 3,500 Healthcare Common Procedure Coding System (HCPCS) codes covered in the ASC payment system, 75% of the ASC volume for Medicare beneficiaries was attributed to just 27 (less than 1%) of these codes in 2016. Furthermore, the 2018 MedPAC report noted that patients treated in ASCs differ than patients treated in hospitals in ways that intensify health care inequities. The report noted that *“there is evidence that patients treated in ambulatory surgical centers (ASCs) are different in several ways from those in hospital outpatient departments (HOPDs). Our analysis of Medicare claims from 2016 revealed that the following groups represented a smaller share of ASC patients compared with HOPD patients: Medicare beneficiaries who also have Medicaid coverage (dual eligibles), African Americans (who are more likely to be dually eligible), beneficiaries who are eligible for Medicare because of disability (under age 65), and beneficiaries who are age 85 or older”*.

**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.”**

As illustrated above in response to Criterion 3, the applicant overstates Novant Health’s need for incremental ORs in Forsyth County by using faulty assumptions in projecting future utilization of ORs. As such, the alternative of Maintaining the Status Quo represents the least costly and most effective alternative. Using reasonable and sound projections, Novant Health does not have a need for additional ORs and has more than adequate surgical capacity to meet current and future demand for surgical services.

**Criterion 5 – “Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”**

As discussed under Criterion 3 above, the NHCOS application’s utilization methodology is based on faulty assumptions because it overstates the expected growth rate in surgical cases and does not appropriately reduce baseline volumes for known provider losses. The financial projections in the application are based on those unreliable utilization

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projections, and therefore, the application is not based on a reasonable projection of costs and charges and fails to demonstrate financial feasibility under Criterion 5.

**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.”**

Because NHCOS's proposed utilization projections are unreliable and not supported as discussed above, the proposed project fails to demonstrate that it will not result in unnecessary duplication as required under Criterion 6.

**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:**

- ...
- 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;”**

As discussed under Criterion 1 above, the NHCOS application projects to serve a much smaller percentage of self pay and Medicaid patients than the Forsyth County facility outpatient surgery average. Consequently, the NHCOS application does not adequately demonstrate that the medically underserved will be served by its proposed service. Therefore, the application is non-conforming to Criterion 13(c).

**Criterion (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.”**

As discussed above, the NHCOS application fails to demonstrate that the proposal will have a positive impact upon the cost effectiveness, quality, and access to the services proposed. NHCOS has failed to demonstrate a need for its proposal, and will not improve access to residents of Forsyth County in need of surgical services. Its revenue projections are overstated, and the project will not be cost effective. Therefore, the project is non-conforming with Criterion 18a.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

**(a) 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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.**

As discussed under Criterion 3 above, the NHCOS application utilization projections are unreasonable, and therefore the application fails to demonstrate a need for the number of proposed operating rooms and is non-conforming with this rule.

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

Because the assumptions upon which the NHCOS application projects utilization are overly aggressive and overstated, the application is non-conforming with this rule.



**WAKE FOREST BAPTIST HEALTH COMMENTS**

**REGARDING FORSYTH MEMORIAL HOSPITAL, INC.**  
**D/B/A NOVANT HEALTH FORSYTH MEMORIAL**  
**HOSPITAL APPLICATION**

**G-11517-18**

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING FORSYTH MEMORIAL HOSPITAL, INC. D/B/A NOVANT HEALTH FORSYTH MEMORIAL HOSPITAL APPLICATION, G-11517-18**

**Criterion 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.”**

Policy GEN-3 Basic Principles states: “A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The Novant Health Forsyth Medical Center (NHFMC) application for two additional ORs at Novant Health Forsyth Medical Center Main (NHFMC-Main) does not conform to Criterion 1 as it does not adequately demonstrate that the project will maximize healthcare value for resources expended.

*Value*

The proposed project will not maximize value for healthcare resources expended as the project involves an expansion of existing resources that are not fully utilized. Following the SMFP operating room need determination methodology, Novant Health surgical facilities in Forsyth County have a current surplus of 8.3 operating rooms with a 2020 projected surplus of 6.81 ORs. Converted to a utilization rate, the Novant Health ORs in Forsyth County are utilized at 18.4% below capacity with the Novant Health Forsyth Medical Center ORs utilized at 14.6% below capacity. By comparison, the operating rooms at North Carolina Baptist Hospital (NCBH) are utilized at 10.3% above capacity, have a current deficit of 4.7 ORs and a projected 2020 deficit of 6.65 ORs. Development of the proposed two NHFMC-Main ORs will not maximize healthcare value for resources expended as their development is unnecessary and represents an imprudent expenditure of resources.

Table 1  
Utilization of Forsyth County ORs

Facility	IP Surgical Cases	OP Surgical Cases	Total Adjusted Estimated Surgical Hours	OR Need	OR Supply	OR Surplus / Deficit (Surplus is "-")	OR Utilization
NHCOS	0	0	0	0.0	2	-2.0	0.0%
NHKOS	0	0	0	0.0	2	-2.0	0.0%
NHFMC	9,262	17,706	51,607	26.5	31	-4.5	85.4%
NHMPH	871	8,665	17,994	10.3	10	0.3	102.5%
<b>Novant Health</b>	<b>10,133</b>	<b>26,371</b>	<b>69,601</b>	<b>36.7</b>	<b>45</b>	<b>-8.3</b>	<b>81.6%</b>
WFBH-OSC	0	0	0	0.0	0	0.0	NA
PSCNC	0	169	507	0.4	3	-2.6	12.9%
NCBH	14,534	19,925	96,823	49.7	45	4.7	110.3%
<b>WFBMC</b>	<b>14,534</b>	<b>20,094</b>	<b>97,330</b>	<b>50.0</b>	<b>48</b>	<b>2.0</b>	<b>104.2%</b>
POSC*	0	2,514	1,927	1.5	2	-0.5	73.4%

Source: 2018 NC SMFP

\*Single Specialty Demonstration Project

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING FORSYTH MEMORIAL HOSPITAL, INC. D/B/A NOVANT HEALTH FORSYTH MEMORIAL HOSPITAL APPLICATION, G-11517-18**

**Criterion (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.”**

The applicant does not conform to Criterion 3 as it does not adequately demonstrate the need that this population has for the services proposed.

**Demonstration of Need**

The applicant does not adequately demonstrate the need that this population has for the services proposed as the applicant relies on the usage of faulty assumptions in the development of projected volumes and utilization of the Novant Health operating rooms. The key elements of these faulty assumptions include:

- Illogical Methodology for Translating to Calendar Year that is Inconsistent with Form C Instructions
- Overly Aggressive Projected Annual Growth Rate of Surgical Cases
- Inaccurate Baseline Surgical Data

***Illogical Methodology for Translating to Calendar Year that is Inconsistent with Form C Instructions***

In lieu of providing actual historic FY 2015, 2016, and 2017 surgical volume as instructed in Form C, the applicant chose to use the federal fiscal year information that is reported in the license renewal applications and then apply an illogical methodology to convert FFY 2017 data to CY 2017. The applicant applies a methodology to convert FFY 2017 volume to CY 2017 by 1) multiplying FFY 2017 volume by the projected annual growth rate, 3.4% and 2) adding one quarter of the product to the FFY 2017 total surgical cases to convert to CY 2017. This methodology essentially inflates the CY 2017 by a hypothetical growth factor. The rationale provided by the applicant for applying this methodology is that the accounting period for Novant Health is a calendar year, and therefore the federal fiscal year information needed to be converted to a calendar year for the utilization projections. Instead of relying on this methodology, the applicant should have appropriately reported actual surgical utilization for the applicant’s past three fiscal years: CYs 2015, 2016, and 2017 as instructed in Form C.

***Overly Aggressive Projected Annual Growth Rate of Surgical Cases***

The applicant provides historical surgical data for FFY 2015 to FFY 2017 as reported in the hospital license renewal applications and calculates the CAGR for inpatient and outpatient surgical cases. The CAGR is 4.7% for inpatient cases and 2.9% for outpatient cases. The applicant uses the combined inpatient and outpatient CAGR of 3.4% to project future Novant Health surgical volumes. The applicant supports the use of the 3.4% growth rate by discussing the potential impact of new surgical recruits and continued ramp-up of recently recruited surgeons. However, the applicant does not provide specifics related to projected volumes of the planned incremental and ramping-up surgeons. A closer look at the Novant Health historic volumes illustrates that the two-year CAGR of 3.4% is the derivative of just one year of positive growth – from FFY 2016 to FFY 2017. It is unreasonable for the applicant to assume that volume will grow steadily for eight years into the future based upon a positive CAGR that is driven by just one year of positive volume growth. Reference Table 2 below.

A few more years of Novant Health surgical history provides a more comprehensive picture of the peaks and valleys in Novant Health surgical volume. As illustrated by the historic surgical volumes, a very high positive annual change can be followed by a low annual change or a negative annual change (for example, outpatient volume grew 9.5% from FFY 2014 to 2015 and then 1.2% from FFY 2015 to 2016). A CAGR representing a longer time horizon normalizes these variations and provides a more realistic barometer for projecting future volumes. Illustrated in Table 3 below is NHFMC’s five-year CAGR from FFY 2012 to FFY 2017, which represents a total CAGR of 2.0%, with

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inpatient volume at 0.0% and outpatient at 2.9%.<sup>3</sup> If the more realistic CAGR of 2.0% were substituted in Novant’s volume methodology, the Novant Health CY 2024 OR need would decrease to 0.9 ORs with the need at FMC Main decreasing to 0.2 ORs. Reference Table 4.

Table 2  
Novant Health Forsyth Medical Center & Novant Health Medical Park Hospital  
Inpatient and Outpatient Annual Surgical Volume, FFY 2015-2017

	Inpatient		Outpatient		Total	
	Cases	Annual % Δ	Cases	Annual % Δ	Cases	Annual % Δ
<b>FFY 2015</b>	10,416	-	26,058	-	36,464	-
<b>FFY 2016</b>	10,133	-2.7%	26,371	1.2%	36,504	0.1%
<b>FFY 2017</b>	11,426	12.8%	27,574	4.6%	39,000	6.8%
<b>2-YR CAGR (2015-2017)</b>		<b>4.7%</b>		<b>2.9%</b>		<b>3.4%</b>

Source: Section C, p. 20, NHFMC CON Application

Table 3  
Novant Health Forsyth Medical Center & Novant Health Medical Park Hospital  
Inpatient and Outpatient Annual Surgical Volume, FFY 2012-2017

	Inpatient		Outpatient		Total	
	Cases	Annual % Δ	Cases	Annual % Δ	Cases	Annual % Δ
<b>FFY 2012</b>	11,447	-	23,927	-	35,374	-
<b>FFY 2013</b>	12,415	8.5%	23,045	-3.7%	35,460	0.2%
<b>FFY 2014</b>	12,983	4.6%	23,805	3.3%	36,788	3.7%
<b>FFY 2015</b>	10,416	-19.8%	26,058	9.5%	36,464	-0.9%
<b>FFY 2016</b>	10,133	-2.7%	26,371	1.2%	36,504	0.1%
<b>FFY 2017</b>	11,426	12.8%	27,574	4.6%	39,000	6.8%
<b>5-YR CAGR (2013-2017)</b>		<b>0.0%</b>		<b>2.9%</b>		<b>2.0%</b>

Source: License Renewal Applications

Table 4  
Novant Health OR Need with 2.0% Growth Rate

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.1	-1.8	-1.5	-1.1	-0.8	-0.5	-0.1	0.2
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.3	-2.3	-2.2	-2.2	-2.1	-2.0	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	0.8	0.5	-0.7	-0.5	-0.3	-0.1	0.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.6	1.7	1.7	1.8	1.9
<b>Total</b>	<b>-5.5</b>	<b>-5.3</b>	<b>-4.4</b>	<b>-3.4</b>	<b>-2.6</b>	<b>-1.7</b>	<b>-0.9</b>	<b>0.0</b>	<b>0.9</b>

**Inaccurate Baseline Surgical Data**

The Novant Health surgical volume and utilization projections are developed by growing the FFY 2017 surgical volume reported on the license renewal applications and in the respective SMFPs, converted to Calendar Year 2017,

<sup>3</sup> NHFMC recognized this historical slow growth from FFY 2012 to demonstrate that NHFMC Main would have adequate capacity following relocation of operating rooms to NHKOS and NHCOS in order to demonstrate conformity with Criterion 3a. See Exhibit 1, NHKOS Agency Findings, Project ID # G-11150-16, pp. 11-13 and Exhibit 2, NHCOS Agency Findings, Project ID # G-11300-17, pp. 15-17.

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and then growing at the two-year historic CAGR of 3.4%. This methodology provides inaccurate baseline data that impacts the future volume and utilization projections. These inaccuracies include:

- Lack of adjustment of baseline data to reflect provider losses
- Lack of recognition of the impact of the opening of Wake Forest Baptist Health – Outpatient Surgery Clemmons on outpatient gynecology surgery volumes at NHFMC

Lack of Adjustment of Baseline Data to Reflect Provider Losses

Wake Forest Baptist Health (WFBH) recently recruited a high-volume Orthopaedic surgeon from OrthoCarolina. Dr. Frank Edward Pollock Jr operated solely at Novant Health facilities prior to his recruitment to Wake Forest Baptist in March of 2018. A review of the Truven market data illustrates that Dr. Frank Pollock accounted for 526 surgical encounters at Novant Health facilities during FFY 2017. As Dr. Pollock is now part of WFBH and will no longer operate at Novant Health facilities, the 526 Novant Health surgical encounters that he performed at Novant Health facilities should be removed from the FFY 2017 baseline. Reference Table 5 below.

All other factors being constant, removal of Dr. Pollock’s surgical encounters from the baseline year reduces the Novant Health OR need to 5.0 ORs by CY 2024. Reference Table 6 below.

Table 5  
FFY 2017 Surgical Volume at Novant Health Facilities  
Dr. Frank Pollock

Facility Name	Pollock, Frank E		Grand Total
	Inpatient	Outpatient	
Clemmons Med Ctr	-	1	1
Forsyth Med Ctr	198	318	516
Kernersville Med Ctr	-	1	1
Medical Park	-	8	8
<b>Grand Total</b>	<b>198</b>	<b>328</b>	<b>526</b>

Source: Truven

Table 6  
Novant Health OR Need with Reduction of 526 Surgeries to Account for Loss of Dr. Frank Pollock

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.6	-2.0	-1.5	-0.9	-0.3	0.3	0.9	1.5
<b>KMC</b>	-0.3	-0.3	-0.7	-1.0	-1.0	-0.9	-0.8	-0.7	-0.6
<b>CMC</b>	-3.7	-3.4	-2.3	-2.2	-2.1	-2.0	-1.9	-1.8	-1.7
<b>HOS</b>	1.4	1.5	1.7	1.9	2.1	2.3	2.5	2.7	2.9
<b>OOS</b>	-0.5	-0.5	-0.4	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	1.0	0.8	-0.3	0.0	0.4	0.7	1.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.6	1.7	1.9	2.0	2.1	2.3
<b>Total</b>	<b>-5.5</b>	<b>-5.7</b>	<b>-4.2</b>	<b>-2.7</b>	<b>-1.3</b>	<b>0.2</b>	<b>1.8</b>	<b>3.4</b>	<b>5.0</b>

Lack of recognition of the impact of the opening of WFBH-OSC on outpatient gynecology surgery volumes at NHFMC

The February 2018 opening of WFBH-OSC provides a convenient new surgical location for WFBH providers and patients. Historically, WFBH Obstetricians and Gynecologists have performed the majority of their surgeries at NHFMC. NCBH does not have a birthing program, and as such WFBH Obstetrician/Gynecologists provide delivery services at NHFMC and have spent a great majority of their hospital time at NHFMC. Typically providers opt to

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perform surgery at NHFMC as it is more convenient and less challenging to obtain dedicated block time as compared to operating at NCBH where OR capacity constraints create difficulties in attaining dedicated block time. However, the opening of WFBH-OSC provides a new, convenient ambulatory surgical location for providers and patients as well as a lower-cost alternative to hospital-based outpatient surgery. The new WFBH-OSC is located on the same physical grounds as the primary WFBH Obstetrics/Gynecology outpatient clinic. As evidenced in the letter of support of the Wake Forest Ambulatory Ventures, LLC CON application to develop WFBH-OSC (Project ID # G-8608-10), Dr. Andrea Fernandez projected that up to 140 outpatient gynecologic surgeries would be performed at WFBH-OSC per year. Please see **Exhibit 3** for Dr. Fernandez’s letter of support. These projections hold true today, and the projected cases will shift from NHFMC, as it represents the primary surgical facility for WFBH OB/Gyn providers.

The reduction of the Novant Health FFY 2017 baseline volume by an additional 140 cases to account for this shift of WFBH Ob/Gyn providers to WFBH-OSC reduces the Novant Health OR need to 4.9 ORs by CY 2024. Reference Table 7 below.

Table 7

Novant Health OR Need with Reduction of Additional 140 Surgeries to Account for WFBH Provider Volume Shift

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.7	-2.1	-1.6	-1.0	-0.5	0.1	0.7	1.4
<b>KMC</b>	-0.3	-0.3	-0.7	-1.0	-1.0	-0.9	-0.8	-0.7	-0.6
<b>CMC</b>	-3.7	-3.4	-2.3	-2.2	-2.1	-2.0	-1.9	-1.8	-1.7
<b>HOS</b>	1.4	1.5	1.7	1.9	2.1	2.3	2.5	2.7	2.9
<b>OOS</b>	-0.5	-0.5	-0.4	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	1.0	0.8	-0.3	0.0	0.4	0.7	1.1
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.6	1.7	1.9	2.0	2.1	2.3
<b>Total</b>	-5.5	-5.8	-4.3	-2.8	-1.4	0.1	1.7	3.2	4.9

**Conclusion**

The applicant’s overly aggressive growth rate combined with the applicant’s failed omission of known provider losses and likely volume shifts to WFBH-OSC results in an unrealistic projection of utilization and OR need. Adjusting the CAGR to the more reasonable 2.0% annual growth rate coupled with appropriate reductions in the FFY 2017 baseline volume to account for known provider losses and the likely shift of 50% of WFBH provider outpatient surgery volume to WFBH-OSC results in a CY 2024 OR need of 0.2 ORs with a surplus of 0.5 OR at NHFMC Main. This illustrates that with the use of reasonable projections, there is not a need for additional Novant Health ORs. Reference Table 8 and 9 below.

Table 8

Novant Health OR Need with 2% Annual Growth and Reduction of 670 Surgeries to Account for Loss of Drs. Frank and David Pollock and WFBH Provider Volume Shift

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.8	-2.4	-2.1	-1.8	-1.5	-1.1	-0.8	-0.5
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.4	-2.3	-2.3	-2.2	-2.1	-2.1	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	0.8	0.5	-0.7	-0.5	-0.3	-0.1	0.0
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.6	1.7	1.7	1.8	1.9
<b>Total</b>	-5.5	-5.9	-5.1	-4.1	-3.3	-2.4	-1.6	-0.7	0.2

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING FORSYTH MEMORIAL HOSPITAL, INC. D/B/A NOVANT HEALTH FORSYTH MEMORIAL HOSPITAL APPLICATION, G-11517-18**

Table 9

Novant Health OR Need with 2% Annual Growth and Reduction of 550 Surgeries to Account for Loss of Drs. Frank and David Pollock

	FFY 2017	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
<b>FMC Main</b>	-2.9	-3.7	-2.3	-2.0	-1.7	-1.4	-1.0	-0.7	-0.4
<b>KMC</b>	-0.3	-0.3	-0.7	-1.1	-1.2	-1.2	-1.1	-1.1	-1.0
<b>CMC</b>	-3.7	-3.4	-2.4	-2.3	-2.3	-2.2	-2.1	-2.1	-2.0
<b>HOS</b>	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.3
<b>OOS</b>	-0.5	-0.5	-0.5	0.8	0.0	0.0	0.0	0.0	0.0
<b>MPH</b>	0.5	0.6	0.8	0.5	-0.7	-0.5	-0.3	-0.1	0.0
<b>KOS</b>	0.0	0.0	-1.4	-0.9	-0.8	-0.6	-0.6	-0.6	-0.5
<b>COS</b>	0.0	0.0	0.0	-0.7	1.6	1.7	1.7	1.8	1.9
<b>Total</b>	-5.5	-5.8	-5.0	-4.0	-3.2	-2.3	-1.5	-0.6	0.3

**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.”**

As illustrated above in response to Criterion 3, the applicant overstates Novant Health’s need for incremental ORs in Forsyth County by using faculty assumptions in projecting future utilization of ORs. As such, the alternative of Maintaining the Status Quo represents the least costly and most effective alternative. Using reasonable and sound projections, Novant Health does not have a need for additional ORs and has more than adequate surgical capacity to meet current and future demand for surgical services.

**Criterion 5 – “Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”**

As discussed under Criterion 3 above, the NHFMC application’s utilization methodology is based on faulty assumptions because it overstates the expected growth rate in surgical cases and does not appropriately reduce baseline volumes for known provider losses. The financial projections in the application are based on those unreliable utilization projections, and therefore, the application is not based on a reasonable projection of costs and charges and fails to demonstrate financial feasibility under Criterion 5.

**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.”**

Because NHFMC's proposed utilization projections are unreliable and not supported as discussed above, the proposed project fails to demonstrate that it will not result in unnecessary duplication as required under Criterion 6.

**Criterion (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.”**

As discussed above, the NHFMC application fails to demonstrate that the proposal will have a positive impact upon the cost effectiveness, quality, and access to the services proposed. NHFMC has failed to demonstrate a need for its proposal, and will not improve access to residents of Forsyth County in need of surgical services. Its revenue projections are overstated, and the project will not be cost effective. Therefore, the project is non-conforming with Criterion 18a.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

***(a) 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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.***

As discussed under Criterion 3 above, the NHFMC application utilization projections are unreasonable, and therefore the application fails to demonstrate a need for the number of proposed operating rooms and is non-conforming with this rule.

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

Because the assumptions upon which the NHFMC application projects utilization are overly aggressive and overstated, the application is non-conforming with this rule.



**WAKE FOREST BAPTIST HEALTH COMMENTS**

**REGARDING THE MOSES H. CONE MEMORIAL  
HOSPITAL APPLICATION, TRIAD SURGERY CENTER**

**G-11516-18**

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING THE MOSES H. CONE MEMORIAL HOSPITAL APPLICATION, TRIAD SURGERY CENTER, G-11516-18**

**Criterion 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.”**

Policy GEN-3 Basic Principles states: “A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The Triad Surgery Center (TSC-CONE) application does not conform to Criterion 1 as it does not adequately demonstrate that the project will promote equitable access and maximize healthcare value for resources expended. In fact, the applicant discourages equitable access through the planned development of a surgery center in area that the applicant describes as having “considerably higher income, lower poverty rates...” than the county as a whole. Healthcare value is not promoted as the project represents a duplication of existing and planned healthcare resources in Kernersville and in Guilford County.

*Equitable Access*

The proposed project will not promote equitable access in the delivery of health care services. In fact, the proposed project will exacerbate inequities that exist in health care service delivery. As evidenced by the payer mix projections on page 87 in Section L of the application, the proposed project is projected to serve just 0.2% self-pay patients overall, with the operating room component of the project projected to serve 0.3% self-pay patients. Furthermore, the project is projected to serve just 0.9% Medicaid patients overall with operating room portion projected to serve 1.0% Medicaid patients. In comparison, the total self-pay surgical cases in Forsyth County surgical facilities during FFY 2017 (as reported in the 2018 hospital and ambulatory surgery center license renewal applications) was 4.7% for inpatient cases and 3.9% self-pay patients for outpatient cases. The percent of Medicaid patients was 14.4% for inpatient cases and 13.7% for outpatient cases. The project is projecting to serve 92% fewer self-pay patients, 93% fewer Medicaid patients, and 55% greater managed care patients that are currently being served by the existing surgical facilities in Forsyth County.

**Table 1  
Forsyth County Facility FFY 2017 Surgical Payer Mix**

Payer Source	Forsyth County Surgical Payer Mix		Projected Payer Mix of Project (OR Only)	% Difference in Payer Mix (Proposed - Forsyth County / Forsyth County)
	IP	OP		
Self-Pay	4.7%	3.9%	0.3%	-92.3%
Medicare	46.0%	37.1%	31.1%	-16.2%
Medicaid	14.4%	13.7%	1.0%	-92.7%
Managed Care / Commercial	30.3%	41.4%	64.1%	54.8%
Other	4.6%	3.8%	3.5%	-7.9%

*Data Source: 2018 hospital and ambulatory surgery center license renewal applications*

**WAKE FOREST BAPTIST HEALTH COMMENTS REGARDING THE MOSES H. CONE MEMORIAL HOSPITAL APPLICATION, TRIAD SURGERY CENTER, G-11516-18**

*Value*

The proposed project will not maximize value for healthcare resources expended as it represents a duplication of services. Novant Health has CON approval for the development of a separately licensed ASC in Kernersville that will include two licensed ORs. This facility is projected to be complete in July of 2018 and anticipated to perform 2,226 surgical cases by its third project year. Novant Health Kernersville Outpatient Surgery (NHKOS) will serve the same primary market as TSC-CONE plans to serve.

It is important to note that both NHKOS and TSC-CONE include zip code 27265 in their markets. Zip code 27265 is located in the city of High Point in Guilford County. The city of High Point has more than adequate access to hospital and ambulatory surgery center operating rooms through High Point Regional Health (HPRH) with 11 ORs and 68% utilization, High Point Surgery Center (HPSC) with six ORs and 53% utilization, and Premier Surgery Center (PSC) with two ORs and 0% utilization. There is a total excess capacity of eight ORs in High Point, five of which are in ambulatory surgery centers. Instead of duplicating existing and planned ambulatory surgery centers in Kernersville and High Point, the applicant should coordinate with existing providers to maximize the utilization of the existing and planned facilities in High Point and Kernersville in order to maximize value by maximizing the utilization of existing and planned health care resources.

Table 2  
High Point ORs and OR Utilization

Facility Name	# ORs* a	Total Surgical Hours b	Standard Hours per OR c	% Utilization (b / (a*c)) d	OR Need (b / c) e	Excess Capacity (a-c)
HPRH	10	10,168	1500	68%	6.8	3.2
HPSC	6	4,211	1312.5	53%	3.2	2.8
PSC**	2	0	0	0%	0.0	2.0

Data Source: 2018 SMFP Tables 6A and 6B

\*HPRH inventory excludes one dedicated c-section OR

\*\*Chronically underutilized facility

**Criterion (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.”**

The applicant does not conform to Criterion 3 as it does not adequately demonstrate the need that this population has for the services proposed and does not adequately demonstrate the extent to which all residents of the area, particularly 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.

**Demonstration of Need**

The applicant does not adequately demonstrate the need that this population has for the services proposed due to the following reasons:

- There is not a current need for additional ASCs in Forsyth County / Kernersville
- There is not a need for a Cone Health ASC in Forsyth County
- The proposed service does not meet the demand for surgical services in Forsyth County
- The utilization methodology is based on faulty assumptions

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***Not a Current Need for Additional ASCs in Forsyth County / Kernersville***

Demand for Ambulatory Surgical Services is not driving the OR Need in Forsyth County

The applicant discusses the shift to outpatient services that has been impacting the healthcare industry during the past 30 years as part of the rationale for the need for an ASC in Kernersville. The applicant reviews NC statewide surgical volume trends, pointing to a statewide CAGR of 1.5% in outpatient surgeries compared to 1.0% in inpatient surgeries from FFY 2014 to FFY 2016. The applicant also reviews surgical volumes trends in Forsyth County and illustrates a CAGR of -3.1% inpatient surgeries compared to 3.5% in outpatient surgeries. Although these data points are in fact accurate, they are also misleading. The shift to outpatient services in health care is undisputable, however the need for the ORs in Forsyth County cannot be attributed to this shift to outpatient and cannot be met by more outpatient/ambulatory ORs. If the surgical data is reviewed more closely, it is clear that the need for ORs in Forsyth County was driven by utilization North Carolina Baptist Hospital (NCBH). It is also quite evident by this closer review that growth in inpatient surgical volume has outpaced growth in outpatient surgical volume at NCBH. As such, meeting the need for ORs in Forsyth County requires an applicant to offer both inpatient and outpatient surgical services.

From a statewide perspective, the facilities with the greatest OR deficits are North Carolina’s Academic Medical Centers (AMCs). In three of the four OR Service Areas with an AMC and a need determination for ORs in the 2018 SMFP (Durham, Forsyth, Mecklenburg, and Orange), the AMCs experienced greater inpatient surgical growth as compared to outpatient. The only exception to this is Duke University Hospital in Durham, whose inpatient growth (0.7%) was essentially equivalent to its outpatient growth (0.8%). This further supports that fact that the need for additional ORs in not only Forsyth County, but the state as a whole, must involve the development of both inpatient and outpatient surgical services to truly meet the demand that is driving the need.

Table 3  
Surgical Growth, Inpatient v Outpatient  
Counties with a Need Determination, Facilities within each County with a Deficit

	OR Deficit	Inpatient				Outpatient			
		FFY 2014	FFY 2015	FFY 2016	CAGR	FFY 2014	FFY 2015	FFY 2016	CAGR
<i>Buncombe</i>									
Orthopaedic Surgery Center of Asheville	0.50	0	0	0	NA	3,201	3,138	3,016	-2.9%
Asheville Eye Surgery Center	0.60	0	0	0	NA	3,931	4,074	4,648	8.7%
<i>Durham</i>									
Duke University Hospital	5.77	16,920	17,344	17,151	0.7%	22,292	23,728	22,642	0.8%
NC Specialty Hospital	2.59	1,685	1,597	1,629	-1.7%	3,583	3,737	3,606	0.3%
<i>Forsyth</i>									
<b>North Carolina Baptist Hospital</b>	<b>6.65</b>	<b>13,944</b>	<b>14,214</b>	<b>14,534</b>	<b>2.1%</b>	<b>19,749</b>	<b>19,549</b>	<b>19,925</b>	<b>0.4%</b>
<i>Mecklenburg</i>									
<b>Carolinas Medical Center</b>	<b>16.57</b>	<b>19,414</b>	<b>21,242</b>	<b>21,215</b>	<b>4.5%</b>	<b>21,074</b>	<b>21,593</b>	<b>22,756</b>	<b>3.9%</b>
CHS – University	0.99	1,067	1,019	846	-11.0%	7,036	6,854	6,513	-3.8%
<i>Orange</i>									
<b>UNC Hospitals</b>	<b>6.48</b>	<b>12,139</b>	<b>12,845</b>	<b>13,529</b>	<b>5.6%</b>	<b>16,547</b>	<b>16,960</b>	<b>15,736</b>	<b>-2.5%</b>
<i>Wake</i>									
Duke Raleigh Hospital	6.77	3,586	3616	4,389	10.6%	9,132	9,875	10,855	9.0%

Source: 2016-2018 SMFPs

Forsyth County will be transitioning from a county with zero multispecialty freestanding ASCs to a county with three multispecialty freestanding ASCs by June 2019. Wake Forest Baptist Health – Outpatient Surgery Clemmons (WFBH-OSC) is a multispecialty ASC with three licensed ORs that opened in February 2018; Novant Health Kernersville Outpatient Surgery (NHKOS) is a planned ASC for Kernersville with two licensed ORs and a planned opening of July 2018; Novant Health Clemmons Outpatient Surgery (NHCOS) is a planned ASC for Clemmons with

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two licensed ORs and a planned opening for June 2019. In total, these new ASCs will provide access to seven new freestanding ASC ORs in Forsyth County with a surgical capacity of 8,352 cases or 18% of all outpatient surgical cases in the Forsyth County OR Service Area<sup>4</sup>.

Growth and Aging of the Population is not Driving the need for an ASC in Forsyth County

The applicant points to the projected population growth and aging of the population in Forsyth County as rationale for a need for an ASC in Forsyth County. The applicant notes that the population ages 65+ is projected to grow at a CAGR of 3.1% while the population ages 0-64 is projected to grow at a CAGR of 1.0%. While it is true that persons over age 65 tend to be higher utilizers of health care services, there is no data provided to support that persons over age 65 have a higher demand and utilization of ambulatory surgical center services or that they need more access to ASCs. To the contrary, the 2018 MedPAC Report to Congress on Medicare Payment Policy noted that “increases in the number of facilities and fairly stable volume of services provided to Medicare beneficiaries suggest that beneficiaries have adequate access to care in ASCs”. The report continues to state that the volume of services per FFS beneficiary declined by 0.5% from 2015 to 2016. This compares to an average annual growth of 0.7% per from 2011 to 2015.

There is not a Need for Additional ASC Capacity in Forsyth County and Kernersville

To support the need for an ASC in Kernersville, the applicant provides data points on the number of ORs per 10,000 population in Kernersville, Clemmons, and Winston-Salem as well as OR need based on the distribution of the population. Based on this data, the applicant argues that Kernersville is underserved in compared to the other parts of the County. This information is misleading as the ORs in Forsyth County, particularly the ORs in Winston-Salem, service a much broader geography than their home County or zip codes. Adjusting the OR inventory in each market area, as defined by the applicant, by the percentage of surgical services provided to patients from Forsyth County illustrates that Kernersville has more ORs per 10,000 than Clemmons and Winston-Salem.

Table 4  
Adjusted OR Inventory for Percentage of Patients Served from Forsyth County

	Total ORs	% Forsyth County Patients	Adjusted Inventory
<i>Kernersville</i>			
Novant Health Kernersville Medical Center (NHKMC)	4	54.4% <sup>1</sup>	2.2
NHKOS	2	64.9% <sup>2</sup>	1.3
<b>Total</b>	<b>6</b>		<b>3.5</b>
<i>Clemmons</i>			
WFBH-OSC	3	31.2% <sup>3</sup>	0.9
Novant Health Clemmons Medical Center (NHCMC)	5	54.4% <sup>4</sup>	2.7
NHCOS	2	54.2% <sup>5</sup>	1.1
<b>Total</b>	<b>10</b>		<b>4.7</b>
<i>Winston-Salem</i>			
Novant Health Forsyth Medical Center (NHFMC)	22	54.4% <sup>6</sup>	12.0
Novant Health Medical Park Hospital (NHMPH)	10	52.1% <sup>7</sup>	5.2
NCBH	45	26.8% <sup>8</sup>	12.0
Piedmont Outpatient Surgery Center (POSC)	2	41.7% <sup>9</sup>	0.8
<b>Total</b>	<b>79</b>		<b>30.0</b>
<b>Grand Total</b>	<b>95</b>		<b>38.3</b>

<sup>4</sup> Excludes Piedmont Outpatient Surgical Center Cases

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- 1: Based on NHFMC Total Surgical Patient Origin Data from the 2018 LRA
- 2: Based on the proposed patient origin from the NHKOS CON application
- 3: Based on the patient origin in the NCBH CON application for four incremental ORs
- 4: Based on NHFMC Total Surgical Patient Origin Data from the 2018 LRA
- 5: Based on the proposed patient origin from the NHCOS CON application
- 6: Based on NHFMC Total Surgical Patient Origin Data from the 2018 LRA
- 7: Based on NHMPH Total Surgical Patient Origin Data from the 2018 LRA
- 8: Based on NCBH Total Surgical Patient Origin Data from the 2018 LRA
- 9: Based on POSC Total Surgical Patient Origin Data from the 2018 LRA

Table 5  
 ORs per 10,000 Population by Market Area  
 Adjusted to Account for Services to Patients Outside of Forsyth County

	2017 Population	Total ORs	Adjusted OR Inventory*	ORs per 10,000 Population
Kernersville	65,426	6	4	1.64
Clemmons	40,577	10	5	0.81
Winston-Salem	292,151	79	30	0.91

\*Totals from Table 4

**Need for a Cone Health ASC in Forsyth County:**

One of the reasons offered as demonstration of the need for the proposed ASC is the need for a Cone Health ASC to support the Triad Health Network (THN). Cone Health primarily serves residents of Guilford, Rockingham, Randolph, and Alamance Counties. Similarly, THN providers are primarily located within these counties (reference the THN website: <https://www.triadhealthcarenetwork.com/about-us/aco-information/>). During FFY 2017, 90% of surgical services provided at Moses Cone Hospital were to residents of Guilford (64%), Rockingham (13%), Randolph (8%), and Alamance (4%) Counties. Only 3% of Moses Cone Hospital’s total surgical services were provided to residents of Forsyth County<sup>5</sup>. As such, the need for an ambulatory surgery center to support THN would be best to be located within the counties primarily served by both THN and Cone Health and not in Forsyth County, which comprises only 3% of Moses Cone’s surgical volume.

Cone’s historical utilization also does not support the assumption that its referring physicians and surgeons have a need for more outpatient operating rooms. According to SMFP data utilizing Cone’s own License Renewal Applications, the number of outpatient surgeries performed at Cone Health has been essentially flat for the past five years, as shown in Table 6 below.

Table 6  
 Cone Health Outpatient Surgical Volume Growth Rate\*

	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Outpatient Surgical Cases	15,870	16,251	16,229	16,139	15,788
Outpatient CAGR	-0.11%				

\* Source: 2015 – Proposed 2019 SMFPs

To the extent that Cone Health believes that it needs to develop a separately-licensed ASC to provide services to this population, it could file a CON application to relocate existing ORs to a site in Guilford County. According to the TSC-CONE application, the proposed TSC-CONE site is only two miles from the Guilford County line. There should be plenty of business sites along I-40 near the county line able to accommodate the space needed for the proposed facility. According to the 2018 SMFP, Cone Health has a surplus of 8.53 ORs. Based on utilization data collected by the SHCC for the Proposed 2019 SMFP, that surplus has grown to 8.57 ORs. Developing additional new

<sup>5</sup> Source: 2018 License Renewal Application

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ORs only a few miles when Cone Health already has so much capacity does not meet the need of Cone Health or its patients for outpatient surgery services in eastern Forsyth / western Guilford Counties.

### ***Proposed Service Does not meet the Demand for Surgical Services in Forsyth County***

As the development of the proposed service consists of a two operating room ASC in Kernersville, it is not meeting the demand for surgical services in Forsyth County. The demand for surgical services in Forsyth County was driven by the utilization of the ORs at NCBH, which has a projected deficit of 6.65 ORs in the 2018 SMFP. As illustrated above, NCBH has experienced greater inpatient surgical growth as compared to outpatient. Furthermore, NCBH is a tertiary acute care academic teaching hospital. As such, it provides a diverse array of surgical services to both inpatients and outpatients, many of which cannot be duplicated at another acute care facility and certainly not at an ASC. Developing yet a fourth ASC in Forsyth County, and a second in Kernersville, is not meeting the demand for surgical services in the County.

### ***The Utilization Methodology is based on Faulty Assumptions***

The utilization methodology is based on referrals from four primary care practices to surgical specialists. They assume a percent of the referrals will result in a surgery, which vary by surgical specialty from 5% to 80%. The applicant then assumes that 70% of all surgical cases will be outpatient, ASC appropriate, and does not provide any variability by surgical specialty. Lastly, the applicant assumes that 100% of the patients referred from Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine that will require outpatient, ASC-appropriate surgery will opt to have their surgery at TSC-CONE. The applicant assumes 60% of the patients from Lebauer High Point and Lebauer Oak Ridge will opt to have their surgery at TSC-CONE.

- Percentage of Outpatient, ASC-Appropriate Surgeries is too Aggressive
- Percentage of Patients that choose Surgery at TSC-CONE is too Aggressive

#### Percentage of Outpatient, ASC-Appropriate Surgeries is too Aggressive

The applicant estimates that 70% of all surgeries resulting from Primary Care referrals to specialists will be outpatient, ASC-appropriate. This is a faulty assumption, however. Research shows that only up to 40% of surgeries are appropriate for ASCs<sup>6</sup>. Though the applicant believes that the proposed methodology will result in a higher proportion of low-acuity, outpatient surgical cases that are safe for an ASC because the surgeries will stem from a referral from a primary care provider, no supporting data is provided to illustrate this point. The expected percentage should be more aligned with what has been noted in published research, 40%. Furthermore, the applicant assumes the same percentage of outpatient, ASC-appropriate surgeries for all specialties. This is also a faulty assumption, as the percentage of outpatient, ASC-appropriate surgeries will vary by specialty. To illustrate this point, NCBH has provided in the table below the distribution of its FY 2017 surgical cases by the surgical specialties outlined in the TSC-CONE application. The second column illustrates the percentage of each surgical specialty that is outpatient, ASC Appropriate, as defined by NCBH<sup>7</sup>. The percentage of cases that are appropriate for an ASC range from 100% for Podiatry and Dermatology to just 6% for Neurosurgery. The largest percentage lies within Urology with just 35%. While NCBH has a disproportionate share of high-acuity patients, and it cannot be assumed that these percentages will be consistent with other health care providers in the area, the data does support the 40% assumption that has been noted in published research as well as illustrate the variability in the percentages by surgical specialty.

Table 7

<sup>6</sup> Erhun F, Malcolm E, Kalani M, et al. Opportunities to improve the value of outpatient surgical care. Am J Manag Care. 2016;22(9):e329-335.

<sup>7</sup> Definition includes cases that meet the following criteria: OP, MCR Reimbursable Primary CPT for an ASC, ASA Level 1-3, Adult, Discharged Home, Discharged from PACU, Case Length < 150 minutes

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Outpatient ASC Appropriate Surgical Cases at NCBH

	Percentage Outpatient, ASC Appropriate at NCBH
Orthopedics	25%
Urology	35%
General Surgery	23%
Neurosurgery	6%
Ob/Gyn	21%
Plastic Surgery	30%
ENT	25%
Dermatology	NA (100% HOPD outside of ORs)
Podiatry	NA (100% OP at DMC)
Gynecology	Combined with Ob/Gyn
Average (including Dermatology and Podiatry)	41%

Percentage of Patients Projected to choose Surgery at TSC-CONE is too Aggressive

The applicant assumes that 100% of the patients referred from Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine that will require outpatient, ASC-appropriate surgery will opt to have their surgery at TSC-CONE. The applicant assumes 60% of the patients from Lebauer High Point and Lebauer Oak Ridge will opt to have their surgery at TSC-CONE. This assumption is faulty because 1) it assumes that the four primary care practices will only refer to surgeons with privileges at TSC-CONE and 2) it assumes that an overly aggressive proportion of patients will chose TSC-CONE for their surgery. A recent study comparing the cost of care for identical procedures performed in hospital versus ASC settings found that, when given the choice, only 37% of patients opted for the ASC<sup>8</sup>. Assuming that 100% and 60% of patients will chose TSC-CONE is an extremely aggressive and unfounded assumption.

**Access**

As addressed in comments regarding Criterion 1, the proposed project does not enhance access, particularly for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The project is expected to serve just 0.3% self-pay and 1.0% Medicaid patients in its ORs. This is drastically different to the existing mix of surgical patients in Forsyth County. The project will promote inequities in healthcare, not expand access. From a surgical specialty perspective, the project will provide enhanced access to a limited scope of outpatient surgical services to the healthiest subset of the population. The 2018 MedPAC Report to Congress noted that, while there are approximately 3,500 Healthcare Common Procedure Coding System (HCPCS) codes covered in the ASC payment system, 75% of the ASC volume for Medicare beneficiaries was attributed to just 27 (less than 1%) of these codes in 2016. Furthermore, the 2018 MedPAC report noted that patients treated in ASCs differ than patients treated in hospitals in ways that intensify health care inequities. The report noted that *“there is evidence that patients treated in ambulatory surgical centers (ASCs) are different in several ways from those in hospital outpatient departments (HOPDs). Our analysis of Medicare claims from 2016 revealed that the following groups represented a smaller share of ASC patients compared with HOPD patients: Medicare beneficiaries who also have Medicaid coverage (dual eligibles), African Americans (who are more likely to be dually eligible), beneficiaries who are eligible for Medicare because of disability (under age 65), and beneficiaries who are age 85 or older”*.

**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.”**

<sup>8</sup> Fabricant PD, Seeley MA, Rozell JC, et al. Cost savings from utilization of an ambulatory surgery center for orthopaedic day surgery. J Am Acad Orthop Surg. 2016;24(12):865-871.



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Section E of the TSC-CONE Application fails to discuss the alternative of relocating ORs from Cone Hospital to a location near Kernersville in western Guilford County. Given the large surplus of operating rooms at the hospital, this would be a more effective alternative than allowing Cone Health to develop an ASC with ORs that it does not need and which would not effectively meet the needs of Forsyth County patients.

**Criterion 5 – “Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”**

As discussed under Criterion 3 above, the TSC-CONE application’s utilization methodology is based on faulty assumptions because it overstates the likely number of physician referrals which will result in outpatient surgery. The financial projections in the application are based on those unreliable utilization projections, and therefore, the application is not based on a reasonable projection of costs and charges and fails to demonstrate financial feasibility under Criterion 5.

**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.”**

Because TSC-CONE's proposed utilization projections are unreliable and not supported as discussed above, the proposed project fails to demonstrate that it will not result in unnecessary duplication as required under Criterion 6.

**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:**

- ...
- 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;”**

As discussed under Criterion 1 above, the TSC-CONE application projects to serve a much smaller percentage of self pay and Medicaid patients than the Forsyth County facility outpatient surgery average. Consequently, the TSC-CONE application does not adequately demonstrate that the medically underserved will be served by its proposed service. Therefore, the application is non-conforming to Criterion 13(c).

**Criterion (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.”**

As discussed above, the TRC application fails to demonstrate that the proposal will have a positive impact upon the cost effectiveness, quality, and access to the services proposed. TSC-CONE has failed to demonstrate a need for its proposal, and will not improve access to residents of Forsyth County in need of surgical services. Its revenue projections are overstated, and the project will not be cost effective. The application does not adequately demonstrate that the

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proposed service will have a positive impact on access by the medically underserved. Therefore, the project is non-conforming with Criterion 18a.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

***(a) 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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.***

As discussed under Criterion 3 above, the TSC-CONE application utilization projections are unreasonable, and therefore the application fails to demonstrate a need for the number of proposed operating rooms and is non-conforming with this rule.

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

Because the assumptions upon which the TSC-CONE application projects utilization are overly aggressive and overstated, the application is non-conforming with this rule.

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**Criterion 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.”**

Policy GEN-3 Basic Principles states: “A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

The Triad Center for Surgery (TCS) application does not conform to Criterion 1 as it does not adequately demonstrate that the project will promote equitable access and maximize healthcare value for resources expended.

*Equitable Access*

The proposed project will not promote equitable access in the delivery of health care services. In fact, the proposed project will exacerbate inequities that exist in health care service delivery. As evidenced by the payer mix projections on page 85 in Section L of the application, the proposed project is projected to serve just 1.02% self-pay patients overall, with the operating room component of the project projected to serve 1.00% self-pay patients. Furthermore, the project is projected to serve just 3.60% Medicaid patients overall with operating room portion projected to serve 3.82% Medicaid patients. In comparison, the total self-pay surgical cases in Forsyth County surgical facilities during FFY 2017 (as reported in the 2018 hospital and ambulatory surgery center license renewal applications) was 4.7% for inpatient cases and 3.9% self-pay patients for outpatient cases. The percent of Medicaid patients was 14.4% for inpatient cases and 13.7% for outpatient cases. The project is projecting to serve 54% fewer self-pay patients, 72% fewer Medicaid patients, and 37% greater “other” patients, which is primarily composed of Worker’s Compensation, than are currently being served by the existing surgical facilities in Forsyth County.

**Table 1  
Forsyth County Facility FFY 2017 Surgical Payer Mix**

Payer Source	Forsyth County Surgical Payer Mix		Projected Payer Mix of Project (OR Only)	% Difference in Payer Mix (Proposed - Forsyth County / Forsyth County)
	IP	OP		
Self-Pay*	4.7%	3.9%	1.8%	-54.4%
Medicare	46.0%	37.1%	46.6%	25.6%
Medicaid	14.4%	13.7%	3.8%	-72.1%
Managed Care / Commercial	30.3%	41.4%	42.6%	2.9%
Other	4.6%	3.8%	5.2%	37.4%

Data Source: 2018 hospital and ambulatory surgery center license renewal applications  
\*Includes charity care

*Value*

The proposed project will not maximize value for healthcare resources expended as it is not meeting the demand for operating room services in Forsyth County and thus proposing the development of unnecessary operating rooms. The applicant represents the project as the development of a multispecialty ASC in Forsyth County; however, it is evident by the distribution of the surgical cases that the operating rooms will truly serve just three surgical specialties:

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orthopedics, neurosurgery, and ophthalmology. NC Gen Statute § 131E-176 15(e) defines a multispecialty ambulatory surgical program as a “formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: *gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.*” Though the applicant adheres to this definition by the planned provision of orthopedics, ophthalmology, oral, and plastic surgery in the ORs, only a small minority of the volume is projected for oral/facial and plastic surgery, just over 1.0% of the total cases in Project Year 1 and less than 1.0% of cases in Project Year 3.

Specialty	Volume Projections			Volume Distribution		
	PY 1	PY 2	PY 3	PY 1	PY 2	PY 3
Orthopedics	1,262	1,642	2,021	54.0%	56.0%	57.4%
Neurosurgery	270	324	378	11.6%	11.1%	10.7%
Ophthalmology/Oculoplastic	780	936	1,092	33.4%	31.9%	31.0%
Oral and Facial Surgery	15	18	21	0.6%	0.6%	0.6%
Plastic Surgery	11	11	11	0.5%	0.4%	0.3%
Pain Management	0	0	0	0.0%	0.0%	0.0%
<b>Total</b>	<b>2,338</b>	<b>2,930</b>	<b>3,522</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The proposed mix of the services is not representative of the needs in Forsyth County. Outpatient orthopedic surgery, the primary surgical service projected for the proposed surgery center comprises 57% of the projected TCS surgical cases in PY 3 compared to just 14% of all FFY 2017 surgical volume in Forsyth County facilities. In addition, outpatient orthopedic surgery in Forsyth County facilities is one of just two outpatient surgical services that have declined from FFY 2015 to FFY 2017 (reference Table 3 below). The need for ORs in Forsyth County is not driven by the need for more outpatient orthopedic surgery OR capacity, the primary surgical service for the TCS project. The development of this project will result in the development of unnecessary ORs that will not meet the need for surgical services in Forsyth County and therefore it does not maximize value for healthcare resources expended.

	Inpatient				Outpatient			
	FFY 2015	FFY 2016	FFY 2017	% Change	FFY 2015	FFY 2016	FFY 2017	% Change
CT	933	946	1,098	18%	87	100	90	3%
General	4,659	5,142	4,918	6%	7,277	7,232	7,819	7%
Neurosurgery	2,958	3,013	3,079	4%	1,721	1,748	1,836	7%
OB and Gyn	1,187	1,171	947	-20%	3,158	3,059	2,973	-6%
Open Heart	1,343	1,353	1,340	0%	-	-	-	-
Ophthalmology	87	118	81	-7%	7,637	7,979	8,831	16%
Oral/Dental	31	61	46	48%	973	1,131	1,063	9%
Orthopedics	6,563	7,283	6,880	5%	10,660	1,0371	10,476	-2%
Other	2,227	2,413	2,130	-4%	1,359	1,332	1,007	-26%
Otolaryngology	955	823	854	-11%	6,199	6,315	6,197	0%
Plastic Surgery	643	715	711	11%	2,476	2,468	2,517	2%
Podiatry	NA	NA	505	-	NA	NA	487	-
Urology	1,387	1,371	1,228	-11%	5,522	5,514	5,777	5%
Vascular	1,657	1,752	1,924	16%	9,33	848	1,003	8%
<b>Grand Total</b>	<b>24,630</b>	<b>26,161</b>	<b>25,741</b>	<b>5%</b>	<b>48,002</b>	<b>48,097</b>	<b>50,076</b>	<b>4%</b>

Source: Hospital and ASC LRAS, 2016-2018; Excludes all C-Sections (in C-Section OR and not in C-Section OR)

**Criterion (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.”**

The applicant does not conform to Criterion 3 as it does not adequately demonstrate the need that this population has for the services proposed and does not adequately demonstrate the extent to which all residents of the area, particularly 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.

**Demonstration of Need**

The applicant does not adequately demonstrate the need that this population has for the services proposed due to the following reasons:

- There is not a current need for additional ASCs in Forsyth County
- The proposed service does not meet the demand for surgical services in Forsyth County

***Not a Current Need for Additional ASCs in Forsyth County***

Growth and Aging of the Population is not Driving the need for an ASC in Forsyth County

The applicant points to the projected population growth and aging of the population in Forsyth County as rationale for a need for an ASC in Forsyth County. The applicant notes that the population ages 65+ is projected to grow at a greater rate than other age segments and sites an article from the Annals of Surgery that notes that aging of the population will result in increases in the demand for surgical services. The article noted by the applicant was published in 2003 using data from 1996. The article projects surgical demand through 2020 for a selected subset of specialties (Ophthalmology, Cardiothoracic, General Surgery, Neurosurgery, Orthopedics, Otolaryngology, and Urology). The proposed date of services offered for TCS is January 1, 2021; as such the first year of operation is beyond the forecast horizon of this particular article, making the projected surgical demand from the article irrelevant. Furthermore, though this article projects increases in demand for surgical services attributed to individuals over the age of 65, it provides no discussion of increases in the demand for *ambulatory* surgical services.

While it is true that persons over age 65 tend to be higher utilizers of health care services, there is no data provided to support that persons over age 65 have a higher demand and utilization of *ambulatory* surgical center services or that they need more access to ASCs. To the contrary, the 2018 MedPAC Report to Congress on Medicare Payment Policy noted that “beneficiaries have adequate access to care in ASCs”. The report continues to state that the volume of services per FFS beneficiary declined by 0.5% from 2015 to 2016. This compares to an average annual growth of 0.7% per from 2011 to 2015.

Demand for Ambulatory Surgical Services is not driving the OR Need in Forsyth County

The applicant discusses the shift to outpatient services that has been impacting the healthcare industry as part of the rationale for the need for the TCS ASC. Their discussion includes points regarding advances in surgical technologies and anesthesia techniques as well as ASC reimbursement and ambulatory surgery trends. Although these data points are in fact accurate, they are also misleading. The shift to outpatient services in health care is undisputable, however the need for the ORs in Forsyth County cannot be attributed to this shift to outpatient and cannot be met by more outpatient/ambulatory ORs.

If the surgical data is reviewed more closely, it is clear that the need for ORs in Forsyth County was driven by utilization North Carolina Baptist Hospital (NCBH). It is also quite evident by this closer review that growth in inpatient surgical volume has outpaced growth in outpatient surgical volume at NCBH. As such, meeting the need for ORs in Forsyth County requires an applicant to offer both inpatient and outpatient surgical services.

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From a statewide perspective, the facilities with the greatest OR deficits are North Carolina’s Academic Medical Centers (AMCs). In three of the four OR Service Areas with an AMC and a need determination for ORs in the 2018 SMFP (Durham, Forsyth, Mecklenburg, and Orange), the AMCs experienced greater inpatient surgical growth as compared to outpatient. The only exception to this is Duke University Hospital in Durham, whose inpatient growth (0.7%) was essentially equivalent to its outpatient growth (0.8%). This further supports that fact that the need for additional ORs in not only Forsyth County, but the state as a whole, must involve the development of both inpatient and outpatient surgical services to truly meet the demand that is driving the need.

Table 3  
Surgical Growth, Inpatient v Outpatient  
Counties with a Need Determination, Facilities within each County with a Deficit

	OR Deficit	Inpatient				Outpatient			
		FFY 2014	FFY 2015	FFY 2016	CAGR	FFY 2014	FFY 2015	FFY 2016	CAGR
<i>Buncombe</i>									
Orthopaedic Surgery Center of Asheville	0.50	0	0	0	NA	3,201	3,138	3,016	-2.9%
Asheville Eye Surgery Center	0.60	0	0	0	NA	3,931	4,074	4,648	8.7%
<i>Durham</i>									
Duke University Hospital	5.77	16,920	17,344	17,151	0.7%	22,292	23,728	22,642	0.8%
NC Specialty Hospital	2.59	1,685	1,597	1,629	-1.7%	3,583	3,737	3,606	0.3%
<i>Forsyth</i>									
<b>North Carolina Baptist Hospital</b>	<b>6.65</b>	<b>13,944</b>	<b>14,214</b>	<b>14,534</b>	<b>2.1%</b>	<b>19,749</b>	<b>19,549</b>	<b>19,925</b>	<b>0.4%</b>
<i>Mecklenburg</i>									
<b>Carolinas Medical Center</b>	<b>16.57</b>	<b>19,414</b>	<b>21,242</b>	<b>21,215</b>	<b>4.5%</b>	<b>21,074</b>	<b>21,593</b>	<b>22,756</b>	<b>3.9%</b>
CHS – University	0.99	1,067	1,019	846	-11.0%	7,036	6,854	6,513	-3.8%
<i>Orange</i>									
<b>UNC Hospitals</b>	<b>6.48</b>	<b>12,139</b>	<b>12,845</b>	<b>13,529</b>	<b>5.6%</b>	<b>16,547</b>	<b>16,960</b>	<b>15,736</b>	<b>-2.5%</b>
<i>Wake</i>									
Duke Raleigh Hospital	6.77	3,586	3,616	4,389	10.6%	9,132	9,875	10,855	9.0%

Source: 2016-2018 SMFPs

The applicant provides a methodology that projects a need for ambulatory ORs in the Forsyth County OR service area by growing the FFY 2016 base year ambulatory surgical cases in Forsyth County by 1.18%, the historical CAGR, through 2023. The result of the analysis, on page 34 of the application, illustrates a ‘need’ for 2 ORs in 2020 growing to 4 ORs in 2023. The applicant provides no discussion of existing operating room supply in this illustration. Novant Health facilities account for over half of all outpatient surgical volume in Forsyth County and have a projected surplus of 6.81 ORs per the 2018 SMFP. This projected surplus provides more than enough operative capacity to meet the projected ‘need’ illustrated by the applicant.

Lastly, Forsyth County will be transitioning from a county with zero multispecialty freestanding ASCs to a county with three multispecialty freestanding ASCs by June 2019. Wake Forest Baptist Health – Outpatient Surgery Clemmons (WFBH-OSC) is a multispecialty ASC with three licensed ORs that opened in February 2018; Novant Health Kernersville Outpatient Surgery (NHKOS) is a planned ASC for Kernersville with two licensed ORs and a planned opening of July 2018; Novant Health Clemmons Outpatient Surgery (NHCOS) is a planned ASC for Clemmons with two licensed ORs and a planned opening for June 2019. In total, these new ASCs will provide access to seven new freestanding ASC ORs in Forsyth County with a surgical capacity of 8,352 cases or 18% of all outpatient surgical cases in the Forsyth County OR Service Area<sup>9</sup>.

<sup>9</sup> Excludes Piedmont Outpatient Surgical Center Cases

***Proposed Service Does not meet the Demand for Surgical Services in Forsyth County***

As the development of the proposed service consists of a two operating room ASC in Winston-Salem, it is not meeting the demand for surgical services in Forsyth County. The demand for surgical services in Forsyth County was driven by the utilization of the ORs at NCBH, which has a projected deficit of 6.65 ORs as identified in the 2018 SMFP. As illustrated above, NCBH has experienced greater inpatient surgical growth as compared to outpatient. Furthermore, NCBH is a tertiary acute care academic teaching hospital. As such, it provides a diverse array of surgical services to both inpatients and outpatients, many of which cannot be duplicated at another acute care facility and certainly not at an ASC. Developing yet a fourth ASC in Forsyth County, and a second in Kernersville, is not meeting the demand for surgical services in the County.

**Access**

As addressed in comments regarding Criterion 1, the proposed project does not enhance access, particularly for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The project is expected to serve just 1.8% self-pay and 3.8% Medicaid patients in its ORs. This is drastically different to the existing mix of surgical patients in Forsyth County. The project will promote inequities in healthcare, not expand access. From a surgical specialty perspective, the project will provide enhanced access to a limited scope of outpatient surgical services to the healthiest subset of the population. The 2018 MedPAC Report to Congress noted that, while there are approximately 3,500 Healthcare Common Procedure Coding System (HCPCS) codes covered in the ASC payment system, 75% of the ASC volume for Medicare beneficiaries was attributed to just 27 (less than 1%) of these codes in 2016. Furthermore, the 2018 MedPAC report noted that patients treated in ASCs differ than patients treated in hospitals in ways that intensify health care inequities. The report noted that *“there is evidence that patients treated in ambulatory surgical centers (ASCs) are different in several ways from those in hospital outpatient departments (HOPDs). Our analysis of Medicare claims from 2016 revealed that the following groups represented a smaller share of ASC patients compared with HOPD patients: Medicare beneficiaries who also have Medicaid coverage (dual eligibles), African Americans (who are more likely to be dually eligible), beneficiaries who are eligible for Medicare because of disability (under age 65), and beneficiaries who are age 85 or older”*.

***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.”***

Section E of the TCS application fails to demonstrate that the proposed alternative is the least costly or most effective to meeting the needs of the proposed project as the applicant does not discuss the development of an ASC with two ORs and fewer than three procedure rooms. The applicant provides projections for the procedure rooms that total 1,035 cases by Project Year 3. The procedure room projection is one-third of the projection for OR cases (3,522 cases in Project Year 3) but requires more procedural capacity than the ORs. If the same standards of 68.6 minutes per case and 1,312.5 hours per room are applied to the procedure room projection, the applicant only needs 0.90 or one minor procedure room to accommodate the projected volume. Furthermore, if the applicant’s own capacity threshold of 1,832 hours per room are applied to the procedure room projection, the need drops to 0.65 of a procedure room. The applicant notes in its application that the procedure rooms will be used for training and in-services; however, the development of two procedure rooms for the uses beyond what is needed to accommodate the projected volume does not represent the most effective or least costly alternative for the project.

According to the CON application, the primary physicians who support the proposal and intend to invest in the facility are with OrthoCarolina. Several of those same physicians,<sup>10</sup> including TCS’ proposed Medical Director, William L. Craig, III, MD, wrote letters of support for NHCOS 2017 CON application to develop a freestanding ASC (Project I.D. No. G-

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<sup>10</sup> One OrthoCarolina physician who supported the 2017 NHCOS application, John E. Ritchie, M.D., appears to no longer be associated with OrthoCarolina.



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11300-17). A list of the OrthoCarolina physicians supporting both applications is below, and copies of their support letters in the NHCOS application are attached as **Exhibit 4**.

<b>Physician</b>	<b>NHCOS 2016 Application, Ex. 4</b>	<b>TCS Application, Ex. C.4(b)</b>
Daniel S. Biggerstaff, MD	p. 151	p. 72
William L. Craig, MD	p. 151A	p. 77
David V. Janeway, MD	p. 151B	p. 74
Michael Lauffenberger, MD	p. 151C	p. 76

The TCS application fails to demonstrate why the use of the two ORs approved and under development at NHCOS is not a less costly or more effective alternative for its physicians to provide ASC services in Forsyth County.

**Criterion 5 – “Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”**

The total working capital of \$700,000 found in Section F of the application does not match the working capital and start-up costs in the amortization table in Section Q, which provides an amortization schedule for \$100,000 in working capital and start-up costs. As such, the corresponding interesting expense in Form F.3 (line 17) reflects \$100,000 in working capital and start-up costs, not \$700,000. The financial projections therefore underrepresent the expenses and do not conform to Criterion 5 as the financial feasibility of the proposal is misrepresented.

**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.”**

The applicant provides the patient origin of Piedmont Outpatient Surgery Center (POSC) as reported in the 2018 license renewal application as documentation that the TCS will not serve a substantial portion of patients from outside of adjacent HSAs. The applicant does not conform to Criterion 9 as it does not document that that it is not projected to serve a substantial portion of patients from outside of adjacent HSAs. The applicant should use its own projected patient origin to respond to this Criterion. POSC is a single-specialty demonstration project providing only outpatient otolaryngology services; it is faulty to conclude that TCS, a proposed multispecialty ASC, will have the same patient origin as POSC. The applicant provides no rationale as to why they expect that the patient origin of TCS will match that of POSC.

**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:**

...

**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;”**

As discussed under Criterion 1 above, the TCS application projects to serve a much smaller percentage of self pay and Medicaid patients than the Forsyth County facility outpatient surgery average. Consequently, the TCS application does

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not adequately demonstrate that the medically underserved will be served by its proposed service. Therefore, the application is non-conforming to Criterion 13(c).

**Criterion (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.”***

As discussed above, the TCS application fails to demonstrate that the proposal will have a positive impact upon the cost effectiveness, quality, and access to the services proposed. TCS has failed to demonstrate a need for its proposal, and will not improve access to residents of Forsyth County in need of surgical services. Its revenue projections are overstated, and the project will not be cost effective. The application does not adequately demonstrate that the proposed service will have a positive impact on access by the medically underserved. Therefore, the project is non-conforming with Criterion 18a.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

***(a) 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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.***

As discussed under Criterion 3 above, the TCS application utilization projections are unreasonable, and therefore the application fails to demonstrate a need for the number of proposed operating rooms and is non-conforming with this rule.

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

Because the assumptions upon which the TCS application projects utilization are overly aggressive and overstated, the application is non-conforming with this rule.

**WAKE FOREST BAPTIST HEALTH**

**COMPARATIVE COMMENTS**

## **WAKE FOREST BAPTIST HEALTH COMPARATIVE COMMENTS**

In past reviews, the Agency has used a number of factors to compare competing CON applications proposing to develop operating rooms. However, the Agency has been reluctant to use several of factors in these comparative reviews where some of the applicants are projecting to perform both inpatient and outpatient surgeries, and others are proposing only outpatient surgeries. In particular, the Agency has consistently found in prior reviews that it is not possible to make conclusive statements about which applicant represents the most effective alternative with regard to gross revenue, net revenue and operating costs (which are considered in almost every review), due to the difference in the revenues and costs associated with the different types of cases. Therefore, those factors are not discussed here.

NCBH believes that the factors below demonstrate that its proposal is equally effective as or comparatively superior to the other applications and should be approved.

### **Conformity with Applicable Statutory and Regulatory Review Criteria**

As discussed in the individual comments above, the NHFMC, NHCOS, TSC and TCS-Cone applications are not conforming with all applicable statutory and regulatory review criteria as discussed in these Comments. Therefore, those applications are not approvable and are not effective alternatives. NCBH is conforming with all applicable statutory and regulatory review criteria, and therefore is the most effective alternative with respect to conformity with statutory and regulatory review criteria.

### **Geographic Accessibility**

All five applications in this review propose to develop ORs in either Clemmons, Winston-Salem or Kernersville. Clemmons is on the far western edge of Forsyth County, Kernersville is on the far eastern edge of Forsyth County, and Winston-Salem is in the center of the county, essentially equidistant between them. All three cities are connected by I-40, and the distance and drive time between NHCOS in Clemmons and TSC-Cone's proposed site in Kernersville is only 22 miles and 22 minutes. While the majority of the existing and approved ORs are located in Winston-Salem, approximately 65% of the Forsyth County population lives there.<sup>11</sup> Winston-Salem also is the location of the two larger medical centers which provide more complex inpatient and outpatient surgeries. Finally, there are a total of 16 existing and approved ORs either currently located or projected to be operational within the next year in Clemmons and Kernersville. As discussed in the comments above regarding the NHCOS application, Clemmons has the smallest population area of the three cities, and there are already five multispecialty ASC ORs and two hospital-based ORs located there. Therefore, no more ORs are needed in the Clemmons area, and the NHCOS application is the least effective alternative of the three applications. Given all of the remaining factors, the other applicants should be considered comparable with regard to the geographic accessibility of the proposed ORs.

### **Physician Support**

Each of the applicants submitted multiple letters of support from surgeons and other providers expressing an interest or intent performing surgeries in the proposed operating rooms and letters from other physicians expressing a willingness to refer their patients to the respective facilities. However, the NCBH application provided significantly more letters than any other applicant from individual surgeons who currently *perform* surgeries at the hospital and who express an intent to use the four new operating rooms if they are approved. Therefore, the NCBH application is the most effective proposal with regard to physician support.

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<sup>11</sup> See <http://worldpopulationreview.com/us-cities/winston-salem-population/> and <http://worldpopulationreview.com/us-counties/nc/forsyth-county-population/>

**WAKE FOREST BAPTIST HEALTH COMPARATIVE COMMENTS**

**Patient Access to Inpatient and Outpatient Surgical Services**

According to Table 6A of the Proposed 2019 SMFP, excluding dedicated C-section and trauma/burn ORs (which are not considered in the SMFP determination), there are 88 existing and 7 new approved ORs in the Forsyth County operating room service area, for a total of 95 ORs. The current breakdown of existing operating rooms is as follows: 9 inpatient ORs; 11 ambulatory ORs; and 72 shared ORs. The 7 incremental ORs approved for NCBH are dedicated ambulatory ORs.

In addition, NHFMC has received CONs to relocate 4 ORs from its licensed facility to develop two new freestanding ASCs in Clemmons and Kernersville. Based on these approvals, Forsyth County will be transitioning from a county with zero multispecialty freestanding ASCs to a county with three multispecialty freestanding ASCs by June 2019. Wake Forest Baptist Health – Outpatient Surgery Clemmons (WFBH-OSC) is a multispecialty ASC with three licensed ORs that opened in February 2018; Novant Health Kernersville Outpatient Surgery (NHKOS) is a planned ASC for Kernersville with two licensed ORs and a planned opening of July 2018; Novant Health Clemmons Outpatient Surgery (NHCOS) is a planned ASC for Clemmons with two licensed ORs and a planned opening for June 2019. In total, these new ASCs will provide access to seven new freestanding ASC ORs in Forsyth County with a surgical capacity of 8,352 cases or 18% of all outpatient surgical cases in the Forsyth County OR Service Area.<sup>12</sup>

Upon completion of all of these projects, following will be the distribution of ORs in Forsyth County:

<b>Facility</b>	<b>Dedicated Inpatient Surgery<sup>‡</sup></b>	<b>Shared Inpatient/ Ambulatory Surgery</b>	<b>Dedicated Ambulatory Surgery</b>	<b>Total Existing and Approved ORs</b>
NH Forsyth Medical Center*	3	15		18
NH Hawthorne Outpatient Surgery*			4	4
NH Clemmons Medical Center*		5		5
NH Kernersville Medical Center*		4		4
NH Medical Park Hospital		10		10
NHCOS			2	2
NHKOS			2	2
NCBH	2	35	8	45
Clemmons Medical Park ASC			3	3
Piedmont Outpatient Surgery Center			2	2
<b>TOTAL</b>	<b>5</b>	<b>69</b>	<b>21</b>	<b>95</b>

\* All of these facilities operate under NHFMC's license

‡ Excludes 2 rooms from NH Forsyth Medical Center for dedicated C-section ORs and 2 rooms from NCBH for Trauma/Burn ORs

The demand for surgical services in Forsyth County was driven by the utilization of the ORs at NCBH, which has a projected deficit of 6.65 ORs as identified in the 2018 SMFP. As explained on p. 31 of the NCBH application, while overall growth in healthcare has leaned towards the outpatient setting, NCBH has experienced greater growth in *inpatient* surgery. From FY 2014-2017, inpatient surgical volume grew 7.3% at NCBH while outpatient surgical volume was relatively flat at -0.1%. Even with the recent opening of the operating rooms at Davie Medical Center in Davie County (“DMC”), the combined historic surgical volume at NCBH and DMC reveals the same findings, however, that surgical volume growth was greater for inpatient cases (8.2%) compared to outpatient cases (6.8%). To the extent that NCBH is in need of additional space for complex outpatient surgery cases, much of that need will be met by its CON-approved outpatient ORs which are currently under development.

<sup>12</sup> Excludes Piedmont Outpatient Surgical Center cases. That facility is an ASC demonstration project that is in the SMFP inventory but is not included in the need determination calculations.

## **WAKE FOREST BAPTIST HEALTH COMPARATIVE COMMENTS**

Novant Health facilities in Forsyth County, on the other hand, report an overall surplus of almost 5 ORs. Novant Health in recent years has already been approved in 2017 and 2018 to develop new 2-OR ASCs in Kernersville and Clemmons, which can meet the ASC needs that Novant Health notes in its CON applications.

As such, meeting the need for ORs in Forsyth County requires an applicant to offer both inpatient and outpatient surgical services. Because the NHFMC and NCBH applications are the only ones which propose to offer both services in their ORs, they are more effective alternatives than the NHCOS, TCS and TSC-CONE applications.

### **Patient Access to Multiple Surgical Specialties**

In Section C, pages 19-22 and Section H, p. 91 of the NCBH application, NCBH reports that in FY 2017, 211 individual physicians performed cases in 12 inpatient and outpatient surgical specialties and dozens of subspecialties at its Winston-Salem campus. As shown on Table C.1.1, NCBH offers a total of 58 subspecialties within those 12 specialties.

On page 61 of its application, NHFMC reports having 139 surgical medical staff in 21 surgical specialties. NHFMC projects to recruit additional surgeons, but does not indicate that they will perform cases in new subspecialties.

The NHCOS application does not project future cases by specialty. However, Exhibit H-Letters of the NHCOS application contains letters of support from surgeons expressing an intent to seek privileges at the facility in 7 outpatient surgical specialties, as follows: (1) OB/GYN; (2) urology, (3) general surgery; (4) neurological surgery; (5) spine surgery; (6) podiatry; and (7) orthopedics.

In Section C, page 42 of its application, TSC-CONE projects to perform cases in 10 outpatient surgical specialties, as follows: (1) orthopedics; (2) dermatology; (3) ENT; (4) urology; (5) general surgery; (6) gynecology; (7) podiatry; (8) neurosurgery; (9) OB/GYN; and (10) plastic surgery.

In Section C, page 37 of its application, TCS projects to perform surgical cases in 6 outpatient surgical specialties, as follows: (1) orthopaedics; (2) neurosurgery; (3) ophthalmology/ocularplastics; (4) oral and facial surgery; (5) plastic surgery; and (6) pain management.

Therefore, with regard to providing Forsyth County patients with access to more multiple surgical specialties NCBH is the most effective alternative, NHFMC is a less effective alternative, and NHCOS, TSC-CONE and TCS are the least effective alternatives.

### **Access by Underserved Groups**

The following tables show the current average Forsyth County outpatient surgery payor source, followed by each applicant's projected payor sources in the second full operating year (OY2) following completion of each of the proposed projects.<sup>13</sup>

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<sup>13</sup> Projected payor source data is contained in Section L Section Q, Form F.4 of each application. The NCBH application did not break out inpatient and outpatient surgical cases. However, that information can be derived based on NCBH's inpatient and outpatient case mix.

**WAKE FOREST BAPTIST HEALTH COMPARATIVE COMMENTS**

Payor Source	Forsyth Co. OP Avg.*	NHFMC		NCBH		NHCOS	TSC-CONE	TCS
		Outpt.	Total	Outpt.	Total			
Self-Pay/Charity**	3.9%	4.1%	4.1%	5.0%	5.4%	1.5%	0.3%	1.79%
Medicare	37.1%	49.1%	49.2%	27.4%	33.8%	44.2%	31.1%	50.27%
Medicaid	13.7%	10.4%	9.3%	21.8%	19.8%	5.3%	1.0%	3.60%
Managed Care / Commercial	41.4%	48.0%	34.9%	40.4%	34.8%	44.4%	64.1%	39.68%
Other	3.8%	2.7%	2.5%	5.3%	6.1%	4.6%	3.5%	4.66%

\* Data Source: 2018 hospital and ambulatory surgery center license renewal applications

\*\* The NCBH application did not separately break out charity care, since that is not considered a payor source. However, as a practical matter, patients receiving charity care would be included among the patients categorized as self-pay.

The two hospitals project significantly higher percentage of care to self-pay/charity patients, and clearly are superior to the three proposed ASCs in that category.

With regard to care to Medicare patients, each of the applications’ overall Medicare percentage is comparable to or higher than the Forsyth County average. However, a comparison of Medicare percentage is not likely to be helpful in this review. Outpatient ASCs often have high Medicare percentages because they tend to perform outpatient orthopaedic and ophthalmic cases on people over 65. TCS, in particular, projects that over 88% of its surgical cases will be in these categories. Medicare reimbursement for these types of outpatient surgery is often quite lucrative. While elderly (and hence Medicare) patients are included within the category of “medically underserved,” under the CON law. Conversely, NCBH’s lower Medicare percentage is not indicative of less commitment to these patients. The reality is that NCBH projects to perform a significantly higher number of Medicare cases (11,788) of Medicare cases than any of the other applicants. The next closest is NHFMC, with only 8,229 projected Medicare cases.

Therefore, the applicants’ relative percentages of care to Medicare patients is not an accurate comparison of their relative commitment to the medically underserved. To the extent that the Agency deems this category relevant, NCBH clearly is the most effective alternative in terms of the number of surgeries performed on Medicare recipients.

NCBH’s Medicare percentage also reflects the fact that a significant portion of surgical care is provided to children. Brenner Children’s Hospital, which is on the NCBH campus and operated under its license, is one of the premier children’s hospitals in the State. Brenner Children’s Hospital’s Surgery division is one of the largest pediatric surgical centers in western North Carolina with leading clinical experts that perform the most advanced pediatric surgical procedures in the region using state-of-the-art technology. With 7 surgical suites dedicated to the care of children, Brenner’s General Surgery division is one of just 4 pediatric surgical centers in North Carolina.<sup>14</sup>

Patients ages 0-17 comprise 23% of NCBH’s outpatient cases compared to 11% of its inpatient cases.<sup>15</sup> As the only children’s hospital in the region, NCBH clearly does more pediatric surgical cases than others. Below is the current NCBH outpatient surgery payer mix for pediatric and adult patients.

Payor Source	Pediatric Cases	Adult Cases
Self-Pay	0.9%	6.4%
Medicare	0.2%	37.3%
Medicaid	59.3%	8.3%
Managed Care	38.2%	41.2%
All Other	1.4%	6.7%

<sup>14</sup> See <https://www.brennerchildrens.org/Pediatric-General-Surgery/>

<sup>15</sup> The information in this paragraph is for informational purposes only to enable the Agency to consider the relative importance of different comparative factors. To the extent that the Agency would consider this information an amendment to the NCBH Application, NCBH asks that it not be considered.

## WAKE FOREST BAPTIST HEALTH COMPARATIVE COMMENTS

As noted in this chart, almost 60% of the children served are Medicaid patients. This fact supports NCBH's significantly higher percentage of Medicaid patients than any of the other applications. Further, as with Medicare patients, NCBH's ORs will serve a significantly higher number of Medicaid cases (6,841) than any of the other applicants. Again, the next closest is NHFMC, which projects only 1,552 total Medicaid surgical cases in the second year of the project. While Medicare patients are technically defined as medically underserved, Medicare reimbursement for surgical services is relatively good. Conversely, Medicaid pays below the facility's cost to provide the service, resulting in many providers providing little or no care to Medicaid patients, who are often the most vulnerable.

Therefore, NCBH is the most effective alternative under this comparative factor.

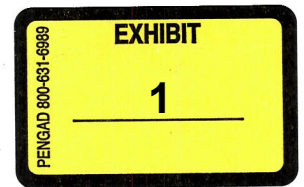
### **Summary**

In summary, NHCOS is the least effective alternative with regard to geographic access to surgery services, and the remaining applications are equally effective. NCBH is the most effective alternative among the applicants with regard to conformity with applicable statutory and regulatory review criteria, physician support, patient access to inpatient and outpatient surgical services, patient access to multiple surgical specialties, and access by underserved groups. NCBH is the superior applicant and should be approved to develop the 4 operating rooms identified in the 2018 SMFP for Forsyth County.



**INDEX OF EXHIBITS TO WAKE FOREST BAPTIST HEALTH WRITTEN COMMENTS**

1. Portions of NHKOS Agency Findings, Project ID # G-11150-16
2. Portions of NHCOS Agency Findings, Project ID # G-11300-17
3. Portions of January 4, 2012 Supplemental Settlement Information submitted to the CON Section by Wake Forest Ambulatory Ventures, LLC for Project ID # G-8608-10
4. OrthoCarolina physician letters of support for NHCOS 2017 CON application to develop a freestanding ASC, Project I.D. # G-11300-17.



**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

**FINDINGS**

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

Decision Date: August 26, 2016  
 Findings Date: August 26, 2016

Project Analyst: Mike McKillip  
 Team Leader: Fatimah Wilson  
 Assistant Chief: Martha Frisone

Project ID #: G-11150-16  
 Facility: Novant Health Kernersville Outpatient Surgery  
 FID #: 160113  
 County: Forsyth  
 Applicant: Novant Health Kernersville Outpatient Surgery, LLC  
 Project: Develop a new ambulatory surgery center by relocating two existing operating rooms from Novant Health Forsyth Medical Center in Winston-Salem to a new facility on the campus of Novant Health Kernersville Medical Center

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

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

C

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

Section VI.14, page 80, the applicant projects that 44 percent of surgical cases will be provided to Medicare or Medicaid recipients at the proposed facility. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

**Conclusion**

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

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

**Novant Health Forsyth Medical Center  
Operating Rooms by Type**

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

Source: 2016 Hospital License Renewal Application.

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

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

*“As reflected in the following table, surgical utilization at NHFMC has declined in the last four years. When new Novant Health surgical programs opened in Kernersville and Clemmons, patients appropriate for the services and the market choose to seek care at these new facilities.*

***Novant Health Forsyth Medical Center Historical Surgical Volumes***

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

Source: Exhibit 3, Table 7

On page 51, the applicant states,

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

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

**Projected Surgical Utilization Novant Health Forsyth Medical Center**

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

Source: Exhibit 3, Table 8

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

As shown in the table above, the applicant projects to perform 5,754 inpatient surgical cases and 5,407 outpatient surgical cases in the shared operating rooms at NHFMC in the third operating year of the project (2021). Based on the utilization standards required in 10A NCAC 14C .2103 (b)(1), the number of operating rooms required would be  $14 [(5,407 \times 1.5 \text{ hours}) + (5,754 \times 3.0 \text{ hours}) = 25,373 \text{ hours}; 25,373 \text{ hours}/1,872 \text{ hours} = 13.6 \text{ operating rooms}]$ . Therefore, based on the applicant's utilization projections, NHFMC would have adequate capacity to meet the need for surgical services for the population presently served following relocation of the two shared surgical operating rooms from NHFMC to the proposed ambulatory surgical facility.

In Section III.3(d), page 52, the applicant states,

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

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



**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 (NHFM) 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.

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 NHCMC 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**

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

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**

<b>Surgical Facility</b>	<b>CY 2012</b>	<b>CY 2013</b>	<b>CY 2014</b>	<b>CY 2015</b>	<b>CY 2016</b>	<b>CAGR 2012-2016</b>
<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**

	<b>PY1 Jul2019-Jun2020</b>	<b>PY2 Jul2020-Jun2021</b>	<b>PY3 Jul2021-Jun2022</b>
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:



**BODE, CALL & STROUPE, L.L.P.**

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January 4, 2012

**HAND DELIVERY**

Scott T. Stroud  
Assistant Attorney General  
N.C. DEPARTMENT OF JUSTICE  
114 West Edenton Street, Suite 421  
Raleigh, North Carolina 27601

Re: *Wake Forest Ambulatory Ventures, LLC v. NCDHHS, DHSR, CON Section*, 11 DHR 5140

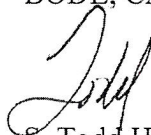
Dear Scott:

Per our conversation today, please find enclosed Supplemental Settlement Materials responding to the Required State Agency Findings in the above matter. We have also hand delivered copies to Martha Frisone and Gebrette Miles at the CON Section.

Please do not hesitate to contact me if you have any questions.

Very truly yours,

BODE, CALL & STROUPE, LLP

  
S. Todd Hemphill

STH:sh

Encl.

cc w/enc.: Martha Frisone (hand delivery)  
Gebrette Miles (hand delivery)  
J. McLain Wallace, Jr. (via e-mail only)  
Lynn Pitman (via e-mail only)  
Jennifer Houlihan (via e-mail only)

model to the citizens of Wake Forest Baptist Health's ("WFBH) 15-county outpatient service area.

**Demographic Data**

Given the approximate location of the Clemmons Medical Park ASC to NCBH, the NCBH 15-county service area was used to project future demand. The following table summarizes growth projections for the NCBH outpatient service area as provided by Thomson-Reuters Healthcare.

<b>Population - WFBMC 15-County Outpatient Service Area</b>					
<i>Age Group</i>	<i>Actual Population 2000</i>	<i>Estimated Population 2011</i>	<i>2000-2011 Average Annual Growth</i>	<i>Projected Population 2016</i>	<i>2011-2016 Average Annual Growth</i>
0-17	293,229	328,466	1.1%	339,886	0.7%
18-44	486,508	480,654	-0.1%	482,209	0.1%
45-64	292,904	383,576	2.8%	399,173	0.8%
65+	161,651	209,358	2.7%	245,308	3.4%
<b>Total:</b>	<b>1,234,292</b>	<b>1,402,054</b>	<b>1.2%</b>	<b>1,466,576</b>	<b>0.9%</b>

Source: Thomson-Reuters Healthcare Market Planner Plus

The service area is expected to continue growing by 0.9% per year through 2015. Currently, 56% of the population who receive surgery are ages 45 and over. Therefore, this trend was taken into consideration in our analysis based on the expectation that the 45-64 and 65 and older age groups represent the segment of the population that will most likely utilize the ORs proposed in this project. These age groups are estimated to grow .8% per year and 3.4% per year respectively for the period 2011-2016.

**Physician Support**

The need for the proposed project is consistent with the high demand for ambulatory surgical procedures and the widespread support from numerous surgeons who practice in Forsyth County. The following table summarizes the letters of support from WFUHS faculty with the number of cases to be performed in the three licensed operating rooms.

<b>Name</b>	<b>Specialty</b>	<b>PY1 Cases</b>	<b>PY2 Cases</b>	<b>PY3 Cases</b>
Mims	ENT	342	351	360
Goldman	ENT	333	353	374

Evans	ENT	379	401	426
Fernandez	OB/GYN	133	137	140
Sprinkle	Podiatry	346	358	371
Sigur	Podiatry	277	287	297
Guo	Spine	575	610	649
Curl	Sports Medicine	175	175	175
Poehling	Sports Medicine	335	344	354

Please see the letters of support included in Exhibit 2.

### **Operating Room Methodology**

NCBH and WFUHS re-engaged in broad based planning discussions to address the issues the Division of Surgical Sciences is experiencing as it relates to current OR capacity, block scheduling, and the increased number of faculty and planned recruitment efforts. This planning process included a review of historical growth rates for surgical case volumes, evaluation of current and future capacity constraints, assessment of healthcare trends and emerging technologies. That information was used to inform the growth methodologies used to project future OR demand at NCBH. Population growth of our 19-county service area and the growth rates reported in both the Pediatrics ED and Cancer Center Expansion Certificate of Need applications were considered as well. The projections were vetted through senior leadership and growth rates that reflect these variables were developed.

The following outlines a carefully reviewed methodology to justify the need for incremental ORs:

**Step 1:** Define the patient population

In order to project adequate need for surgical services, NCBH began by identifying all inpatient and outpatient patient status cases performed at the Inpatient, Outpatient, and Pediatric Surgical Center Sites that are on NCBH's license in the date range July 1, 2006 through June 30, 2011 for all surgical specialties. Currently NCBH is licensed for 40 ORs, all of which are located in Ardmore Tower.

**Step 2:** Calculate the compounded annual growth rates for inpatient and outpatient surgical case volumes for each of the historical years FY 2007 through FY 2011, which is summarized in the table below.

December 4, 2011

Dr. Tom Sibert  
President and Chief Operating Officer  
Wake Forest University Baptist Medical Center Health System  
Medical Center Blvd.  
Winston Salem, NC 27157

RE: Letter of Support for Clemmons Medical Park Ambulatory Surgery Center Certificate of Need Applications

Dear Dr. Sibert,

I am writing to express my support for the Certificate of Need application submitted by Wake Forest Ambulatory Ventures, LLC and support Wake Forest Baptist Health's efforts to establish a new freestanding ambulatory surgery center as a more patient-centered and cost effective facility for ambulatory surgical services. As a Board-certified Gynecologist, I intend to obtain privileges at the new proposed ambulatory surgery center. Key benefits of the project include:

- Supports the Gynecology clinic located in the Clemmons Medical Office Building
- Outstanding patient satisfaction
- Dramatic cost savings for patients and third party payers
- Improved access for Medicare, Medicaid and charity care patients

My projections for the number of ambulatory surgery cases at the proposed center are as follows:

Ambulatory Surgery Cases performed at Clemmons Medical Park ASC	Year 1	Year 2	Year 3
	133	137	140

In support of the CON project application, I agree to comply with the regulatory standards and reporting requirements that relate to the Certificate of Need approval. Pending CON approval and development of this project, I intend to obtain privileges at this new facility as well as maintain my medical staff privileges and on-call obligations at Wake Forest University Baptist Medical Center (hospital).

Sincerely,



Andrea S. Fernandez, M.D.  
Section Head, Obstetrics & Gynecology  
Assistant Professor, Obstetrics & Gynecology  
Department of Obstetrics & Gynecology

**Table of Exhibits**  
**Novant Health Clemmons Outpatient Surgery, LLC**  
**CON Application Filed 2/15/2017**

Exhibit #	Exhibit Description
1	Novant Health, Inc. Articles of Incorporation; Novant Health Clemmons Outpatient Surgery, LLC Articles of Organization; Organizational Chart
2	List of Novant Health Corporate Officers
3	Utilization Projections; OR Relocation Letter
4	Surgeon Support Letters
5	Anesthesiology, Pathology, & Radiology Support & Professional Coverage Letters; Surgery Center Medical Director's Letter
6	Surgery Patient Screening Criteria
7	Funds Letters; Novant Health, Inc. Audited Financial Statements
8	Policies: Patient Non-Discrimination Statement; Patient Bill of Rights & Responsibilities; Charity Care; Catastrophic Settlement; Uninsured Discount; Business Office Policies: Admissions, Charges, & Financial Counseling policy; Billing and Collecting Patient Balances
9	PTA Letter; List of Patient Transfer Agreements; Template Patient Transfer Agreement; List of Clinical Education Agreements
10	Surgery Center Quality of Care Tools, Policies, & Programs; Clinical Improvement Plan; Infection Prevention Plan-Surgical & Procedural Sites; Patient Safety Plan-First Do No Harm; World Health Organization Implementation Manual Surgical Safety Checklist (1 <sup>st</sup> Edition)
11	Utilization Review Plan; Risk Management Plan
12	Surgery Center Equipment List; Medical Equipment Management Plan
13	Land Title; Zoning Information; Map of Surgery Center Location
14	Line Drawings; Architect's Certified Construction Cost Letter; Site Plan
15	Novant Health Sustainable Energy Management Plan; Novant Health Utility Management Plan
16	Novant Health Board Chair Letter; Management Team Support Letters
17	Community Support Letters
18	Policies: Language Access Services; Corporate Interpreter Services; Interpreter Services-Bilingual Staff Linguistic Competency Program; Communication Needs of Patients & Families; Communication Handoffs
19	Policies for Responses to CON Application Question II.3
20	Medical Staff Credentialing Letter + Attachments
21	Clemmons Medical Office Building Exemption Request

# **Orthopedic Surgeon Support Letters**



February 13, 2017

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

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

Dear Ms. Frisone:

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

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

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

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


Sincerely,

Daniel S. Biggerstaff, MD  
OrthoCarolina

*File: ClemmonsASCOrthoSuppLtrBiggerstaff.docx*



February 13, 2017

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

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Dear Ms. Frisone:

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

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Sincerely,



William L. Craig, III, MD  
OrthoCarolina  
Fellow American Academy of Orthopaedic Surgeons

*File: ClemmonsASCOthoSuppLtrCraig.docx*



February 13, 2017

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

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Dear Ms. Frisone:

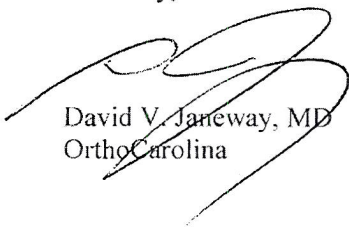
I am a board-certified orthopedic surgeon, specializing in sports medicine, and arthroscopic and reconstructive surgery of the shoulder and knee. I am an active member of the medical staffs at Novant Health Medical Park Hospital, Novant Health Forsyth Medical Center, and Novant Health Kernersville Medical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

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Sincerely,



David V. Janeway, MD  
OrthoCarolina

*File: ClemmonsASCOrthoSuppLtrJaneway.docx*



February 13, 2017

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

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

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Sincerely,

Michael P. Lauffenburger, MD  
OrthoCarolina

*File: ClemmonsASCSTrLauffenburger.docx*