

August 31, 2020

Celia Inman, Project Analyst Health 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: Comments on Forsyth County Operating Room CON Applications

Dear Ms. Inman:

Enclosed please find comments prepared by North Carolina Baptist Hospital regarding the competing CON applications by Novant Health Medical Park Hospital and Triad Surgery Center to develop new operating rooms (ORs) in Forsyth County, pursuant to the OR need identified in the 2020 State Medical Facilities Plan. Thank you for the opportunity to submit these comments for consideration regarding this important community need.

If you have any questions about the information presented here, please feel free to contact me at 336.716.1275.

Sincerely,

Jena Folger

Jena Folger Vice President, Network Growth, Strategy & Business Development

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS FORSYTH COUNTY OPERATING ROOMS

Submitted by North Carolina Baptist Hospital August 31, 2020

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the 2020 State Medical Facilities Plan (SMFP) for two additional operating rooms in Forsyth County; North Carolina Baptist Hospital (NCBH), Novant Health Medical Park Hospital (NHMPH), and Triad Surgery Center (TSC, which is Moses Cone Memorial Hospital or MCMH). In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by NHFMC and TSC, and a discussion about whether the material in their applications complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the three competing proposals represents the best choice for the community for development of additional operating rooms in Forsyth County.

Key issues for the Healthcare Planning and Certificate of Need Section to consider in making the decision include whether an application is conforming to all statutory review criteria, which project reasonably demonstrates the need for the proposed operating rooms, which project does not represent unnecessary duplication of existing services and which application represents the most effective alternative for development of the need-determined operating rooms.

Based on the following comments, it is clear that the Novant Health and Triad Surgery Center applications should each be denied.

General Comments

The 2020 SMFP identifies a need for two additional operating rooms in Forsyth County. Based on the standard methodology in the 2020 SMFP, NCBH has a need for an additional 4.72 operating rooms (ORs) by 2022, and a system need of 2 ORs. The need for additional operating room capacity in Forsyth County is driven solely by the surgical utilization at NCBH in relation to its approved OR capacity, and not by any other Forsyth County surgical facility. Based on the 2020 SMFP standard methodology, no other hospital or ambulatory surgery center in Forsyth County has a need for additional ORs at this time. In fact, Novant Health facilities together demonstrate a surplus of 6.41 ORs, as shown on Table 6B of the 2020 SMFP.

Projected Total Projected Deficit Final Adjusted Projected Surplus (Surplus npatient Case Surgical Hours for ORs Estimated Adjusted Service mbulatory Surgical lequired Growth Planning mbulatory Hours in 2022 Time Case Time 2022 Inventory "-") Need Cases Cases Factor H0166 Duolin Vidant Duplin Hospital 440 80. 1.458 64.6 2.157 -1.28 2.157 -1.56 1.4 Duplin Total Arringdon Ambulatory Surgical Center Durham Durham AS0041 James E. Davis Ambulatory Surgical 0 0.0 5.877 54.0 5,293 5.90 5,609 4.2 0.2 Center††† H0015 18,300 22,215 138.3 129,703 5.96 137,432 70.48 6.48 Durham Duke University Hospital** H0233 Duke Regional Hospital^^/††† 13.37 13 0.37 Durham 4.061 210.0 3.581 132.9 22,147 5.90 23,467 Duke University Health System Total 88.12 85 3.12 3,344 Durham H0075 North Carolina Specialty Hospital^/^^/† 1,521 137.7 89.4 8,474 5.96 8,979 5.00 1.00 2018 SMFP Need Determination Durham 0.0 0.00 -4.00 0.0 Durham Total Edgecombe H0258 Vidant Edgecombe Hospital†/††† 559 107.8 1.844 62.6 2.927 -1.14 2.927 1.95 -3.05 Edgecombe Total Forsyth Novant Health Clemmons Outpatient 0.0 0.0 0.00 -2.00 Forsyth AS0149 Novant Health Kernersville Outpatient 247 44.0 181 189 0.14 Surgery Forsyth H0209 Novant Health Forsyth Medical Center 10.821 157.2 10 030 82.0 55 500 4.04 57.851 29.67 33 -3 33 Novant Health Medical Park Hospital 217.0 8,797 102.0 18,177 4.05 18,914 10.78 0.78 H0229 891 10 Forsyth 40.59 47 Novant Health Total -6.41 Forsyth AS0021 Wake Forest Baptist Health Outpatien 0.0 178 86.8 258 4.05 268 0.2 Surgery Center - Clemmons****/†††† 53.72 Forsyth H0011 North Carolina Baptist Hospital** 14 460 241.5 19,786 128.8 100.675 4.05 104,753 4.72 Wake Forest Baptist Health Total 53.92 1.92 AS0134 Piedmont Outpatient Surgery Center 0.0 2,385 48.0 1,908 4.05 1.51 -0.49 0 Forsyth Triad Center for Surgery 0 0.0 0 0.0 0 0 0.00 -2.00 1.92 Forsyth Total

Table 6B: Projected Operating Room Need for 2022

Operating Room Need & Capacity

In the 2020 SMFP, NCBH is the facility that generated the need for additional ORs based on the increasing number of patients who choose NCBH for their surgical care, and in consideration of the inadequate OR capacity at the hospital. Moreover, the OR need at NCBH has been a constant for several years. Conversely, Novant Health has demonstrated a substantial surplus of ORs over this same time period. The following chart shows the deficits and surpluses generated respectively by NCBH (and also for parent Wake Forest Baptist Health) and by Novant Health over the past three years. NCBH's operating room deficits stand in sharp contrast with Novant Health's consistent annual surpluses of ORs.

Forsyth County Health Systems Operating Room Deficit or Surplus

	2016	2017	2018
Novant Health	(6.81)	(4.98)	(6.41)
NCBH	6.65	6.04	4.72
WFBH	3.65	3.29	1.92

Source: 2018-2020 SMFPs

surplus shown as negative

The continuing deficit of ORs in the annual SMFPs is clear evidence that demand for NCBH surgical services in Forsyth County is strong, and that NCBH needs additional capacity as proposed in its application; otherwise, OR capacity constraints will continue to challenge NCBH's ability to timely provide surgical care to patients in need.

In addition, Table 6B of the 2020 SMFP also shows there is no need for additional ORs at the existing ambulatory surgery centers (ASCs) in Forsyth County. In fact, the opening of four new multispecialty ASCs, provides adequate incremental ASC capacity in Forsyth County at the present time. Specifically, four new ASCs (WFBH OSC -Clemmons, Novant Health Kernersville Outpatient Surgery, Novant Health Clemmons Outpatient Surgery, and Triad Center for Surgery) with a combined inventory of nine ORs, have recently or are planned to soon open in Forsyth County. The opening of these facilities provides additional ASC capacity of over 11,000 cases, and for the near term, along with the other existing Forsyth County ASC, Piedmont Outpatient Surgery Center, provides adequate ASC capacity in Forsyth County. As documented in NCBH's application, in its March 2020 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) stated that "Beneficiaries have adequate access to care in ASCs. The number of ASC facilities has increased, and the volume of services provided to Medicare beneficiaries in ASCs also has increased." Therefore, there is currently no need for another Forsyth County ASC such as proposed by Moses Cone Hospital.

¹ Report to the Congress: Medicare Payment Policy; March 2020, Medicare Payment Advisory Commission, p. 147.

Comparative Analysis

The Agency typically performs a comparative analysis when evaluating applications in a competitive batch review. The purpose is to help identify the proposal that would bring the greatest overall benefit to the community. The following table summarizes objective metrics that the Agency utilized in the 2018 Forsyth County OR Review (and other previous Agency OR reviews), which are appropriate for comparing the three applications in this Forsyth County operating room batch review.

Forsyth County Operating Room Batch Review Application Comparative Analysis

Metrics					
Comparative Factor	NCBH	Medical Park Hospital	Triad Surgery Center		
Conformity with Review Criteria	Yes	No	No		
Physician Support	More Effective	Less Effective	Less Effective		
Geographic Accessibility	Equally Effective	Equally Effective	Less Effective		
Patient Access to New Provider	Equally Effective	Equally Effective	Not Approvable		
Patient Access to Multiple Services	More Effective	Less Effective	Less Effective		
Patient Access to Lower Cost Surgical Services	Less Effective	Less Effective	Not Approvable		
Projected Average Net Revenue/Case	Inconclusive	Inconclusive	Inconclusive		
Projected Average Operating Expense/Case	Inconclusive	Inconclusive	Inconclusive		
Access by Underserved Groups: Charity Care	More Effective	Less Effective	Less Effective		
Access by Underserved Groups: Medicare	Effective	Not Approvable	Not Approvable		
Medicare Cases	10,602	4,555	599		
Access by Underserved Groups: Medicaid	More Effective	Less Effective	Less Effective		

Based on this comparative analysis, and considering that the NCBH application conforms to all CON Review Criteria and best achieves the Basic Principles of the 2020

SMFP (Policy GEN-3), NCBH represents the most (indeed the only) effective alternative for development of the need-determined operating rooms in Forsyth County.

Conformity with Review Criteria

As shown below, Table 6B of the 2020 SMFP indicates that Forsyth County is projected to have a deficit of two operating rooms in 2022. NCBH is projected to have a deficit of 4.72 ORs (1.92 deficit for combined WFBH facilities), and Novant Health (all facilities) is projected to have a combined surplus of 6.41 ORs.

2020 SMFP, Table 6B Operating Room Need Projections

Facility Name	Adjusted Planning Inventory	Projected 2022 OR Deficit or (Surplus)
Novant Health Forsyth MC	33	-3.33
Novant Health MPH	10	0.78
Novant Health Clemmons OS	2	-2.0
Novant Health Kernersville OS	2	-1.86
Novant Health Total	47	-6.41
WFBH OSC - Clemmons	3	-2.8
North Carolina Baptist Hospital	49*	4.72
WFBH Total	52	1.92

*Includes 11 ORs previously approved but not yet operational.

Source: 2020 SMFP

As shown in the table, of the two applicants that currently offer surgical services in Forsyth County, NCBH is the only one projected to have a deficit in 2022 (per the 2020 SMFP). Continuing a long time trend, Novant Health is projected to have a combined surplus of 6.41 operating rooms.

It behooves the Agency to evaluate the degree to which the capacity of the applicants with existing facilities represented a surplus or deficit, as compared to need based on patient demand. Such an evaluation of need is necessary to determine the degree to which applicants that are existing facilities may have surplus capacity, as avoiding excess capacity is a foundational finding of the North Carolina CON statute. The Certificate of Need Statutory Findings of Fact 4 and 6 state:

- 4) "That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services."
- 6) "That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers."

See § 131E-175. Findings of Fact on page 459 of the 2020 SMFP.

As stated in the statute, excess capacity leads to unnecessary use of expensive resources, overutilization of healthcare services, and an economic burden on the public. Therefore, NHMPH's application does not demonstrate the need for additional operating rooms, and is not conforming to Criteria 1, 3, 4, 5, 6 and 18a.

As described in the specific comments on the following pages regarding the TSC application, Moses Cone Hospital does not demonstrate the need for operating rooms, and is therefore not conforming to Criteria 1, 3, 4, 5, 6, 13 and 18a.

Demonstration of Physician Support

NCBH included over 200 letters of support from physicians, NHMPH included 24 physician letters of support, and TSC included 10 physician letters of support. Therefore, with regard to physician support, the NCBH application is the most effective alternative.

Geographic Accessibility

The NCBH and NHMPH applications are equally effective with regard to geographic access because they both propose to add operating rooms at existing licensed hospitals in Winston-Salem, which is the population and geographic center of Forsyth County.

TSC proposes to develop an ASC in Kernersville. The TSC application (page 19) expansively defines "Kernersville" to include a collection of seven zip codes in Forsyth and Guilford counties. Only two of these zip codes, 27284 and 27285, are actually Kernersville zip codes, and one of these zip codes, 27285, is for post office boxes in Kernersville. The other zip codes that TSC defines as "Kernersville" are located in other towns and cities mostly in Guilford County, including:

- 27009: Belews Creek (Forsyth County)
- 27051: Walkertown (Forsyth County)
- 27235: Colfax (Guilford County)
- 27265: High Point (Guilford County)
- 27310: Oak Ridge (Guilford County)

It is misleading to suggest that "Kernersville" is larger than it actually is. According to the US Census Bureau, as of July 1, 2019, the estimated population of Kernersville is 24,660.² Kernersville (zip code 27284) currently has six ORs and two GI endoscopy rooms. Four of the six ORs are located at Novant Health Kernersville Medical Center (NHKMC). Two of the six ORs are located at Novant Health Kernersville Outpatient Surgery (NHKOS), which opened in 2018. The two existing GI endoscopy rooms in Kernersville are operated by Digestive Health Specialists, P.A (DHS). In addition, Gastroenterology Associates of the Piedmont (GAP) was previously approved to relocate two GI endoscopy rooms from Winston-Salem to an ASC in Kernersville, Kernersville Endoscopy Center (KEC) (Project I.D. No. G-11442-17). Thus, there will soon be four endoscopy rooms in Kernersville.

High Point zip code 27265, which TSC calls "Kernersville," is the home of Premier Surgery Center, a two-OR facility that opened in 2016. It is a freestanding multispecialty ASC owned by WFBH. In nearby High Point zip code 27262, there are six ORs at High Point Surgery Center, which is also an ASC. High Point Regional Health, also located in zip code 27262, has eight shared ORs. Zip code 27265 already has abundant access to ORs.

Kernersville is approximately midway between Winston-Salem and Greensboro, so Greensboro providers are a viable option for Kernersville residents, especially considering that TSC projects that more than 50% of its surgical cases will be for Guilford County residents. Moses Cone Memorial Hospital is licensed for 13 ambulatory ORs and 37 shared operating rooms in Guilford County. Yet in the TSC application, MCMH did not discuss the alternative of relocating some of its existing underutilized ORs to develop a western Guilford County ASC.

Patient Access to Broader Range of Services

As a leading Academic Medical Center, NCBH provides inpatient and outpatient surgical care in practically every surgical specialty. Wake Forest School of Medicine surgeons include fellowship-trained surgeons in many subspecialties. During FY2019 at NCBH, 33,024 surgical procedures were performed across numerous surgical

² https://www.census.gov/quickfacts/fact/table/kernersvilletownnorthcarolina,US/PST045219

specialties and many more surgical subspecialties. The following table (shown on page 17 of NCBH's application) outlines NCBH's surgical specialties and subspecialties. NCBH will utilize the two incremental shared inpatient/outpatient operating rooms in support of current and future of needs of all surgical specialties and subspecialties offered at NCBH.

Surgical Specialties and Subspecialties Offered at NCBH

Specialty	Subspecialty
Cardiothoracic	
Surgery	Cardiac Surgery
	Pediatric Cardiac Surgery
	Thoracic Surgery
General Surgery	Bariatric Surgery
	Breast Surgery
	Colon and Rectal Surgery
	Endocrine Surgery
	Gastrointestinal Surgery
	Liver and Bile Duct Surgery
	Pancreatic Surgery
	Laparoscopic Surgery
	Pediatric Surgery
	Surgical Oncology
	Transplant Surgery
	Burn Surgery
	Emergency General Surgery
Neurosurgery	Adult Neurosurgery
	Pediatric Neurosurgery
	Gamma Knife
	Spine Surgery
Obstetrics-	
Gynecology	General Gynecology
	Maternal Fetal Medicine
	General Obstetrics
	Gynecologic Oncology
	Urogynecology And Pelvic Reconstructive Surgery
	Reproductive Endocrinology and Infertility
Ophthalmology	Cornea
	Retina and Uveitis
	Oculofacial Plastic Surgery
	Orbital Surgery
	Glaucoma
	Neuro-Ophthalmic
	Pediatric Ophthalmology

Specialty	Subspecialty
	Ocular Oncology
Orthopaedic Surgery	Foot and Ankle
	Hand, Shoulder, and Elbow
	Joint Replacement
	Spine
	Sports Medicine
	Trauma
	Pediatric Orthopaedic Surgery
	Orthopaedic Oncology
Otolaryngology	Voice and Swallowing
	Head and Neck Cancer
	Facial Plastic and Reconstructive Surgery
	Rhinology
	Otology and Neurotology
	Endoscopic Skull Base Surgery
	Pediatric Otolaryngology / Head and Neck Surgery
Plastic Surgery	Craniofacial
	Hand
	Burn / Microsurgery
	Pediatrics
Urology	General Urology
	Men's Health
	Pediatric Urology
	Urologic Oncology
Vascular Surgery	

By comparison, NHMPH represents serving multiple specialties at its facility, but as shown on its 2020 hospital license renewal application (reproduced below), last year nearly 74% of surgical cases at NHMPH were for just three specialties (general surgery, orthopedics, and urology), and over 87% were for just five specialties (general surgery, orthopedics, urology, plastic, and GYN).

2020 Renewal Application for Hospital: Novant Health Medical Park Hospital

All responses should pertain to October 1, 2018 through September 30, 2019.

License No: H0229 Facility ID: 943343

Campus – if multiple sites: Novant Heath	<u>1 Medical Park</u> Hospital Onli	J
		J

d) Non-Surgical Cases by Category WIA

Enter the number of non-surgical cases by category in the table below. Count each patient undergoing a procedure or procedures as one case regardless of the number of non-surgical procedures performed. Categorize each case into one non-surgical category — the total number of non-surgical cases is an unduplicated count of non-surgical cases. Count all non-surgical cases, including cases receiving services in operating rooms or in any other location.

Non-Surgical Category	Inpatient Cases	Ambulatory Cases
Endoscopies OTHER THAN GI Endoscopies		
Performed in Licensed GI Endoscopy Rooms		
NOT Performed in Licensed GI Endoscopy Rooms		
Other Non-Surgical Cases		
Pain Management		
Cystoscopy		
YAG Laser		
Other (specify)		

e) Surgical Cases by Specialty Area

Enter the number of surgical cases performed in licensed operating rooms only, by surgical specialty area. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was having surgery. Categorize each case into one specialty area — the total number of surgical cases is an unduplicated count of surgical cases. Count all surgical cases performed only in licensed operating rooms. The total number of surgical cases should match the total number of patients listed in the Patient Origin Tables on pages 28 and 29.

Surgical Specialty Area	Inpatient Cases	Ambulatory Cases
Cardiothoracic (excluding Open Heart Surgery)		
Open Heart Surgery (from 8.(a) 4. on page 9)		建筑等级产品的企
General Surgery	490	3332
Neurosurgery		70
Obstetrics and GYN (excluding C-Sections)	7	588
Ophthalmology		370
Oral Surgery/Dental		35
Orthopedics		1,086
Otolaryngology	PI	445
Plastic Surgery	32	Ca4
Podiatry		
Urology	189	1,923
Vascular		
Other Surgeries (specify) Pain Mant/Anes/Family Med		244
Number of C-Sections Performed in Dedicated C-Section ORs		
Number of C-Sections Performed in Other ORs		
Total Surgical Cases Performed Only in Licensed ORs	814	8,616

f) Number of surgical procedures performed in unlicensed Procedure Rooms:

Revised 5/2019

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In even greater contrast to NCBH, Moses Cone proposes for TSC to be a multi-specialty ASC, but as stated on page 9 of the Form C Assumptions and Methodology in its application (reproduced below), over 55% of TSC surgical cases would be for just two specialties (orthopedics and ENT), and over 75% are for just four specialties (orthopedics, ENT, urology, and general surgery).

Table 5: CY 2019 Number of Surgical Cases Resulting in Surgery at Proposed ASF

	LeBauer Elam	LeBauer High Point	Cone Health Primary Care at MC Kernersville^	LeBauer Brassfield	LeBauer Horse Pen Creek	LeBauer Summerfield Village	Piedmont Triad Family Medicine^	LeBauer Oak Ridge	SMC High Point	Total
Percent to Choose Proposed ASF for Surgery	5%	60%	100%	30%	30%	40%	100%	60%	60%	
Orthopedics	15	98	197	39	33	19	114	12	21	548
ENT	10	100	110	36	25	20	26	17	-	344
Urology	4	50	40	22	12	9	18	6	-	161
General Surgery	5	43	53	17	13	6	12	6	1	155
Podiatry	4	38	23	14	6	7	10	8	0	110
Ophthalmology	4	37	43	8	7	3	5	5	0	112
Ob/Gyn	0	4	4	0	1	1	1	1	-	10
Spine Surgery	4	32	37	15	5	4	6	4	2	109
Gynecology	2	13	3	5	3	3	3	3	-	35
Plastic Surgery	0	3	7	1	1	2	2	1	-	17
Total	49	419	517	156	106	73	198	62	25	1,603

Clearly, NCBH is the most effective alternative in terms of offering Forsyth County residents access to a broader range of surgical specialties, and the applications submitted by NHMPH and MCMH are both less effective alternatives.

Access for Medically Underserved

Self-Pay/Charity & Medicaid

A key factor in considering the relative accessibility of the alternative proposals is the extent to which each applicant expands access to the medically underserved, particularly self-pay/indigent/charity patients and Medicaid recipients. Generally, the application proposing to serve the higher percent of total patients who are self-pay and Medicaid patients is the more effective alternative with regard to this comparative factor. The following table summarizes the projected self-pay and Medicaid payor mixes for the competing applicants.

Projected Outpatient Self-Pay/Charity & Medicaid Payor Mixes, PY3

Payor Type	NCBH	NHMPH	TSC
Self-pay/ charity/indigent	5.2%	3.0%	1.5%
Medicaid	20.0%	4.2%	1.1%
Combined	25.2%	7.2%	2.6%

Source: CON Applications

As shown in the table above, NCBH projects a much higher combined self-pay/charity care/indigent and Medicaid payor mix. Therefore, the application submitted by NCBH is the more effective alternative with regard to access for the medically underserved, and the applications submitted by NHMPH and MCMH are less effective alternatives.

Projected Charity Care

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this comparative factor.

Projected Charity Care, PY3

Applicant	Projected Total Charity Care	Charity Care per Case	% of Net Revenue
NCBH	\$167,088,231	\$4,697	25.4%
NHMPH	\$4,167,385	\$390	4.1%
TSC	\$179,839	\$99	2.8%

Source: CON Applications, Form F.2

As shown in the table above, NCBH projects the most charity care in dollars, the highest charity care per surgical case, and the highest charity care as a percent of net revenue.

Therefore, the application submitted by NCBH is the more effective alternative with regard to access to charity care, and the applications submitted by NHMPH and MCMH are less effective alternatives.

As indicated in these tables, in terms of access for the medically underserved self-pay/indigent and Medicaid populations, NCBH's proposal represents the most effective alternative, as NCBH projects to serve a greater percentage of both self-pay/charity/indigent patients and Medicaid recipients, as well as a far greater amount of charity care per patient.

Medicare

Each application projects to serve a substantial Medicare percentage, as shown on the table below.

Projected Medicare Payor Mix, PY3

Payor Type	NCBH	NHMPH	TSC	
Medicare	29.8%	42.6%	33.1%	

Source: CON Applications

A comparison of the projected number of Medicare surgical cases at each facility is also instructive, as NCBH projects to serve far more Medicare surgery patients than either NHMPH or MCMH.

Projected Medicare Surgical Cases, PY3

Payor Type	NCBH	NHMPH	TSC
Medicare	10,602	4,555	599

Source: CON Applications

In summary, NCBH's proposal for service to self-pay/charity/indigent, Medicaid and Medicare recipients will provide the best and most appealing projection of access for

medically underserved patients of the competing proposals. Therefore, the NCBH application is the most effective alternative with respect to access.

Maximize Healthcare Value

Average Net Revenue & Average Operating Expense per Surgical Case

A typical issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for development of additional operating rooms. Please see the following tables.

Projected Average Net Revenue per Surgical Case

Project Year	NCBH	NHMPH	TSC	
3	\$18,466	\$9,469	\$3,572	

Source: CON Applications

Projected Average Operating Expense per Surgical Case

Project Year	NCBH	NHMPH	TSC
3	\$17,384	\$6,626	\$2,703

Source: CON Applications

Generally, the application proposing the lowest average net revenue and lowest average operating expense is the more effective alternative with regard to this comparative factor. However, significant differences in the facilities and the breadth and complexity of surgical services proposed by each of the applicants (as previously discussed) impacts the averages shown in the table above. Thus, the result of this comparative analysis is inconclusive.

Capital Cost

This comparative analysis demonstrates NCBH's commitment to efficient allocation of capital resources. NCBH's proposal to add ORs is much less expensive than either NHMPH or TSC, as shown in the following table.

Capital Cost

	NCBH	NHMPH	TSC
Capital Cost	\$5,409,640	\$8,761,564	\$13,984,589

Source: CON Applications

NCBH most effectively satisfies the value requirement of Policy GEN-3, and is a comparatively superior application.

Specific comments regarding the TSC application

The TSC application is a resubmission of Moses Cone Memorial Hospital's 2018 CON application to develop a new ASC in Forsyth County.

Comments specific to Criterion 1

The Triad Surgery Center 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 an area that MCMH itself 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 TSC 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 80 of the application, TSC is projected to serve just 1.3% self-pay patients overall, with the operating room component of the project projected to serve 1.5% self-pay patients. Furthermore, the project is projected to serve just 0.9% Medicaid patients overall, with the operating room portion projected to serve only 1.1% Medicaid patients. In comparison, the total combined self-pay surgical cases for all Forsyth County surgical facilities during FY2019 (as reported in the various 2020 hospital and ambulatory surgery center license renewal applications and portrayed in the following table) was 3.6% self-pay patients for outpatient cases, and the percent of Medicaid patients was 13.1% for outpatient cases. Thus, the MCMH project projects to serve 58% fewer self-pay patients, 92% fewer Medicaid patients, and 43% greater managed care patients than are currently being served combined by the existing surgical facilities in Forsyth County.

Forsyth County Licensed Facilities FY2019 Outpatient Surgery Payor Mix Comparison with Projected TSC Payor Mix

Payor Source	Total Forsyth County Facilities	TSC	% Difference
	Ĭ		
Self-pay	3.6%	1.5%	-58.3%
Medicare	37.8%	33.1%	-12.4%
Medicaid	13.1%	1.1%	-91.6%
Insurance	43.7%	62.7%	+43.5%
Other	1.7%	1.6%	-5.9%
Total	100.0%	100.0%	

Source: 2020 hospital & license renewal applications for NCBH, NHFMC, NHMPH, POSC, & WFBH OSC-C

Value

The proposed MCMH project will not maximize value for healthcare resources expended as it represents a duplication of services. Novant Health has recently developed a separately licensed ASC (NHKOS) in Kernersville with two licensed ORs. This facility serves the same primary market as MCMH plans to serve with TSC.

As previously stated, it is important to note that MCMH includes zip code 27265 in its TSC markets. Zip code 27265 is located in the city of High Point in Guilford County. High Point has more than adequate access to hospital and ambulatory surgery center operating rooms through High Point Regional Health (HPRH) with 11 ORs, High Point Surgery Center (HPSC) with six ORs, and Premier Surgery Center (PSC) with two ORs. There is a total excess capacity of seven ORs in High Point, most of which are in the two ambulatory surgery centers. Instead of duplicating existing and planned ambulatory surgery centers in Kernersville and High Point, MCMH should consider redeploying its own Guilford County OR assets in order to maximize value by maximizing the utilization of existing and planned health care resources.

Comments specific to Criterion 3

MCMH does not demonstrate the need for its proposed ASC. Forsyth County has recently transitioned from a county with zero multispecialty freestanding ASCs to a county with four multispecialty ASCs (WFBH OSC - Clemmons, Novant Health Kernersville Outpatient Surgery, Novant Health Clemmons Outpatient Surgery, and Triad Center for Surgery) with a combined inventory of nine ORs, which have recently or are planned to soon open in Forsyth County. The opening of these facilities provides ASC capacity of over 11,000 cases, and for the near term, provides adequate incremental ASC capacity within Forsyth County.

Kernersville is approximately midway between Winston-Salem and Greensboro, so Greensboro providers are a viable option for Kernersville residents, especially considering that MCMH projects that more than 50% of its surgical cases will be for Guilford County residents. The TSC application has no information on surgical or GI facilities in Guilford County that Kernersville residents use. Kernersville is on the county line, and facilities in the adjacent county could be considered in determining need in this sub-county area. Kernersville is not a surgical services desert; there is choice and competition in the local market for surgical services. As previously described, there are eight surgical programs in the Piedmont Triad area with six different owners. There are hospital-based ORs and ORs located in freestanding ASCs. All are within a maximum of 18 miles of Kernersville. Patients and physicians in

Kernersville have many choices of surgical facilities. No additional ORs are needed in Kernersville at this time.

On page 10 of the Form C assumptions, the MCMH methodology includes a 2.1% annual growth factor, which MCMH says it based on Forsyth County outpatient surgery growth. However, it is unreasonable to assume that the 2.1% growth factor should be applicable to the TSC project because MCMH projects that greater than 50% of its patients are projected to be from Guilford County, and the 2.1% annual growth assumption is unrealistic when compared to the five-year CAGR (FY2014-FY2019) for ambulatory surgery at Cone Health facilities in Guilford County, which is just 0.15%, as shown in the table below.

Cone Health Outpatient Surgical Cases

Year	FY2014	FY2019	5-Year CAGR
OP Surgery Cases	16,251	16,370	0.15%

Source: Cone Health hospital license renewal applications

This historical surgical utilization at Cone Health does not support the assumption that its referring physicians and surgeons have a need for additional operating rooms. To the extent that MCMH 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 MCMH ORs to a site in Guilford County. According to the MCMH application, the proposed TSC site is only two miles from the Guilford County line. According to the 2020 SMFP, Cone Health has a surplus of 8.31 ORs, and so could readily reallocate those underutilized resources from Moses Cone Memorial Hospital.

MCMH's utilization methodology is based on another faulty assumption. The applicant estimates that 70% of all surgeries resulting from primary care referrals to specialists will be outpatient, ASC-appropriate. This is not reasonable, however, as research shows that only up to 40% of surgeries are appropriate for ASCs.³ Though MCMH 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, it provides no supporting data to illustrate this point. The expected percentage should be more aligned with what has been noted in published research, 40%.

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³ 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.

Furthermore, the applicant assumes the same percentage of outpatient, ASC-appropriate surgeries for all specialties. This is another flawed assumption, as the percentage of outpatient, ASC-appropriate surgeries will vary by specialty. For example, MCMH's 2020 LRA data shows that the percentages for orthopedics, general surgery and neurosurgery are less than 70 percent ambulatory. Using the overstated 70 percent assumption causes the projected numbers of cases for orthopedics, general surgery and neurosurgery to be unreasonable.

Moses Cone Memorial Hospital 2020 License Renewal Application Data

Surgical Cases	IP	OP	Total	% IP	% OP
Orthopedics	4,796	4,126	8,922	54%	46%
ENT	149	1,110	1,259	12%	88%
General Surgery	1,956	3,922	5,878	33%	67%
Urology	453	2,096	2,549	18%	82%
Podiatry	42	85	127	33%	67%
Ophthalmology	8	426	434	2%	98%
Spine/Neurosurgery	1,273	529	1,802	71%	29%
Total	8,677	12,294	20,971	41%	59%

Source: 2020 MCMH hospital license renewal application

MCMH's 70 percent assumption also fails to consider that lower percentages should be assigned to many of the high-volume cases that include orthopedics, urology, general surgery and neurosurgery, as documented in the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) Statistical Brief 223.⁴

MCMH also assumes that 100% of the patients referred from Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine who will require outpatient, ASC-appropriate surgery, will opt to have their surgery at TSC. MCMH assumes 60% of the patients from Lebauer High Point and Lebauer Oak Ridge will opt to have their surgery at TSC. This assumption is defective because 1) it assumes that the four primary care practices will only refer to surgeons with privileges at TSC and 2) it assumes that an overly aggressive proportion of patients will chose TSC 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.⁵ Assuming that 100% and 60% of patients will chose TSC is an overly optimistic and unfounded assumption.

⁵ 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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⁴ https://www.hcup-us.ahrq.gov/reports/statbriefs/sb223-Ambulatory-Inpatient-Surgeries-2014.pdf

For all these reasons, MCMH's projected utilization is not supported, and the TSC application is not conforming to Criterion 3.

Comments specific to Criterion 4

MCMH failed to demonstrate that its proposal represents the least costly or most effective alternative, and is not conforming to Review Criterion 4. As described previously, MCMH does not demonstrate that projected OR utilization is based on reasonable and supported assumptions. Therefore, because the application does not demonstrate need for the proposed services, it is not an effective alternative, and the TSC application is thus not conforming to Criterion 4.

Comments specific to Criterion 5

Because MCMH did not reasonably demonstrate the need for the proposed ASC (see Criterion 3), it did not demonstrate the financial feasibility of the proposal, and the TSC application is therefore non-conforming to Review Criterion 5.

Comments specific to Criterion 6

MCMH failed to demonstrate the need for its proposed ASC. As described in the comments related to Criterion 3, MCMH failed to demonstrate in its application that the new ASC it proposes to develop is needed.

The TSC project represents an unnecessary duplication of existing and approved resources. As previously described, NHKOS is a freestanding ambulatory surgery center with two ORs which opened in 2018. KEC, with two GI endoscopy rooms, has received CON approval to open in Kernersville. MCMH does not adequately explain why Kernersville needs two more ORs and another GI endoscopy room in addition to NHKOS, KEC, and all the other outpatient ORs and GI endoscopy rooms available in close proximity in Kernersville, High Point, Winston-Salem and Greensboro.

Also, MCMH projects that greater than 50% of TSC patients will be residents of Guilford County. As previously stated, Cone Health has existing health service capabilities in Guilford County, with abundant capacity to serve ambulatory surgery and GI endoscopy patients. It is unreasonable to assume that patients from Guilford County have a need to be referred to Kernersville, because there are several existing ambulatory surgical facilities and hospitals in Guilford County.

For these reasons, the MCMH application does not demonstrate that it is not unnecessarily duplicative, and is non-conforming to Review Criterion 6.

Comments specific to Criterion 13

MCMH fails to comply with Criterion 13c because the proposed project in Kernersville will not provide adequate access to low income persons, including self-pay/indigent and Medicaid patients. Developing a new ASC in Kernersville does not improve access for low income persons who reside in Winston-Salem. As MCMH itself states on page 80 of its application, "the Kernersville region" "has considerably higher income, lower poverty rates, when compared to Forsyth County as a whole". Thus, there is less need for charity care and Medicaid access; that certainly manifests itself in the TSC application.

This project proposes to serve far lower percentages of self-pay/indigent/charity care and Medicaid patients compared to the combined outpatient surgical payor mix for all the licensed facilities in Forsyth County, as seen in the following table:

Forsyth County Licensed Facilities FY2019 Outpatient Surgery Payor Mix

Payor Source	Total Forsyth County Facilities	TSC
Self-pay	3.6%	1.5%
Medicare	37.8%	33.1%
Medicaid	13.1%	1.1%
Insurance	43.7%	62.7%
Other	1.7%	1.6%
Total	100.0%	100.0%

Source: 2020 hospital & license renewal applications for NCBH, NHFMC, NHMPH, POSC, & WFBH OSC-C

Therefore, the MCMH application does not demonstrate adequate access to low income persons (including Medicaid and self-pay/medically indigent), and is non-conforming to Review Criterion 13.

Comments specific to Criterion 18a

As the MCMH application is non-conforming with Criteria (3), (4), (5), and (6), it should also be found non-conforming with Criterion (18a). MCMH did not reasonably demonstrate the need the population projected to be served has for the proposed TSC project, and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of services in Forsyth County. MCMH did not adequately demonstrate the financial feasibility of the proposal. The proposal will limit access and will serve unacceptably low percentages of patients who are low income and Medicaid. Approval of MCMH will decrease competition. There is competition now among Forsyth County surgical facilities under different ownership for patient referrals from the Cone Health primary care practices and proceduralists. If the MCMH application is approved, the Cone Health primary care physicians and proceduralists will have to refer to TSC regardless of how it compares to other surgical facilities in price or quality. Thus, the proposed MCMH project will not have a positive impact on competition.

Comments specific to Section .2100 - Criteria and Standards for Surgical Services and Operating Rooms

MCMH's projected utilization does not conform to 10A NCAC 14C .2103. As previously described, the MCMH methodology is based on several faulty assumptions.

Specific comments regarding the NHMPH application

Comments specific to Criterion 1

The Novant Health Medical Park Hospital application for two additional ORs at NHMPH does not conform to Criterion 1 as it does not adequately demonstrate that the project will maximize healthcare value for resources expended. 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. As previously described, according to the SMFP operating room need determination methodology, Novant Health surgical facilities in Forsyth County collectively have a projected surplus of 6.41 ORs. Converted to a utilization rate, as shown in the following table, the Novant Health ORs in Forsyth County are utilized at 13.6% below capacity. By comparison, the operating rooms at North Carolina Baptist Hospital (NCBH) are utilized at 9.6% above capacity (and the WFBH system is utilized 3.7% above capacity), and NCBH has a projected 2022 deficit of 4.72 ORs.

Utilization of Forsyth County Operating Rooms

Facility	Projected OR Need	OR Inventory	OR Surplus/Deficit	OR Utilization %
NHCOS	0	2	-2	0.0%
NHKOS	0.14	2	-1.86	7.0%
NHFMC	29.67	33	-3.33	89.9%
NHMPH	10.78	10	0.78	107.8%
Total	40.59	47	-6.41	86.4%
WFBH-OSC	0.2	3	-2.8	6.7%
NCBH	53.72	49	4.72	109.6%
Total	53.92	52	1.92	103.7%
POSC	1.51	2	-0.49	75.5%
TCS	0	2	-2	0.0%

Source: 2020 SMFP

Development of the proposed two NHMPH ORs will not maximize healthcare value for resources expended as their development is unnecessary and represents an imprudent expenditure of resources. Therefore, the NHMPH application is not conforming to Criterion 1.

Comments specific to Criterion 3

NHMPH does not demonstrate the need it has for additional operating rooms. Novant Health thinks it has an unmet need for ORs, but in reality, it is not utilizing its existing ORs up to the average annual hours that are assigned to its facilities in the 2020 SMFP. The operating room methodology in the 2020 SMFP categorizes each licensed facility with ORs into Groups (1 through 6), and assigns average annual hours of operation for each Group. Novant Health dislikes this methodology, and irrationally argues that each of its facilities should use the standards for a different OR Group, contrary to the 2020 SMFP. In fact, as stated on page 34 of its application, Novant Health acknowledges that it must adjust the SMFP standards in order to have a chance at obtaining CON approval for its application, when it states "in order for NH Medical Park to demonstrate need across the NH System in Forsyth County, the System has to meet the required need and performance standards. Combining an ASC and two small community hospitals with a tertiary medical center on the NH Forsyth License as Group 2 providers does not accurately reflect the

operational capacities of these facilities and results in a surplus of ORs for NH Forsyth License." Novant Health chooses to operate its existing operating rooms that are licensed under NHFMC (H0209) at less than the standard 1,950 annual hours per operating room assigned in the 2020 SMFP.

Much more problematic is that Novant Health chooses to attempt to demonstrate conformity to the OR Criteria & Standards Performance Standards by applying these different OR Group standard hours per operating room in its methodology for projecting its system OR need in Forsyth County. However, the simple fact of the matter is that NH Clemmons Medical Center, NH Hawthorne Outpatient Surgery, and NH Kernersville Medical Center are all licensed as part of NH Forsyth Medical Center. Therefore, when calculating its OR need, Novant Health <u>must</u> apply the OR standard hours associated with NHFMC, a Group 2 surgical facility, which is 1,950 hours per OR per year. See below the language of the Criteria and Standards for Surgical Services and Operating Rooms, specifically the .2103 Performance Standards (underline added):

10A NCAC 14C .2103 PERFORMANCE STANDARDS

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

Yet, as calculated on page 50 of its application, shown below, Novant Health unilaterally chooses to adjust the standard methodology in the 2020 SMFP.

Step 9: Calculate OR Capacity

OR Capacity = Number of ORs * Standard Hours per OR

Standard Hours per Hour

Group 3: 1,755Group 4: 1,500Group 6: 1,312

Novant Health Affiliates - OR Capacity								
					Project			
			nterim Yea	rs	Partial Year	Proje	ct Full Fiscal	rears .
				1/1/2022-	7/1/2022 -	1/1/2023 -	1/1/2024 -	1/1/2025 -
	2019	2020	2021	6/30/2022	12/30/2022	12/31/2023	12/31/2024	12/31/2025
Novant Health Medical Park Hospital (Group 3)	17,550	17,550	17,550	8,775	10,530	21,060	21,060	21,060
Novant Health Forsyth Medical Center (Group 3*)	31,590	31,590	32,468	17,550	17,550	35,100	35,100	35,100
Novant Health Kernersville Medical Center (Group 4)	6,000	6,000	6,000	3,000	3,000	6,000	6,000	6,000
Novant Health Clemmons Medical Center (Group 4)	,500	7,500	7,500	3,750	3,750	7,500	7,500	7,500
Novant Health Hawthorne Outpatient Surgery Center (Group 6*)	5,248	5,248	5,248	2,624	2,624	5,248	5,248	5,248
Novant Health Orthopedic Outpatient Surgery Center (Group 6	1,968	-		-	-	-	-	-
Novant Health Clemmons Outpatient Surgery (Group 6)	656	2,624	2,624	1,312	1,312	2,624	2,624	2,624
Novant Health Kernersville Outpatient Surgery Center (Group 6)	2,624	2,624	2,624	1,312	1,312	2,624	2,624	2,624
Total	73,136	73,136	74,014	38,323	40,078	80,156	80,156	80,156

Note: Groupings are based on each individual facility not by license as discussed in detail previously.

This decision to flaunt the SHCC's State Medical Facilities Plan and the Operating Room methodology renders the NHMPH application unapprovable.

In addition to this fatal choice, NHMPH's application also suffers from faulty assumptions in projecting surgical cases at its Forsyth County facilities. Specifically, as shown on page 43 of its application (shown below), Novant Health ignores the historical growth rate for its surgical facilities and manufactures entirely different projected growth rates.

		Projected
	CAGR	Growth Rate
NOVANT HEALTH MEDICAL PARK HOSPITAL		
Inpatient OR Procedures	-4.9%	0.5%
Outpatient OR Procedures	1.4%	1.4%
Total	0.8%	
NOVANT HEALTH FORSYTH MEDICAL CENTER		
Inpatient OR Procedures	-5.3%	0.5%
Outpatient OR Procedures	3.5%	3.5%
Total	-1.7%	
NOVANT HEALTH KERNERSVILLE MEDICAL CENTER		
Inpatient OR Procedures	2.7%	1.4%
Outpatient OR Procedures	-12.4%	0.7%
Total	-8.0%	
NOVANT HEALTH CLEMMONS MEDICAL CENTER		
Inpatient OR Procedures	78.0%	0.9%
Outpatient OR Procedures	9.3%	0.7%
Total	33.0%	

The NHMPH application uses unreasonable and overstated annual growth rates for various of its surgical locations that exceed those facilities own historical compound annual growth rates.

As a result of all these deficiencies, the NHMPH application is non-conforming to Criterion 3 and cannot be approved.

Comments specific to Criterion 4

NHMPH failed to demonstrate that its proposal represents the least costly or most effective alternative, and is not conforming to Review Criterion 4. As described previously, NHMPH does not demonstrate that projected OR utilization is based on reasonable and supported assumptions. Therefore, because the application does not demonstrate need for the proposed services, it is not an effective alternative, and the NHMPH application is thus not conforming to Criterion 4.

Comments specific to Criterion 5

Because NHMPH did not reasonably demonstrate the need for the proposed OR addition (see Criterion 3), NHMPH did not demonstrate the financial feasibility of the proposal, and the NHMPH application is therefore non-conforming to Review Criterion 5.

Comments specific to Criterion 6

NHMPH failed to demonstrate the need it has to increase its operating room capacity by two rooms. As described in the comments related to Criterion 3, NHMPH failed to demonstrate in its application that the new ORs it proposes to develop are needed. Therefore, the NHMPH application does not demonstrate that it is not unnecessarily duplicative, and is non-conforming to Review Criterion 6.

Comments specific to Criterion 18a

As the NHMPH application is non-conforming with Criteria (3), (4), (5), and (6), it should also be found non-conforming with Criterion (18a). NHMPH did not reasonably demonstrate the need the population projected to be served has for the proposed project, did not demonstrate its proposal is the least costly or most effective alternative, did not demonstrate the financial feasibility of the project, and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of services in Forsyth County. Thus, the proposed NHMPH project will not have a positive impact on competition.

Comments specific to Section .2100 - Criteria and Standards for Surgical Services and Operating Rooms

NHMPH's projected utilization does not conform to 10A NCAC 14C .2103. As previously described, Novant Health chooses to attempt to demonstrate conformity to the OR Criteria & Standards Performance Standards by applying these different OR Group standard hours per operating room in its methodology for projecting its system OR need in Forsyth County. However, the simple fact of the matter is that NH Clemmons Medical Center, NH Hawthorne Outpatient Surgery, and NH Kernersville Medical Center are all licensed as part of NH Forsyth Medical Center. Therefore, when calculating its OR need, Novant Health <u>must</u> apply the OR standard hours associated with NHFMC, a Group 2 surgical facility, which is 1,950 hours per OR per year. See below the language of the Criteria and Standards for Surgical Services and Operating Rooms, specifically the .2103 Performance Standards (underline added):

10A NCAC 14C .2103 PERFORMANCE STANDARDS

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

CONCLUSION

For all of the foregoing reasons, both the MCMH and the NHMPH applications should be disapproved. Each fails to satisfy multiple CON review criteria, and is also comparatively inferior to the NCBH application. The NCBH application should be approved because it satisfies all the applicable CON review criteria and is comparatively superior to the MCMH and the NHMPH applications.